UNITED STATES SENTENCING COMMISSION

MEETING MATERIALS

WITNESS TESTIMONY

PUBLIC HEARING ON ALTERNATIVES TO INCARCERATION PROGRAMS AND SYNTHETIC DRUGS

MARCH 15, 2017

UNITED STATES SENTENCING COMMISSION
One Columbus Circle, NE
Suite 2-500, South Lobby
Washington, DC 20002-8002
(202) 502-4500 / Fax (202) 502-4699
www.ussc.gov

March 10, 2017

MEMORANDUM

TO: Acting Chair Pryor
Commissioners

FROM: Kenneth Cohen

SUBJECT: Materials for the March 15, 2017 Public Hearing on Alternatives to Incarceration Programs and Synthetic Drugs and for the March 2017 Meeting

Enclosed are materials for the Commission's March 15, 2017 public hearing on Alternatives to Incarceration Programs and Synthetic Drugs, and materials for the Commission's March 2017 meeting. The materials for the public hearing include the agenda, witness bios, and the written statements received to date. Some written statements include lengthy attachments that may be helpful as reference materials, but are not essential reading for the hearing. In addition, behind the "Background Materials" tabs, you will find additional background information on some of the issues that will be discussed at the hearing. As always, late arriving testimony will be forwarded as soon as practicable.

The hearing will take place in the Commissioners Conference Room in the Commission's Suite. The Staff Conference Room will serve as an overflow room for any members of the public who cannot be accommodated in the Commissioners Conference Room. The hearing begins at 9:00 a.m. and adjourns for the day at 2:30 p.m. Please note that the Commission will be having lunch with the judges who will testify during the second panel on Alternatives to Incarceration Programs.

The Commission's briefing session will begin in the Commissioners Conference Room just as soon as the room can be converted back into its usual meeting form and will continue until 5:30 p.m., after which time the March meeting adjourns.

Please call me if you have any questions or need further assistance.

United States Sentencing Commission
March, 2017 Meeting
Washington, DC

Wednesday, March 15, 2017

Public Hearing on Alternatives to Incarceration Programs and Synthetic Drugs
Commissioners Conference Room
9:00 a.m. – 12:30 p.m.

Working Lunch with Judges
Staff Conference Room
12:30 p.m. – 1:30 p.m.

Public Hearing on Alternatives to Incarceration Programs and Synthetic Drugs
Commissioners Conference Room
1:30 p.m. – 2:30 p.m.

Briefing Session
Commissioners Conference Room
3:00 p.m. – 5:30 p.m.

- **Chair's Report**
- **Staff Director's Report**
  - Legislative Update
  - Data Update
  - Training Update
- **Briefings/Discussions of Priorities**
  - **Synthetic Drugs**
  - **Alternatives to Incarceration**

Adjourn

PUBLIC HEARING ON
ALTERNATIVE TO INCARCERATION COURT PROGRAMS
AND SYNTHETIC DRUGS
MARCH 15, 2017
WASHINGTON, DC

9:00 a.m. – 2:30 p.m.

Panel I	**Alternatives to Incarceration: Design and Study**	**9:00 a.m. – 9:45 a.m.**
	Vanessa Price Director National Drug Court Institute National Association of Drug Court Professionals	
	Shannon Carey, Ph.D. Co-President and Senior Research Associate NCP Research	
	Faye Taxman, Ph.D. Professor, Criminology, Law and Society Department Director, Center for Advancing Correctional Excellence George Mason University	
Panel II	**Alternatives to Incarceration: View from the Bench**	**9:45 a.m. – 11:00 a.m.**
	Honorable Dolly M. Gee United States District Court Central District of California	
	Honorable Bruce Hendricks United States District Court District of South Carolina	
	Honorable Leo Sorokin United States District Court District of Massachusetts	
Break		**11:00 a.m. – 11:15 a.m.**

Panel III	**Drugs: Introduction and Trafficking Patterns**	**11:15 a.m. – 11:45 a.m.**
	Eric Wish, Ph.D. Director Center for Substance Abuse Research (CESAR) University of Maryland College Park, MD	
	Shontal Linder Section Chief, Synthetic Drugs and Chemicals Section Diversion Control Division Drug Enforcement Administration	
Panel IV	**Drugs: Community Impact and Supervised Release**	**11:45 a.m. – 12:30 p.m.**
	Captain Osvaldo Tianga Broward Sheriff's Office Broward Country, FL	
	Dr. John Cunha, DO Vice-Chief of Emergency Medicine Holy Cross Hospital, Fort Lauderdale, FL Medical Director Emergency Medical Services for the City of Oakland Park, FL	
	Lisa Rawlings, Ph.D. Chief of Staff Court Services and Offender Supervision Agency Washington, D.C.	
Lunch		**12:30 p.m. – 1:30 p.m.**
Panel V	**Drugs: Chemical Structure and Pharmacological Effects**	**1:30 p.m. – 2:30 p.m.**
	Terrence L. Boos, Ph.D. Section Chief, Drug and Chemical Evaluation Section Diversion Control Division Drug Enforcement Administration	
	Professor Gregory Dudley, Ph.D. Eberly Family Distinguished Professor and Department Chair Department of Chemistry West Virginia University	
	Rick Doblin, Ph.D. Founder and Executive Director Multidisciplinary Association for Psychedelic Studies (MAPS) MDMA-Assisted Psychotherapy	
Adjourn		**2:30 p.m.**

UNITED STATES SENTENCING COMMISSION
ONE COLUMBUS CIRCLE, NE
SUITE 2-500, SOUTH LOBBY
WASHINGTON, DC 20002-8002
(202) 502-4500
FAX (202) 502-4699

March 9, 2017

MEMORANDUM

TO: Acting Chair Pryor
Commissioners
Ken Cohen

FROM: Alternatives to Incarceration Policy Team[1]

SUBJECT: Materials for the March 15, 2017 Public Hearing on Alternatives-to-Incarceration Court Programs

Enclosed are materials for the Commission's March 15, 2017 public hearing on Alternatives to Incarceration. As discussed in last month's memorandum, team members recently have visited alternative-to-incarceration court programs in five federal districts. At the hearing, judges who preside over or oversee three of these programs will testify, including the Honorable Dolly M. Gee (CASA, Central District of California), the Honorable Bruce Hendricks (BRIDGE, District of South Carolina), and the Honorable Leo Sorokin (RISE, District of Massachusetts). Enclosed are publicly available materials describing each of these three programs (which we summarized in last month's memorandum):

- Conviction and Sentence Alternatives ("CASA") Program for Oversight of Post-Guilty Plea Diversion, Interagency Agreement

- BRIDGE Program, Mission Statement and Policies, United States District Court for the District of South Carolina (July 2016)

- RISE Program Packet and Consent Form, United States District Court and United States Probation & Pretrial Services for the District of Massachusetts (2015)

We look forward to seeing you on March 15.

[1] Team members are Ebise Bayisa, April Christine, Emily Herbst, Brent Newton (chair), Lou Reedt, Christine Scott-Hayward, Courtney Semisch, and Julie Zibulsky.

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA

INTERAGENCY AGREEMENT

CONVICTION AND SENTENCE ALTERNATIVES ("CASA") PROGRAM FOR OVERSIGHT OF POST-GUILTY PLEA DIVERSION

1. *Parties:* The parties to this interagency agreement are the following federal agencies for the Central District of California: United States District Court ("the Court"), United States Pretrial Services ("Pretrial Services"), United States Attorney's Office ("USAO"), and Federal Public Defender's Office ("FPD"), all of whom by executing this agreement have committed to providing to selected individuals who agree to Post-Guilty Plea Diversion ("PGP Diversion"), a Conviction And Sentence Alternatives ("CASA") program that will offer a creative blend of treatment, sanction alternatives, and incentives to effectively address offender behavior, rehabilitation, and the safety of the community.

2. *Agreement Regarding Underlying Principles:* The National Association of Drug Court Professionals has identified the following ten key components for successful programs, such as drug reentry programs, that provide alternatives to a standard conviction and sentence. The parties agree that these key components are essential and will be incorporated as principles underlying their participation in implementing the CASA program:

A. For those participants with substance abuse issues, the program integrates alcohol and drug treatment services with justice system case processing.

B. Using a non-adversarial approach, prosecution and defense counsel promote public safety while protecting participants' due process rights.

C. Eligible participants are identified early and promptly placed in the program.

D. For those participants with substance abuse issues, the program provides access to a continuum of alcohol, drug, and other related treatment and rehabilitation services.

E. For those participants with substance abuse issues, abstinence is monitored by frequent alcohol and drug testing.

F. A coordinated strategy governs the program's responses to participants' compliance and non-compliance.

G. Ongoing judicial interaction with each program participant is essential.

H. Monitoring and evaluation measure the achievement of program goals and gauge effectiveness.

I. Continuing interdisciplinary education promotes effective program planning, implementation, and operations.

J. Forging partnerships among the program's agency participants, other public agencies, and community-based organizations generates local support and enhances the program's effectiveness.

3. *CASA Program Overview*: The CASA program will be voluntary for its Participants, who, before beginning participation in the program will be required to: (a) enter into a CASA Program Contract pursuant to which they agree to participate in the program and abide by the governing terms of the program as set forth in the CASA Program Contract; and (b) enter a guilty plea to one or more counts pursuant to a plea agreement that specifies the benefits to be received upon successful completion of the CASA program. Successful Participants will be involved in the CASA program for at least 12 months, though the term of involvement may be extended as necessary to a maximum of no more than 24 months. During their time in the CASA program, Participants will engage in a variety of programs to address underlying causes of their criminal conduct, and will attend regularly scheduled CASA program proceedings that will include reports on their progress in the program. Participants with substance abuse issues will also engage in varying levels and modalities of treatment to address those issues. Failure to abide by the mandates of the CASA program may result in a Participant being terminated from the program and sentenced without receiving the benefits for successful completion of the CASA program specified in the Participant's plea agreement.

4. *Participants*: Participants in the CASA program must be individuals who have been charged in the Central District of California, in a charging instrument presented by the USAO, with a federal crime or crimes carrying a maximum sentence that exceeds one year in prison. Participants will be individuals whose criminal conduct is believed to be motivated by substance abuse issues or other underlying causes that appear amenable to treatment through programs available as part of the CASA program. Participants will be identified and selected using the methods described in paragraphs 6 and 7 below.

5. *Control Group*: In addition to identified active Participants in the CASA program, a group of additional supervisees may be identified by Pretrial Services as the CASA program Control Group. The members of the Control Group will be tracked by Pretrial Services over at least a two-year period. Data regarding the Control Group will be maintained by the Chief Pretrial Services Officer and/or designated delegees who are not responsible for supervision of any member of the Control Group. The data collected on the Control Group will be used to offer a comparison between the success rates of Participants in the CASA program and those who are convicted and sentenced through ordinary procedures. Members of the Control Group who after the two-year tracking period satisfy the criteria for participation in the Central District of California's STAR program (a program available to selected defendants serving a term of supervision as part of their sentence) will be given priority for participation in the STAR Program.

6. *Criteria for Participation in the CASA Program*: To be eligible to participate in the CASA program Participants must (1) be charged in the Central District of California in a charging instrument presented by the USAO with a federal crime or crimes carrying a maximum sentence that exceeds one year in prison; (2) have engaged in criminal conduct that appears motivated by substance abuse issues or other underlying causes that appear amenable to treatment through programs available as part of the CASA program; and (3) have been approved for participation in the CASA program by the CASA Program Team and the district court judge before whom the criminal charges against the Participant were originally pending (the "Originating District Judge"). Pretrial Services will screen all potential Participants to identify possible substance abuse issues.

7. *Selection of Participants:* CASA program Participants will be selected as follows:

(a) Initial identification of prospective Participants will be done by Pretrial Services, the USAO, and the attorney representing the prospective Participant. If both the USAO and the prospective Participant's attorney agree, a prospective Participant may be referred to the CASA Program Team for possible selection as a CASA Progam Participant.

(b) Initial selection of prospective Participants referred by the USAO and the prospective Participant's attorney will be done by the CASA Program Team, which will consist of the CASA Program Judicial Officer, Pretrial Services Officer, Deputy Federal Public Defender, and Assistant United States Attorney, or their designated substitutes.

(c) Once the CASA Program Team has selected a prospective Participant, the attorney representing the prospective Participant will be approached to obtain a speedy trial waiver for the time necessary for the prospective Participant to complete all steps necessary to be accepted as a CASA program Participant. Once a speedy trial waiver is obtained, the CASA Program Team, through correspondence from the CASA Program Pretrial Services Officer that attaches the speedy trial waiver, will seek from the Originating District Judge approval of a referral of the prospective Participant's case to the CASA Program Judicial Officer. A form for the letter and accompanying speedy trial waiver to be sent requesting a referral is attached as **Exhibit 1A**. If the Originating District Judge approves the referral, the Originating District Judge will execute an order referring the prospective Participant's case to the CASA Program Judicial Officer for all purposes, contingent on the prospective Participant being selected as a CASA program Participant. The referral order will contain speedy trial findings. A form for the referral order is attached as **Exhibit 1B**.

(d) Once a prospective Participant's case has been referred, the CASA Program Judicial Officer will appoint the Federal Public Defender's Office to represent the prospective Participant for purposes of the CASA program, including advising the prospective Participant and the prospective Participant's attorney with respect to the decision whether to consent to participating in the CASA program and whether to execute the CASA Program Contract and waiver of confidentiality regarding treatment program information required for participation in the CASA program. A form order to accomplish the appointment of the Federal Public Defender's Office is attached as **Exhibit 2**. For prospective Participants not represented by the Federal Public Defender's Office in the underlying criminal case, the prospective Participant will

continue to be represented by his or her own attorney in the underlying criminal case for purposes of determining whether to enter and entering a guilty plea in that case as required for participation in the CASA program.

(e) Each prospective Participant's voluntary consent to involvement in the CASA program will be confirmed in a written CASA Program Contract to be signed by the prospective Participant, as well as each member of the CASA Program Team. The CASA Program Contract, in the form attached as **Exhibit 3**, will articulate expectations and obligations of the prospective Participant and the other members of the CASA Program Team. As noted above, a prospective Participant will be approached for signature of a CASA Program Contract only after (i) the Originating District Judge has referred the prospective Participant's case to the CASA Program Judicial Officer and (ii) the Federal Public Defender's Office has been appointed to represent the prospective Participant for purposes of the CASA Program. All of the parties to this agreement recognize that an essential component of the CASA Program is every Participant's complete candor with the CASA Program Judicial Officer and the other members of the CASA Program Team. Accordingly, the USAO agrees that the CASA Program Contract will include a provision that statements made and documents and other information provided by a Participant during a formal CASA program proceeding conducted by the CASA Program Judicial Officer or another member of the CASA Program Team shall not be used by the USAO in its case in chief in any criminal prosecution it may subsequently bring against the Participant. The Contract will also contain a waiver by the Participant of the Participant's right to have a court reporter present to transcribe CASA program appearances, except at contested violation hearings or contested hearings to determine whether to terminate the Participant from the CASA program.

(f) Crucial to maximizing each Participant's possibility for success in the CASA Program is that all members of the CASA Program Team have access to full information regarding successes and failures in any program, including any treatment program, to which the Participant is referred as part of the CASA Program. Accordingly, as an adjunct to the CASA Program Contract, each prospective Participant will be required to execute a waiver authorizing access to program information by the CASA Program Judicial Officer, Pretrial Services Officer, Deputy Federal Public Defender, and Assistant United States Attorney, as well as any research partner working with Pretrial Services to evaluate the CASA program and the United States Probation Office. A form waiver for this purpose is attached as **Exhibit 4**. The USAO acknowledges that its access to this treatment program information is only for the purpose of participating in the monitoring and evaluating of a Participant's progress while participating in the CASA Program and for assessing sentencing recommendations following a Participant's completion, successful or unsuccessful, of the CASA Program.

(g) For a prospective Participant who has not yet been convicted and sentenced, participation in the CASA program is contingent on the prospective Participant entering a guilty plea pursuant to a plea agreement containing terms acceptable to the USAO and the prospective Participant to at least one of the criminal charges pending against the prospective Participant. The USAO agrees that the terms of the plea agreement will incorporate the terms of the CASA Program Contract, which will be attached to the plea agreement as an exhibit. The USAO further agrees that the plea agreement will be entered into pursuant to Federal Rule of Criminal

Procedure 11(c)(1)(C) to the extent that it will bind the CASA Program Judicial Officer, upon a Participant's successful completion of the CASA Program, to accord the Participant the benefits for such a successful completion specified in the plea agreement, which may include dismissal with prejudice of the criminal charges against the prospective Participant or a recommended reduction in the prospective Participant's sentence. The USAO may include in the plea agreement such other terms as it deems appropriate.

(h) Once a prospective Participant and all other members of the CASA Program Team have executed the CASA Program Contract; the prospective Participant has executed a waiver authorizing access to treatment program information by the CASA Program Team; and the prospective Participant, his or her attorney, and the USAO have all executed a plea agreement based on participation in the CASA program, then the prospective Participant shall appear for entry of a guilty plea pursuant to the plea agreement before the CASA Program Judicial Officer. If the CASA Program Judicial Officer accepts and agrees to be bound by the plea agreement, the CASA Program Judicial Officer will accept the prospective Participant's guilty plea. Once this occurs, the prospective Participant will become a Participant in the CASA program and the CASA Program Judicial Officer will handle all further proceedings in the criminal case.[1]

(i) If prior to entering a guilty plea in accordance with subparagraph (h) above a prospective Participant fails to complete any of the steps necessary to become a Participant in the CASA program or for any reason voluntarily elects not to pursue participation in the CASA program, the CASA Program Judicial Officer will execute an order returning the underlying criminal case for ongoing proceedings to continue before the Originating District Judge. Similarly, if the prospective Participant appears to enter a guilty plea in accordance with subparagraph (h) above but the CASA Program Judicial Officer rejects and declines to be bound by the plea agreement, the CASA Program Judicial Officer will decline to accept the Participant's guilty plea, the Participant will be released from any obligations under the plea agreement, and the CASA Program Judicial Officer will execute an order returning the underlying criminal case for ongoing proceedings to continue before the Originating District Judge. A form order for these purposes is attached as **Exhibit 5**.

8. *Role of the CASA Program Judicial Officer*: The active involvement of the CASA Program Judicial Officer[2] with Participants in the CASA program is essential. When

---

[1] If the CASA Program Judicial Officer accepts the guilty plea and plea agreement, the matter will not immediately be referred for preparation of a Pre-Sentence Report. Rather, referral for preparation of a Pre-Sentence Report will only occur if required upon a subsequent termination from the CASA program as specified in paragraph 17 below.

[2] Initially, it is anticipated that the CASA program will operate with a team of two district court judges based in Los Angeles, a single district court judge based in Riverside, and a single district court judge based in Santa Ana. While expansion of the number of Participants or other events may result in the need for participation by additional judicial officers, the parties

Participants are excelling in the program, the CASA Program Judicial Officer will provide encouragement. When Participants are in noncompliance with the CASA program or in violation of the terms of their PGP Diversion, the CASA Program Judicial Officer, after receiving the recommendation of the other members of the CASA Program Team, will make a determination as to the appropriate sanction based on the nature of the Participant's noncompliant behavior. If appropriate, sanctions should be progressive in terms of severity. When the CASA Program Team determines that a Participant has exhausted that Participant's opportunities to continue in the CASA program, the CASA Program Judicial Officer will make the final decision to terminate the Participant from the CASA program and proceed to sentencing.

9. *Role of the CASA Program Pretrial Services Officer*: The CASA Program Pretrial Services Officer (the "CPPSO") will be charged with overseeing supervision of Participants and making appropriate treatment referrals with contract and appropriate noncontract treatment and other program agencies based on the needs of individual Participants as determined by the CPPSO and the CASA Program Judicial Officer. In addition:

(a) In preparation for CASA program appearances, the CPPSO will oversee the preparation of reports to inform the parties of Participants' struggles and achievements. To expedite the reporting process, avoid overworking the CPPSO, and create continuity in reporting, a standardized "CASA Program Progress Report," in the form attached as **Exhibit 6**, will be used. The CASA Program Progress Report will not be filed, and is intended only for use in planning for and conducting CASA program appearances. For each Participant, the CPPSO will distribute a CASA Program Progress Report, along with any attachments, to the CASA Program Judicial Officer, Deputy Federal Public Defender, and Assistant United States Attorney at least a full 24 hours before each scheduled CASA program appearance. Scheduling of CASA program appearances will be by the CASA Program Team, bearing in mind the need to facilitate the CPPSO's time to work with treatment and other program providers and prepare CASA Program Progress Reports with information as current as possible.

(b) The CPPSO will work with treatment and other program providers to ensure effective communication between the treatment and other program providers and the CASA Program Team.

(c) When serious problems in supervision arise, the CPPSO will work with the CASA Program Deputy Federal Public Defender and Assistant United States Attorney to intervene immediately and address issues with the Participant. Any such interventions will be described in the next CASA Program Progress Report.

(d) The CPPSO will maintain within each Participant's Pretrial Services file a separately delineated section that will constitute the CASA Program File for each Participant. This CASA Program File will include the Participant's CASA Program Contract, all CASA Program Progress Reports for the Participant, treatment and other program records for the Participant, results of drug testing for the Participant, and all other records relating to the

---

agree that the essential need for continuity in the judicial role mandates that a limited number of judicial officers be involved.

Participant's progress through the CASA program. The CASA Program File for any Participant will be made available to the CASA Program Judicial Officer, Deputy Federal Public Defender, and Assistant United States Attorney as necessary for implementation of the CASA program, and to any research partner working with Pretrial Services to evaluate the CASA Program. The CASA Program File for each Participant will remain a part of the Participant's Pretrial Services file and will be available to the Originating District Judge or any other district judge who assumes responsibility for sentencing the Participant.

10. *Role of the CASA Program Assistant United States Attorney*: The role of the CASA Program Assistant United States Attorney ("CPAUSA") is to participate in a team effort with the CASA Program Judicial Officer and Deputy Federal Public Defender and the CPPSO to encourage each Participant's success in the CASA program, discourage bad decisions and disinterest in the CASA program at their first sign, and participate in CASA program decisions about proper punishments for Participants struggling with the program's requirements. The CPAUSA should be involved in decisions about program planning both when a Participant is succeeding and when a Participant is struggling, may be called on to report on a Participant's progress during a CASA program appearance, and should be prepared to provide assistance to the other members of the CASA Program Team in determining whether a Participant's continued participation in the CASA program is or is not warranted. The CPAUSA's role is expected to be less adversarial than in non-CASA program cases.

11. *Role of the CASA Program Deputy Federal Public Defender*: The role of the CASA Program Deputy Federal Public Defender ("CPDFPD") is to participate in a team effort with the CASA Program Judicial Officer, the CPAUSA, and the CPPSO to encourage each Participant's success in the CASA program, discourage bad decisions and disinterest in the CASA program at their first sign, and participate in CASA program decisions about proper punishments for Participants struggling with the program's requirements. The CPDFPD should be involved in decisions about program planning both when a Participant is succeeding and when a Participant is struggling, may be called on to report on a Participant's progress during a CASA program appearance, and should be prepared to provide assistance to the other members of the CASA Program Team in determining whether a Participant's continued participation in the CASA program is or is not warranted. The CPDFPD's role is expected to be less adversarial than in non-CASA program cases.

12. *CASA Program Proceedings*: All Participants will appear at least monthly before the same CASA Program Judicial Officer and the other members of the CASA Program Team. To ensure continuity, only the CPPSO, CPDFPD, and CPAUSA constituting the CASA Program Team, or their designated substitutes, will be involved in the CASA program and will appear for each CASA program session. The order of Participant appearances at each CASA program session will be set by the CASA Program Judicial Officer as deemed most beneficial to the Participants, with the understanding that, ordinarily, absent being excused by the CASA Program Judicial Officer, Participants will be expected to remain through the appearances of at least some of the other Participants at the particular CASA program session. To effectuate the parties' intent that the CASA program be less adversarial and provide as much support as possible to Participants, all parties agree that conduct that might otherwise constitute a violation of the terms of PGP Diversion or of CASA program rules may be handled informally. In particular:

(a) all conduct that might be considered a violation will be presented to the CASA Program Judicial Officer, the other members of the CASA Program Team, and the Participant through the CPPSO's regular CASA Program Progress Report, or a status report to the CASA Program Judicial Officer filed on an expedited basis if the circumstances so warrant;

(b) absent a determination that termination from the CASA program is justified in accordance with paragraph 17(B)(2) below, any sanction for such a violation, so long as it is within the range of sanctions set forth in paragraph 13 below, will be handled through (i) a directive issued by the CASA Program Judicial Officer at a regular CASA program session in a non-adversarial setting or (ii) if the Participant, the CASA Program Judicial Officer, CPPSO, CPAUSA, and CPDFPD all agree to a particular sanction or treatment intervention, on an expedited basis before the Participant's next scheduled CASA program appearance by means of a modification executed by the Participant and the CASA Program Judicial Officer, CPPSO, and CPDFPD; and,

(c) with the exception of contested violation hearings and contested hearings to determine whether a Participant should be terminated from the CASA program, CASA program proceedings will be conducted without a court reporter, pursuant to a waiver by the Participant in the CASA Program Contract.

For each Participant, after each CASA Program appearance, the CASA Program Judicial Officer will issue a CASA Program Status Report, in the form attached as **Exhibit 7**, reflecting actions taken and scheduling that Participant's next CASA Program appearance. CASA Program Status Reports will be electronically filed.

13. *CASA Program Sanctions*: Noncompliant behavior by a Participant will result in sanctions. The range of possible sanctions has been drafted broadly to insure that some level of sanction is available for every type of violation. Factors that will influence the type of sanction employed include the seriousness of the violation, the number of violations, and the amount of time the Participant has remained compliant, either before a first violation, or between violations. In addition, an important factor will be whether the Participant voluntarily discloses the violation. Dishonesty on the part of the Participant will result in enhanced sanctions. Depending on these factors, any of the sanctions listed below - including termination from the CASA program - will be available. As a general rule, when there are repeat violations, more serious sanctions will be applied incrementally. Sanctions may include, but are not limited to:

- Judicial reprimand delivered during CASA program proceedings in front of other CASA program Participants
- Order to return to CASA program proceedings to observe for a half or full day

- Order to submit written assignment (for example, write out an explanation for non-compliant behavior or violations of any special conditions of PGP Diversion and describe a plan to avoid similar issues in the future)
- Curfew restriction for up to 30 days
- Increase in frequency of progress hearings before the CASA Program Judicial Officer
- Order to participate in community service as part of the CASA program
- Order to complete a term of home confinement (with conditions that may include alcohol monitors and standard location monitoring with GPS)
- Order to complete a term of up to 30 days at a residential reentry center
- Order to complete a term at a residential drug treatment facility.
- Order to spend up to 7 days in jail ("Flash Incarceration") (a form order for Flash Incarceration is attached as **Exhibit 8**)[3]
- Termination from CASA program.

These sanctions are intended to take a creative approach to altering behavior, while cutting the costs associated with first resorting to a traditional "days in jail" sanction. Sanctions imposed should be completed by the Participant's next CASA program appearance, unless the CASA Program Judicial Officer allows more time, and the Participant may be required to report on performance of the sanction at the next CASA program appearance. The CPPSO will monitor compliance with imposed sanctions and report on compliance in a regular CASA Program Progress Report, or, if circumstances warrant, in a status report to the CASA Program Team filed on an expedited basis. If appropriate, any or all of the available sanctions may be ordered more than once during the course of a Participant's progress through the CASA program. A Participant faced with any sanction will have the option of requesting termination from the CASA program and proceeding to sentencing before the CASA Program Judicial Officer.

14. *Adversarial Hearings*: Recognizing that circumstances may arise in which a Participant is alleged to have violated a term of PGP Diversion and/or the CASA program rules and the Participant believes that he or she is innocent in fact of the alleged conduct constituting the violation, the parties agree that a request for an adversarial hearing on whether the Participant in fact committed the alleged conduct will not automatically result in termination from the CASA program. Such adversarial hearings are, however, to be conducted only to determine the question of whether the Participant in fact committed the alleged conduct, and not as an opportunity for the Participant to offer a proffered explanation for admitted or undisputed conduct. Such adversarial hearings shall be conducted with a court reporter present.

---

[3] The 7-day limit applies only to orders for jail time, and does not limit the CASA Program Judicial Officer's ability to order a longer period of time in home confinement, a residential reentry center, or a residential drug treatment facility. Nor does it limit the CPPSO's ability to place a Participant in a residential reentry center for transitional purposes. While the perceived need for a sanction of more than 7-days jail time will ordinarily result in termination from the CASA program, with a Participant's written waiver and the consent of all members of the CASA Program Team, sanctions of more than 7 days in jail may be imposed by the CASA Program Judicial Officer in a non-adversarial setting with the understanding that the Participant will continue participating in the CASA program.

15. *CASA Program Benefits*: Whether a Participant has successfully completed the CASA program shall be determined by the CASA Program Judicial Officer in consultation with the other members of the CASA Team subject to the minimum requirement that a Participant with substance abuse issues shall have demonstrated at least six months of continuous sobriety. A Participant who is determined to have successfully completed the CASA program will receive the benefits specified in the Participant's plea agreement, which may include: (a) being permitted to withdraw the Participant's previously-entered guilty plea, with the criminal charges previously-pending in the underlying criminal case at the time of the guilty plea being dismissed with prejudice; or (b) sentencing by the CASA Judicial Officer, with a joint recommendation from the other members of the CASA Program Team for a reduction in sentence based on the Participant's successful completion of the CASA program.

16. *CASA Program Graduation*: CASA program graduation will take place at the Participant's final, regularly scheduled CASA program appearance. In addition to Participants, Originating District Judges, family members, sponsors, and friends will be invited to attend the graduation. The CASA Program Judicial Officer will present graduating Participants with a Certificate of Completion, and other articles of recognition as determined by the CASA Program Judicial Officer and the other members of the CASA Program Team.

17. *Termination Procedures*: A CASA program Participant may be terminated as successful or unsuccessful as follows:

A. **Successful Termination**: Participants who successfully complete the CASA program will be given a Certificate of Completion, which will close the CASA Program File section of the Participant's Pretrial Services file. For a Participant receiving the benefit of dismissal pursuant to the Participant's plea agreement, on the Participant's request to withdraw the Participant's previously-entered guilty plea, the CASA Program Judicial officer will issue an order vacating that guilty plea and dismissing with prejudice the criminal charges previously pending in the underlying criminal case at the time of that guilty plea. For a Participant receiving the benefit of a recommendation for a reduced sentence pursuant to the Participant's plea agreement, the CASA Program Judicial Officer will issue an order setting forth the sentence reduction recommended by the CASA Program Team, referring the case for preparation of a PSR, and scheduling a date for the imposition of sentence by the CASA Program Judicial Officer. A form order for successful termination, which will be electronically filed, is attached as **Exhibit 9**.

B. **Unsuccessful Termination**: In recognition of the reality of relapse as a part of recovery from drug or alcohol addiction and/or in addressing underlying causes of criminal activity, every effort should be made to continue to work with Participants. All parties realize, however, that there will be some circumstances in which it is appropriate to terminate a Participant from the CASA program as unsuccessful. Unsuccessful termination may be either voluntary or involuntary and, in either circumstance, will result in the Participant proceeding to sentencing

before the CASA Program Judicial Officer on the charge to which the Participant entered a guilty plea without receiving the benefits provided for successful completion of the CASA program in the Participant's plea agreement. The CASA Program Judicial Officer will have access to and may consider for purposes of sentencing the Participant's CASA Program File, which will document all successes, failures, and sanctions that occurred during the CASA program. Circumstances giving rise to involuntary termination of this type may include:

i. New law violations, as ultimately determined by the CASA Program Judicial Officer;
ii. Repeated drug use;
iii. A chronic pattern of refusal to cooperate with the CPPSO;
iv. A chronic pattern of refusal to cooperate with a treatment or other program provider;
v. Repeated refusals to cooperate with the CASA Program's sanctions or to participate in the CASA program in a meaningful manner.

Contested hearings relating to unsuccessful termination will be conducted with a court reporter present. Upon unsuccessful termination, the CASA Program Judicial Officer will issue an order terminating participation in the CASA program, referring the case for preparation of a PSR, and scheduling a date for the imposition of sentence by the CASA Program Judicial Officer. A form order for unsuccessful termination, which will be electronically filed, is attached as **Exhibit 10**.

///

///

///

///

///

///

///

///

///

///

18. *Modification and Supplementation of Agreement*: The parties recognize that as the

CASA program is implemented, modification or supplementation of this Interagency Agreement may be necessary. Any modification or supplementation of this Interagency Agreement shall be in writing, and may be made by the CASA Program Team only upon the consent of all members of that team and with agreement by the CASA Program Judicial Officer that the proposed modification does not need to be referred to the United States District Court for the Central District of California for review and approval.

AGREED ON BEHALF OF:

[Typed Name and Title] United States District Court Central District of California	Date
[Typed Name and Title] United States Pretrial Services Central District of California	Date
[Typed Name and Title] Federal Public Defender's Office Central District of California	Date
[Typed Name and Title] United States Attorney's Office Central District of California	Date

EXHIBIT 1A

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
PRETRIAL SERVICES

REQUEST FOR CASA PROGRAM CONSIDERATION

Date: [Date]
Name: [Prospective Participant's Name]
Docket No.: [Case No.]
Prepared For: Honorable [Judge's Name]
United States District Judge

==========

The above defendant has been identified as a potential candidate for participation in the Conviction And Sentence Alternatives ("CASA") program.

Contingent upon the approval of the Court, the defendant will be offered voluntary participation in the CASA program for a period of at least one year to enable intensive treatment, sanction alternatives and incentives to effectively address the defendant's substance abuse and/or other issues that appear to be contributing causes for defendant's criminal conduct. The defendant and the defendant's attorney have executed the attached speedy trial waiver for a period of forty-five (45) days to provide the time required to make a final determination whether the defendant will participate in the CASA program.

If the defendant indicates an intention to accept the offered participaton in the CASA program, the CASA Program Court will be presented with a plea agreement setting forth the terms on which the defendant will enter a guilty plea providing for defendant's participation in the CASA program. The CASA Program Court will then be asked to accept or reject the plea agreement, in doing so making a final determination whether the defendant will participate in the CASA Program.

It is respectfully recommended that the Court grant approval for the defendant to participate in the CASA Program by executing the attached proposed order, which: (a) refers the defendant's case to the CASA Program Court for all purposes, contingent on defendant being selected to participate in the CASA program; and (b) makes speedy trial findings for a period of forty-five (45) days to provide the time required to make a final determination whether the defendant will participate in the CASA program.

Reviewed by:

[Name of Supervisor]
Supervising Pretrial Services Officer
Telephone No. (000) 000-0000

Respectfully:

[Name of Officer]
Pretrial Services Officer
Telephone No. (000) 000-0000

SPEEDY TRIAL WAIVER

. . . . . United States v. [Defendant's Name]

Case No. [Case No.]

I am the defendant in the above-captioned criminal case. I have discussed with my attorney, and understand: (a) I have a right to have my case proceed to trial within the time period specified by a federal statute, 18 U.S.C. 3161; (b) the nature and conditions of the Conviction and Sentence Alternatives ("CASA") program; (c) I am being considered for participation in the CASA program; and (d) my consideration for participation in the CASA program will take approximately 45 days and will require that my case be referred to the judge overseeing the CASA program. Understanding all of this: (a) I want to be considered for participation in the CASA program; (b) so that I can be considered for participation in the CASA program, I want my case referred to the judge overseeing the CASA program; and (c) I agree that 45 days from the date on which my case is referred to the judge overseeing the CASA program may be excluded from the time period set by statute within which my criminal case would otherwise have to proceed to trial. I have discussed with my attorney, and I understand, that by agreeing to this, I am waiving a right accorded me by statute to have my trial begin within a specified time period. I am waiving this right knowingly and voluntarily because I want to be considered for participation in the CASA program, and not for any other reason.

_____ _____

[DEFENDANT'S NAME] Date

Defendant

I am _____'s attorney. I have carefully and thoroughly discussed with my client this Speedy Trial Waiver, including, in particular: (a) my client's right to have the criminal case against my client proceed to trial within the time period specified by a federal statute, 18 U.S.C. 3161; (b) the nature and conditions of the Conviction and Sentence Alternatives ("CASA") program; (c) that my client is being considered for participation in the CASA program; (d) that my client's consideration for participation in the CASA program will take approximately (45) days and will require that my client's case be referred to the judge overseeing the CASA program; and (e) that by executing this Speedy Trial Waiver, my client will be waiving a right accorded my client by statute to have the trial in this criminal case begin within a specified time period. I believe that my client is executing this Speedy Trial Waiver knowingly and voluntarily because my client wants to be considered for participation in the CASA program, and not for any other reason. I concur in my clients waiver of his speedy trial rights as set forth in this Speedy Trial Waiver.

_____ _____

[ATTORNEY'S NAME] Date

Attorney for Defendant

EXHIBIT 1B

UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, Plaintiff, v. _____, Defendant.	) No. _____)) ORDER REFERRING DEFENDANT TO CASA PROGRAM JUDICIAL OFFICER AND MAKING SPEEDY TRIAL FINDINGS))))

Defendant being under consideration for participation in the Conviction And Sentence Alternatives ("CASA") program, and defendant and defendant's attorney having executed the Speedy Trial Waiver attached as Exhibit A, THE COURT FINDS AND ORDERS AS FOLLOWS:

1. As to defendant, this case is referred to the Honorable [Judge's Name], a CASA Program Judicial Officer, for all purposes, subject to a final determination that defendant is selected for participation in the CASA program. If defendant is not selected for participation in the CASA program, this case shall be returned to this court for all further proceedings.

2. A period of 45-days from the date of this order is necessary for the CASA Program Judicial Officer to make the final determination whether defendant will be selected for participation in the CASA program. Pursuant to 18 U.S.C.

3161(h)(1)(G), (h)(2), and (h)(7)(A), with respect to defendant this 45-day period shall be excluded from the time within which the trial of this case must commence based on the following findings:

(a) Pursuant to 18 U.S.C. 3161(h)(1)(G), this period results from consideration by the court of a proposed plea agreement to be entered into by the defendant and the attorney for the Government as a condition of defendant's possible participation in the CASA program;

(b) By analogy to 18 U.S.C. 3161(h)(2), this period is one during which defendant and the government will be determining whether to enter into a written agreement for post-guilty plea diversion pursuant to which, as part of the CASA program, should defendant demonstrate good conduct during a specified period of time, defendant would receive significant benefits; and

(c) Pursuant to 18 U.S.C. 3161(h)(7)(A), the ends of justice served by excluding this period outweigh the best interest of the public and the defendant in a speedy trial because the failure to provide defendant with the time required for a determination that might enable defendant to participate in the CASA program would result in a miscarriage of justice.

DATED:_____, 2011

_____
[Judge's Name]
United States District Judge

EXHIBIT 2

UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, Plaintiff, v. _____, Defendant.	No. _____ ORDER APPOINTING FEDERAL PUBLIC DEFENDER FOR LIMITED PURPOSE OF PARTICIPATION IN CASA PROGRAM

The above-captioned defendant has been identified by the Court as a candidate for participation in the Conviction And Sentence Alternatives ("CASA") program. The Office of the Federal Public Defender for the Central District of California is hereby appointed to advise defendant regarding the decision whether to participate in the CASA program and, if defendant so elects and is approved to participate, to represent defendant with respect to defendant's participation in the CASA program.

DATED: _____, 2011

_____
HON.
United States District Judge
CASA Program Judicial Officer

EXHIBIT 3

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA

CONTRACT FOR PARTICIPATION
CONVICTION AND SENTENCE ALTERNATIVES ("CASA") PROGRAM
POST-GUILTY PLEA DIVERSION

Name: _____

Docket#: _____

Offense(s): _____

INTRODUCTION

You have been invited to participate in the Conviction And Sentence Alternatives ("CASA") program of the Central District of California as part of post-guilty plea diversion. Participation is entirely voluntary, but will require you to enter guilty plea(s) to one or more of the criminal charges currently pending against you in the case referenced above. The Court will need to make a final determination whether to accept your guilty plea(s) and plea agreement before you can begin participation in the CASA program. If the Court agrees to accept your guilty plea(s) and plea agreement, in doing so approving your participation, and you thereafter successfully complete the CASA program, then, as specified in the plea agreement pursuant to which you enter your guilty plea(s), [those guilty plea(s) will be vacated and the criminal charges against you in the case referenced above will be dismissed with prejudice] [you will receive a sentence that does not include a term of imprisonment]. **[Select alternative that applies, and delete other.]**

CASA PROGRAM BASICS

The CASA Program will last at least one year, with the possibility that it may be extended up to no more than two years. Participants in the program will have their cases referred to the CASA Program Judicial Officer before whom they will enter guilty pleas pursuant to plea agreements with the United States Attorney's Office for the Central District of California ("USAO"). If the CASA Program Judicial Officer accepts a Participant's guilty pleas and plea agreement, it will constitute final approval for participation in the CASA program, which will include a period of supervision by a CASA Program Pretrial Services Officer ("CPPSO"). Participants agree to participate in a drug and alcohol evaluation, and in any and all treatment and testing recommended. In addition to the requirements of actively engaging in any treatment and testing that may be recommended for substance abuse issues, Participants are also required to participate in programs designed to address underlying causes of criminal activity and to comply with all conditions of post-guilty plea diversion that may be required by the plea agreements pursuant to which they entered their guilty plea(s) and by the CPPSO.

You will be assigned an attorney from the Federal Public Defender's Office ("DFPD") who is assigned to the CASA program. An Assistant United States Attorney ("AUSA") will also be assigned to the CASA program. Both the DFPD and AUSA will work with the CPPSO to provide additional support and encouragement for your success in the CASA program.

CASA PROGRAM APPEARANCES

At least once per month, at a time to be determined, you will be required to appear before the CASA Program Judicial Officer to evaluate your progress. Every effort will be made to ensure the time of the appearance does not conflict with your employment or treatment or other programming. The CPPSO, DFPD, and AUSA will be present, as will treatment and/or other program providers. Progress reports from the CPPSO will be provided to the Judicial Officer, the DFPD, and the AUSA. These reports will describe both successes and problems you have experienced. During the appearances to evaluate your progress, there will be no court reporter present, and court proceedings will not be transcribed. By signing this contract, you waive your right to have a court reporter transcribe the court proceedings at these appearances. A court reporter will be present to transcribe any contested violation hearing or any contested hearing to determine whether to terminate you from the CASA program.

CASA PROGRAM TREATMENT AND COUNSELING PROGRAMS

An important part of the CASA program will be your participation in substance abuse treatment and counseling programs and/or other programs addressing underlying causes of criminal activity as determined necessary by the CPPSO and the other members of the CASA Program Team. Treatment and other program providers will be expected to share information regarding your participation and progress in any treatment and counseling programs with all of the members of the CASA Program Team, including the CASA Program Judicial Officer, CPPSO, DFPD, AUSA, and any research partner evaluating the CASA program. Treatment and other program providers will also be present at CASA program appearances, at which they will be expected to discuss your participation and progress with all of the members of the CASA Program Team. To enable treatment and other program providers to freely share information regarding your participation and progress in substance abuse treatment and counseling programs and other programs, you will be required to execute a waiver of confidentiality in the form attached as Exhibit A.

LIMITED USE OF STATEMENTS MADE DURING PROGRAM APPEARANCES

Another important part of the CASA program is your complete candor during your CASA program appearances. To encourage your candor, the USAO has agreed as follows:

(A) Except as otherwise provided in subparagraph (B) below, in any criminal prosecution that may be brought against you by the USAO, the USAO will not offer in evidence in its case-in-chief any statements you make or any documents or other information you provide during your CASA program appearances (collectively "CASA program statements").

(B) Notwithstanding the USAO's agreement set forth in subparagraph (A) above, the USAO may use

(i) information derived directly or indirectly from CASA program statements for the purpose of obtaining and pursuing leads to other evidence, which evidence may be used for any purpose, including any criminal prosecution of you; and

(ii) CASA program statements and all evidence obtained directly or indirectly from CASA program statements for the purpose of cross-examination should you testify, or to refute or counter at any stage of any proceeding (including during the USAO's case-in-chief in any criminal prosecution) any evidence, argument, statement or representation offered by or on your behalf in connection with that proceeding.

The USAO's agreement in subparagraph (A) above is limited to the USAO and cannot bind any other federal, state, local, or foreign prosecuting, enforcement, administrative, or regulatory authorities. Moreover, the USAO's agreement in subparagraph (A) above is limited to CASA program statements and does not apply to any statements made or documents or other information provided by you at any other time, whether oral, written, or recorded.

CASA PROGRAM SUPERVISION VIOLATIONS AND SANCTIONS

CASA program supervision violations and sanctions will ordinarily be handled on the regularly scheduled CASA program calendar. The CASA Program Judicial Officer, however, can schedule an appearance at any time. Sanctions and modifications regarding treatment and other programs may also be handled on an expedited basis with the consent of the parties and the CASA Program Judicial Officer.

If a progress report contains an allegation of noncompliance, you may choose to agree that the allegation is true and waive the traditional protections and procedures afforded to those on pre-trial supervision when they are accused of violating supervision. If you do so, there will be no hearing on whether the allegation is true and the CASA Program Judicial Officer will decide whether a CASA program sanction is appropriate. As noted above, noncompliance may be handled on an expedited basis outside the presence of the CASA Program Judicial Officer if all parties agree.

Noncompliant behavior by you, the Participant, will result in sanctions. The range of possible sanctions has been drafted broadly to assure that some level of sanction is available for every type of violation. Factors that will influence the type of sanction employed include the seriousness of the violation, the number of violations, and the amount of time you have remained compliant, either before a first violation, or between violations. In addition, an important factor will be whether you voluntarily disclose the violation. Dishonesty on your part will result in enhanced sanctions. Depending on these factors, any of the sanctions listed below -- including termination from the CASA program -- is available. As a general rule, where there are repeat violations, more serious sanctions will be applied. Sanctions may include, but are not limited to:

- Judicial reprimand delivered during CASA program proceedings in front of other CASA program Participants
- Order to attend and observe pre-determined CASA program proceedings

- Order to submit written assignment (for example, write out an explanation for your non-compliant behavior and describe a plan to correct it or write out a list of the special conditions of your post-guilty plea diversion and explain how you violated those conditions and how you plan to avoid similar violations in the future)
- Curfew restriction for up to 30 days
- Increase in frequency of progress hearings before the CASA Program Judicial Officer
- Order to participate in community service as part of the CASA program
- Order to complete a term of home confinement (with conditions that may include alcohol monitors and standard location monitoring with GPS)
- Order to complete a term of up to 30 days at a residential reentry center
- Order to complete a term at a residential substance abuse treatment facility
- Order to spend up to 7 days in jail
- Termination from CASA program

If appropriate, sanctions may be ordered more than once during the course of the CASA program.

If you admit to the violation, you may be able to complete the sanction and remain in the CASA program. When expedited action is appropriate and the parties agree, a sanction or adjustment in treatment can be imposed through a modification without an appearance before the CASA Program Judicial Officer. The CPPSO's report at the next CASA program appearance will inform the CASA Program Judicial Officer whether you properly completed the sanction ordered at the last appearance. Failure to complete ordered sanctions may result in added sanctions, or termination from the CASA program.

If you wish to contest the violation allegation, you may do so. The only permissible contested hearing in the CASA program, however, is a claim of actual innocence of the alleged violation. If you wish to have a contested hearing, the DFPD will assist you in contesting the violation allegation. The CASA Program Judicial Officer will ultimately decide whether the allegation is true.

It is important to note that the CPPSO need not wait until your scheduled program appearance to address problems in supervision. If you fail to abide by directions of the CPPSO, or if the CPPSO believes that you have committed other violations of your supervision, the CPPSO will have discretion to contact you directly to address the violation; to arrive at a proposed method of addressing the violation through discussions with the CASA Program Judicial Officer, DFPD, and/or AUSA; or to request the issuance by the CASA Program Judicial Officer of a warrant for your arrest.

TERMINATION FROM THE CASA PROGRAM

You may be involuntarily terminated from the CASA program if you fail to participate in treatment or other programs or if you violate the terms of the CASA program or your post-guilty plea diversion -- including failure to make CASA program court appearances, failure to

participate actively in the CASA program, repeated drug use, or a new law violation. Final decisions regarding involuntary termination will be made by the CASA Program Judicial Officer. If you are involuntarily terminated from the CASA program, you will return to regular pretrial supervision and your case will be set for sentencing before the CASA Program Judicial Officer – in imposing sentence, the CASA Program Judicial Officer will not be bound to provide the benefits that your plea agreement would have required had you successfully completed the CASA program.

You may also at any time voluntarily discontinue your participation in the program and have your criminal case set for sentencing before the CASA Program Judicial Officer – again, however, in such an instance, the CASA Program Judicial Officer will not be bound to provide the benefits that your plea agreement would have required had you successfully completed the CASA program.

Whether your termination from the CASA program is voluntary or involuntary, the CASA Program Judicial Officer will be aware of, and can consider in imposing sentence, all conduct that has taken place during your participation in the CASA program, including successes, failures, and sanctions that occurred during your participaton in the CASA program.

GRADUATION AND BENEFITS

Upon successful completion of the CASA program, as determined by the CASA Program Judicial Officer and the other members of the CASA Program Team subject to the minimum requirement that, if you are determined to have a substance abuse issue, you have demonstrated at least six months of continuous sobriety, you will receive the benefits specified in your plea agreement, which will include [being permitted to withdraw your previously-entered guilty plea(s), with the criminal charges previously pending at the time of your guilty plea(s) dismissed with prejudice] [imposition of a sentence that does not include a term of imprisonment]. **[Select alternative that applies, and delete other.]**

///

///

///

///

///

///

///

///

///

AGREEMENT TO PARTICIPATE

Participant:

I,_____, have read, or someone has read to me in the language I best understand, this Contract and the plea agreement that would be a condition of my participation in the CASA program. I have discussed this Contract and the plea agreement with my attorney and I understand its terms. I have also discussed with my attorney the CASA program and I understand that program. I voluntarily agree to participate in the CASA program subject to the terms set forth in this Contract and the plea agreement. I understand I can revoke my voluntary participation in the CASA program at any time and that, if I do so, my criminal case will be set for sentencing before the CASA program judicial officer without any obligation to provide me the benefits set forth in the plea agreement for successful completion of the CASA program.

_____ _____

Signature Date
[Typed Name]

CASA Program Deputy Federal Public Defender:

I, _____, the Deputy Federal Public Defender representing the Participant in connection with the CASA program, have discussed the CASA program, the plea agreement that would be a condition of participation in the CASA program, and this Contract with the Participant and the Participant's attorney in the underlying criminal matter. I believe that the Participant understands the CASA program, the terms of the plea agreement that would be a condition of participation in the CASA program, and the terms of this Contract, and that the Participant's agreement to participate in the CASA program subject to the terms of this Contract and the plea agreement that would be a condition of participation in the CASA program is knowingly and voluntarily made.

_____ _____

Signature Date
[Typed Name]

CASA Program Assistant United States Attorney:

I,_____, the Assistant United States Attorney representing the United States Attorney's Office for the Central District of California (the "USAO") in the CASA program, agree to the terms of this Contract on behalf of the USAO and accept the above named Participant into the CASA program subject to the terms of this Contract and the plea agreement that would be a condition of the Participant's participation in the CASA program.

_____ _____

Signature Date
[Typed Name]

CASA Program Pretrial Services Officer:

I, _____, the Pretrial Services Officer assigned to the CASA program, accept the above named Participant into the CASA program subject to the terms of this Contract and the plea agreement that would be a condition of the Participant's participation in the CASA program.

_____ _____

Signature Date

[Typed Name]

CASA Program Judicial Officer:

Subject to the Court's acceptance of the Participant's guilty plea(s) and plea agreement, the Court hereby accepts the above named Participant into the CASA Program subject to the terms of this Contract and the plea agreement that would be a condition of the Participant's participation in the CASA program.

_____ _____

Signature Date

[Typed Name]

EXHIBIT 4

AUTHORIZATION TO RELEASE CONFIDENTIAL INFORMATION
CASA PROGRAM
SUBSTANCE ABUSE TREATMENT AND COUNSELING AND OTHER PROGRAMS

I, _____, the undersigned, have voluntarily agreed to participate in the Central District of California's Conviction And Sentence Alternatives ("CASA") program. As part of my participation in the CASA program, I hereby authorize any and all substance abuse treatment and counseling and other programs to which I may be referred as part of the CASA program to release confidential information in their records, possession, or knowledge, of whatever nature may now exist or come to exist, to the following participants in the CASA program: (a) the United States District Court for the Central District of California; (b) United States Pretrial Services for the Central District of California and any research partner working with Pretrial Services to evaluate the CASA program; (c) the Federal Public Defender's Office for the Central District of California; and (d) the United States Attorney's Office for the Central District of California (collectively, "the CASA Program Team").

The confidential information I hereby authorize to be released to the CASA Program Team will include, without limitation: date of entrance to program; attendance records; urine testing results; type, frequency, and effectiveness of therapy (including psychotherapy notes); general adjustment to program rules; type and dosage of medication; response to treatment; test results (psychological, vocational, etc.); date of and reason for withdrawal from program; and prognosis.

I understand that, subject to any exceptions to confidentiality that may apply under federal or state law, the CASA Program Team may use the confidential information hereby authorized to be released only in connection with their evaluation of my participation and progress in the CASA program and my compliance or non-compliance with the terms of my diversion, and their evaluation of the effectiveness of the CASA program as a whole.

I understand that this authorization will remain valid until my termination from the CASA program, whether successfully or unsuccessfully, at which time this authorization for disclosure of confidential information will expire. I understand, however, that confidential information disclosed pursuant to this authorization may subsequently be used by the United States District Court for the Central District of California, United States Pretrial Services for the Central District of California, and/or the United States Probation Office for the Central District of California to initiate or support an action alleging a violation of the terms of my diversion and/or to prepare a Presentence Report, make a recommendation regarding sentencing, and determine the appropriate sentence, as a result of which the information may no longer be deemed confidential and may no longer be protected by federal or state law.

I understand that I have the right to revoke this authorization to release confidential information, in writing, at any time by sending written notification to the United States Pretrial Services Officer assigned to supervise me in the CASA program. I understand that if I revoke this authorization to release confidential information, I will thereby revoke my authorization for further disclosure of such information. I also understand that if I revoke this authorization to release confidential information before I complete the CASA program, it may result in my termination from the CASA program and may be considered a violation of CASA program rules or of a condition of my diversion.

I have read this authorization to release confidential information, have discussed it with my attorney, understand its terms, and by signing below agree to it.

_____ _____
Signature Date
[Typed Name]

I am the attorney representing the individual signing this authorization to release confidential information in connection with the CASA program and have discussed the terms of this authorization with this individual. I believe this individual understands the terms of this authorization and that this individual's agreement to sign this authorization is knowingly and voluntarily made.

_____ _____
Signature Date
[Typed Name]

EXHIBIT 5

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, Plaintiff, v. Defendant.	No. ORDER FOR RETURN OF CASE FROM CASA PROGRAM

This case having been referred to this Court for all purposes, subject to a final determination whether defendant would be selected for participation in the Conviction And Sentence Alternatives ("CASA") program, and a final determination having been made that defendant is not selected for participation in the CASA program, IT IS HEREBY ORDERED as follows:

(1) This case is returned back to the Honorable [Judge's Name], the United States District Judge to whom this criminal case was originally assigned for all purposes.

(2) The court clerk for the Honorable [Judge's Name], having been contacted and having provided a date and time for a status conference in this matter, defendant shall appear in the courtroom of the Honorable [Judge's Name] on [DATE] at [TIME].

DATED: _____

_____
HON.
United States District Judge
CASA Program Judicial Officer

EXHIBIT 6

U.S. District Court - Central District of California
CASA Program Progress Report

Report Date:_____ ***Pretrial Services Officer: _____***
Telephone Number: _____

CASA PROGRAM HISTORY

Start Date:_____ Proj. Completion Date:_____Last Hearing Date:_____

Achievements/problems since last hearing:_____

_____

_____

Recommendation:_____

_____

_____

TREATMENT- ( ) DRUG ( ) M.H. ( ) CO-OCCUR ( ) MEDICAL ONLY

Primary Provider: _____

Secondary Provider(s): _____

Missed Tests/Sessions: ____ Yes ____ No _____

Positive Tests: ____ Yes ____ No_____

Medication(s): ( ) None ( ) Medical Condition only ( ) Psychotropic Meds
Medication Compliant: ____ Yes ____ No

Comments/Concerns: _____

_____

_____

MISCELLANEOUS COMMENTS

_____

_____

_____

EXHIBIT 7

United States District Court

Central District of California

U.S. v. _____ Docket No. _____

CASA Program Status Report (Compliance)

You have had no violations since your last appearance in the CASA program. Accordingly, the CASA Program Team has taken the following actions:

- ☐ Case continued without further action
- ☐ Verbal praise
- ☐ Kudos / Candy Bar
- ☐ Sobriety coin
- ☐ Other: _____
- ☐ Changes in current treatment: _____
  _____
- ☐ Reside and satisfactorily participate in a residential re-entry center (RRC) under the pre-release component for a period not to exceed _____ days or until successfully discharged by the RRC Director and the Pretrial Services Officer. Subsistence is waived.

All previously imposed terms and conditions of your pretrial supervision remain in effect, unless expressly noted otherwise.

Your next CASA program review date is on _____ at _____ ☐ am ☐ pm at the U.S. Courthouse, 312 North Spring Street, Los Angeles, California, 90012. **Failure to appear at this review, or any other review date, may result in a warrant or other sanction(s).**

Order of Court

Considered and ordered this____ day of _____, 20__,
and ordered filed and made part of the records in the above case.

_____
Honorable [Judge's Name]
United States District Judge

_____ : _____

Initials of Deputy Clerk _____

United States District Court

Central District of California

U.S. v. _____ Docket No. _____

CASA Program Status Report (Violation)

You have been found in violation of one or more of the terms of your participation in the CASA program. Accordingly, the CASA Program Team imposes the following:

☐ Judicial reprimand in open Court today.

☐ Attend CASA program proceedings ("sit-in") on _____

☐ Provide a _____ page written assignment due at next review date or _____

☐ Comply with Curfew restrictions (_____ am- _____ pm) starting today and expiring _____

☐ Increase in CASA program appearances ☐ weekly ☐ twice monthly ☐ other _____

☐ Community Service (CASA program requirement) _____ hours due by _____

☐ Comply with Home Confinement (standard/breathalyzer/GPS) for _____ days

☐ Reside and satisfactorily participate in a residential re-entry center (RRC) as a condition of pretrial supervision, for a period not to exceed _____ days or until successfully discharged by the RRC Director and the Pretrial Services Officer. Subsistence ☐ is waived / ☐ is not waived.

☐ Reside at and participate in a residential drug treatment program for _____ days

☐ Flash Incarceration (jail). Self-surrender on _____ to be released on _____

☐ Unsuccessful termination from the CASA program effective _____

☐ Other: _____

☐ Changes in current treatment: _____

All previously imposed terms and conditions of your pretrial supervision remain in effect, unless expressly noted otherwise.

Your next CASA program review date is on _____ at _____ ☐ am ☐ pm at the U.S. Courthouse, 312 North Spring Street, Los Angeles, California, 90012. **Failure to appear at this review, or any other review date, may result in a warrant or other sanction(s).**

Order of Court

Considered and ordered this _____ day of _____, 20__, and ordered filed and made part of the records in the above case.

_____

Honorable [Judge's Name]
United States District Judge

_____ : _____
Initials of Deputy Clerk _____

EXHIBIT 8

United States Pretrial Services

CENTRAL DISTRICT OF CALIFORNIA

U.S. v. <Insert defendant's name> DOCKET NO. <Insert docket number>

PETITION FOR ACTION ON CONDITIONS OF PRETRIAL RELEASE
(CASA Program Custodial Sanction)

COMES NOW GEORGE M. WALKER, CHIEF UNITED STATES PRETRIAL SERVICES OFFICER, presenting an official report upon the conduct of defendant <Insert defendant's name> who was placed under pretrial release supervision by the Honorable <Insert full name>, sitting in the court at <Insert Los Angeles or Riverside or Santa Ana>, California, on the <Insert numerical date> day of <Insert month and year>, under terms and conditions set by the court.

RESPECTFULLY PRESENTING PETITION FOR ACTION OF COURT
FOR CAUSE AS FOLLOWS:

Defendant is a participant in the Conviction And Sentence Alternatives ("CASA") program and has been found by the court to be in violation of the CASA program requirements.

PRAYING THAT THE COURT WILL ORDER defendant, as a sanction for violation(s) of the CASA program requirements, to serve ## [hours] [days] in the custody of the United States Marshals Service as a condition of pretrial release. Defendant shall immediately self-surrender to the United States Marshals Service, Roybal Building, 3rd Floor, Los Angeles, California.

ORDER OF THE COURT

Considered and ordered this ____ day of _____ 2011, and ordered filed and made a part of the records in the above case.

_____
<Insert Full Name of Judicial Officer>
<Insert U.S. District Judge or U.S. Magistrate Judge>

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge, information and belief.

Executed on <Insert month, day, year>

_____
<Insert Officer's Name>
U.S. Pretrial Services Officer

_____
<Insert Supervisor's Name>
Supervising U.S. Pretrial Services Officer

Place: <Insert officer's location>, California

EXHIBIT 9

UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, Plaintiff, v. Defendant.	No. ORDER TERMINATING DEFENDANT'S PARTICIPATION IN CASA PROGRAM AND DISMISSING CRIMINAL CHARGES BASED ON SUCCESSFUL COMPLETION OF CASA PROGRAM

On _____, defendant's case was referred to the undersigned United States District Judge to enable defendant's participation in the Conviction and Sentence Alternatives ("CASA") program. On _____, defendant entered a guilty plea to count _____ of the _____ pursuant to a plea agreement authorizing post-guilty plea diversion to enable participation in the CASA program. Under the CASA program, defendant's compliance with the terms of post-guilty plea diversion is overseen by the CASA Program Team. The CASA Program Team, including the undersigned United States District Judge, has determined that defendant has successfully completed the CASA program and therefore should receive the benefits specified in defendant's plea agreement.

IT IS HEREBY ORDERED that, based on defendant's successful completion of the CASA program, in accordance with the terms of defendant's plea agreement: (a) defendant's participation in the CASA program is terminated; (b) pursuant to Federal Rule of Criminal Procedure 11(d)(2)(B), on defendant's request, a fair and just reason having been demonstrated by defendant's successful completion of the CASA program, defendant's guilty plea withdrawn; (c) pursuant to Federal Rule of Criminal Procedure 48(a), on motion of the government, good cause having been shown by defendant's successful completion of the CASA program, the criminal charges against defendant in the above-captioned case are dismissed with prejudice; and (d) defendant's bond is exonerated.

DATED:

_____

HON.
United States District Judge
CASA Program Judicial Officer

UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, Plaintiff, v. Defendant.	No. ORDER TERMINATING DEFENDANT'S PARTICIPATION IN CASA PROGRAM AND SETTING SENTENCING BASED ON SUCCESSFUL COMPLETION OF CASA PROGRAM

On _____, defendant's case was referred to the undersigned United States District Judge to enable defendant's participation in the Conviction and Sentence Alternatives ("CASA") program. On _____, defendant entered a guilty plea to count _____ of the _____ pursuant to a plea agreement authorizing post-guilty plea diversion to enable participation in the CASA program. Under the CASA program, defendant's compliance with the terms of post-guilty plea diversion is overseen by the CASA Program Team. The CASA Program Team, including the undersigned United States District Judge, has determined that defendant has successfully completed the CASA program and therefore should receive the benefits specified in defendant's plea agreement.

IT IS HEREBY ORDERED that, based on defendant's successful completion of the CASA program, in accordance with the terms of defendant's plea agreement: (a) defendant is referred to the United States Probation Department for preparation of a Presentence Report; and (b) defendant's sentencing is scheduled before the undersigned United States District Judge for _____, at _____, at which time, based on defendant's successful completion of the CASA program, pursuant to the terms of defendant's plea agreement, and subject to defendant's continued compliance with the terms of defendant's pretrial supervision, the court will impose a sentence that does not include a term of imprisonment, the other terms of sentence to be determined at that time.

DATED:

_____

HON.
United States District Judge
CASA Program Judicial Officer

EXHIBIT 10

UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, Plaintiff, v. Defendant.	No. ORDER TERMINATING DEFENDANT'S PARTICIPATION IN CASA PROGRAM

On _____, defendant's case was referred to the undersigned United States District Judge to enable defendant's participation in the Conviction and Sentence Alternatives ("CASA") program. On _____, defendant entered a guilty plea to count _____ of the _____ pursuant to a plea agreement authorizing post-guilty plea diversion to enable participation in the CASA program.

Based on defendant's ☐ conduct while participating in the CASA program ☐ voluntary election to terminate defendant's participation in the CASA program, it has been determined that defendant should be terminated from further participation in the CASA program.

IT IS HEREBY ORDERED that defendant is terminated from further participation in the CASA program.

IT IS HEREBY FURTHER ORDERED that: (a) defendant is referred to the United States Probation Department for preparation of a Presentence Report; (b) defendant's sentencing is scheduled before the undersigned United States District Judge for _____

DATED: _____

_____
HON.
United States District Judge
CASA Program Judicial Officer

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF SOUTH CAROLINA

BRIDGE Program

Mission Statement & Policies

revised July2016

I. MISSION STATEMENT

The BRIDGE Program, a cooperative effort between South Carolina's U.S. District Court, U.S. Probation Office, Federal Public Defender's Office, and U.S. Attorney's Office, provides rehabilitative services to individuals with substance abuse problems who are involved in the federal criminal justice system. The program's purpose is to promote community safety, reduce recidivism, and assist with offender rehabilitation by implementing a blend of treatment and sanction alternatives.

II. INTRODUCTION

The District of South Carolina's BRIDGE Program is South Carolina's federal drug court. It is a voluntary program of at least one year that is designed for criminal defendants who suffer from substance abuse or addiction. All participants must be able and willing to abide by all of the program's rules as well as any additional instructions or orders issued by the presiding judge or by the supervising probation officer. Participants engage in varying levels of treatment in order to address issues of substance abuse. The BRIDGE program holds regularly scheduled, semimonthly court hearings to assess participant progress. Each participant's involvement in the program is approved and confirmed through a written agreement that outlines the program's obligations. This agreement is signed by the participant, his or her attorney, and the BRIDGE Program's supervising U.S. Probation Officer before it is approved by the program's presiding judge.

Participants may enter the BRIDGE Program as either pretrial or post-conviction defendants. Pretrial defendants may be admitted to the program after they have pleaded guilty to federal charges, but before they are sentenced on those charges.

Pretrial defendants who successfully complete the BRIDGE Program can expect the United States Attorney's Office to, in its own discretion, move for downward departure, reduce the charges to a lesser offense, recommend a non-guideline sentence, refer the participant to Pretrial Diversion, or dismiss the charges entirely.

Post-conviction defendants may be admitted to the program after they have been charged with a violation of their supervised release but before they have been sentenced on that violation. Post-conviction defendants who successfully complete the BRIDGE Program may receive a one-year reduction in their term of supervised release or probation.

This program is strictly voluntary; however, participants agree to abide by the program's rules, including its termination procedures. These termination procedures are discussed in further detail below.

The BRIDGE Program strives to incorporate the ten key components for successful drug courts identified by the National Association of Drug Court Professionals:

- Drug courts integrate alcohol and other drug treatment services with justice system case processing.
- Using a non-adversarial approach, prosecution and defense counsel promote public safety while protecting participants' due process rights.
- Eligible participants are identified early and promptly placed in the program.
- Drug courts provide access to a continuum of alcohol, drug, and other related treatment and rehabilitation services.
- Abstinence is monitored by frequent alcohol and drug testing.
- A coordinated strategy governs drug court responses to participants' compliance.
- Ongoing judicial interaction with each program participant is essential.
- Monitoring and evaluation measure the achievement of program goals and gauge effectiveness.
- Continuing interdisciplinary education promotes effective program planning, implementation, and operations.
- Forging partnerships among drug courts, public agencies, and community-based organizations generates local support and enhances drug court program effectiveness.

III. TEAM MEMBERS

The BRIDGE Program Team consists of the presiding judge, court staff, a treatment provider, defense counsel, and representatives from the U.S. Attorney's Office, the Federal Public Defender's Office, and the U.S. Probation Office. All team members play important roles, as outlined below.

Presiding Judge: The presiding judge leads the BRIDGE Program Team and works with other team members to achieve program goals. The presiding judge approves or denies the applications of all BRIDGE Program applicants. His or her active involvement with program participants is essential to the BRIDGE Program's success. He or she provides encouragement and rewards participants when they are performing well in the program. When participants fail to comply with program rules or otherwise engage in misconduct, the presiding judge, with input from the BRIDGE Program Team, imposes appropriate sanctions. While other members of the BRIDGE Program Team provide input, the presiding judge makes all final decisions regarding sanctions and terminations from the program. He or she presides over all team meetings and court hearings, including status conferences held for individual participants.

Supervising Probation Officer: The supervising probation officer assigned to the BRIDGE Program works with other BRIDGE Program Team members to achieve program goals. The supervising probation officer supervises all BRIDGE Program participants. He or she is charged with making appropriate treatment referrals with contract and non-contract agencies based on the needs of each participant. The supervising probation officer works with treatment agencies to ensure effective communication between the treatment providers and the BRIDGE Program Team. He or she attends all team meetings and court hearings, including all status conferences held for individual participants. The supervising probation officer regularly reports on BRIDGE participants' progress. The supervising probation officer makes recommendations regarding sanctions, including termination, and participates in all program planning decisions.

When problems arise with individual participants, the supervising probation officer works with other members of the BRIDGE Program Team to intervene as needed. The supervising probation officer promptly reports to the BRIDGE Program Team regarding all such interventions.

The supervising probation officer maintains files for each BRIDGE participant. These files contain all relevant BRIDGE Program documents, including a fully executed copy of the participant agreement, progress reports, treatment records, and drug testing results.

Assistant U.S. Attorney: The assistant U.S. attorney assigned to the BRIDGE Program works with other BRIDGE Program Team members to achieve program goals. The assistant U.S. attorney may refer defendants to the program; reports or comments on the participants' progress; and advocates on behalf of the government. He or she attends all team meetings and court hearings, including all status conferences held to address issues with individual participants. The assistant U.S. attorney makes recommendations regarding sanctions, including termination, and participates in all program planning decisions.

Assistant Federal Public Defender: The assistant federal public defender assigned to the BRIDGE Program works with other BRIDGE Program Team members to achieve program goals. The assistant federal public defender is, wherever possible, appointed to represent BRIDGE participants for purposes of drug court only. The assistant federal public defender may refer defendants to the program; reports or comments on the participants' progress during court hearings and team meetings; and advocates on behalf of his or her clients. He or she attends all team meetings, all drug court hearings, and any status conferences held for his or her clients. The assistant federal public defender makes recommendations regarding sanctions, including termination, and participates in all program planning decisions.

Defense Counsel: While the assistant federal public defender is often appointed to represent BRIDGE Program participants for the purposes of drug court only, some participants choose to be represented in drug court by their privately-retained or court-appointed defense attorneys. Defense counsel work with other BRIDGE Program Team members to achieve program goals. Defense counsel may refer defendants to the program; report or comment on their clients' progress; and advocate on behalf of their clients. They attend all status conferences held for their

clients, and frequently attend team meetings and drug court hearings. Defense counsel make recommendations regarding sanctions, including termination, for their clients.

Treatment Provider: The treatment provider works with other BRIDGE Program Team members to achieve program goals. The treatment provider assesses each participant, determines the appropriate level of substance abuse treatment, and provides said treatment. The treatment provider provides regular progress reports to the BRIDGE Program Team. He or she attends all team meetings and all drug court hearings. The treatment provider makes recommendations regarding sanctions, including termination, and participates in all program planning decisions.

Court Staff: Members of the courthouse staff support the BRIDGE Program in a number of ways. Court staff work with the supervising probation officer to prepare reports to the entire BRIDGE Program Team; prepare the presiding judge for drug court hearings and status conferences; record minutes for each drug court hearing; and provide assistance in all other aspects of the program as necessary. Court staff make recommendations regarding sanctions, including termination, and participate in all program planning decisions.

IV. PROGRAM ELIGIBILITY

When considering criminal defendants for admission to the BRIDGE Program, the following eligibility criteria are considered:

- Verified evidence or history of current substance abuse and/or addiction;
- Unrelated pending criminal cases, active warrants, or active capias;
- Mental health comorbidities and their severity;
- Desire to enter the program as well as willingness and ability to comply with requirements;
- Nature of pending charge, criminal history, and danger posed to the community;
- History of sex offense convictions or charges; and
- Reliable transportation for all required program events.

Criminal defendants with a history of violent crime, sex offenses, or severe mental health conditions are not eligible for the BRIDGE Program. Juvenile defendants are not eligible for the BRIDGE Program. For additional guidance, please see ***Appendix 1, Expanded Eligibility Criteria***.

V. THE REFERRAL PROCESS

Judges, defense attorneys, probation officers, assistant U.S. attorneys, and members of the BRIDGE Program Team may refer criminal defendants to the program. The referrer completes and submits the initial referral form found on the U.S. Probation Office's website. Please see ***Appendix 2, Initial Referral Form***. Members of the BRIDGE Program Team meet periodically, at the discretion of the presiding judge, to review referrals.

After a criminal defendant has been referred to the program, the supervising U.S. probation officer then screens the defendant's criminal record, substance abuse and/or mental health history, willingness and ability to participate in the program, as well as other relevant factors to determine suitability for the program. As part of this screening process, the supervising probation officer usually interviews the criminal defendant and discusses the program's requirements.

If the supervising probation officer determines that the criminal defendant would be an appropriate candidate for the BRIDGE Program, he or she presents that candidate to the presiding judge for his or her approval. When considering candidates for the BRIDGE Program, both the supervising probation officer and presiding judge review the eligibility criteria described above and in the expanded eligibility criteria. If the presiding judge agrees to accept the criminal defendant into the BRIDGE program, the supervising probation officer also seeks approval from both the assistant U.S. attorney and district judge assigned to the case.

If the criminal defendant is not already in substance abuse treatment, the supervising probation officer will then refer him or her for a thorough substance abuse evaluation. If viewed by the treatment provider as an appropriate candidate, the defendant will be accepted into the program.

VI. PROGRAM ENROLLMENT

All criminal defendants admitted to the BRIDGE Program must review the participant overview and sign the participant agreement before they begin participating in the program. The participant agreement outlines the BRIDGE Program's rules and expectations. It must be signed by the participant and his or her attorney, the supervising probation officer, and the presiding judge. When completing the participant agreement, the criminal defendant also acknowledges whether he or she consents to the appointment of the assistant federal public defender as his or her attorney solely for the purposes of the BRIDGE Program. Please see ***Appendix 3, BRIDGE Program Participant Agreement***, and ***Appendix 4, BRIDGE Program Participant Overview***, for more details.

Participants are generally expected to complete the program in twelve to eighteen months. The length of the program depends, in great part, on each participant's ability to succeed in the program. Individuals who struggle in treatment but remain dedicated to recovery may be given an extension of time to complete the program.

VII. PROGRAM PHASES

The BRIDGE Program comprises three phases. The phases are designed to allow each participant to establish a sober and law-abiding lifestyle. The phases encourage participants to develop an understanding of their substance abuse or dependence by recognizing patterns of use, factors that influence use, and the impact of use on themselves, their families, and their communities. While each phase has a specific purpose with distinct and achievable goals, the participants work throughout toward the development of a community-based sober support system. Each participant must successfully complete all levels in order to graduate from the program.

Phase One – Early Recovery

Phase Length: Approximately four months

Goals: Participants abstain from drug and alcohol use, engage in treatment and stabilize in the appropriate level of treatment services. Participants develop an understanding of addiction, patterns of use, and factors that influence use. Participants establish early recovery tools and a foundation of support for recovery.

Expectations for Participants:

- Abstain from use of all mood- or mind-altering drugs or alcohol, even if those substances are legally available;
- Do not commit any crimes or acquire any criminal charges;
- Comply with all bond or supervised release conditions;
- Attend all BRIDGE Program court hearings, which occur semimonthly;
- Participate in substance abuse treatment as directed;
- Attend at least three self-help meetings weekly and submit verification;
- Submit to drug and alcohol testing as ordered by the presiding judge or as deemed appropriate by the supervising probation officer;
- Submit to community and/or home visits as deemed appropriate by the supervising probation officer;
- Develop a plan to comply with any court-ordered restitution and, if possible, begin making payments;
- Complete and submit for approval a phase report that reflects on progress in the program and sets goals for the next phase; and
- Maintain sobriety for at least two consecutive months prior to moving into Phase Two.

Phase Two – Primary Treatment & Continued Care

Phase Length: Approximately five months

Goals: Participants begin to identify and understand adverse consequences of drug/alcohol use and take responsibility for same. Participants continue abstinence and continue to build a sober support network in the community.

Expectations for Participants:

- Abstain from use of all mood- or mind-altering drugs or alcohol, even if those substances are legally available;
- Do not commit any crimes or acquire any criminal charges;
- Comply with all bond or supervised release conditions;
- Attend all BRIDGE Program court hearings, which occur semimonthly;
- Participate in substance abuse treatment as directed;
- Attend at least three self-help meetings weekly and submit verification;
- Submit to drug and alcohol testing as ordered by the presiding judge or as deemed appropriate by supervising probation officer;
- Submit to community and/or home visits as deemed appropriate by the supervising probation officer;
- Seek and secure full-time employment/community service or enroll in and attend a full-time educational or vocational program;
- If offered and deemed necessary, participate in an available life-skills (Moral Reconation Therapy) or comparable program, as directed by U.S. Probation Office.
- If offered and deemed necessary, participate in an available personal finance or comparable program, as directed by U.S. Probation Office.
- Identify personal wellness activity and begin weekly participation;
- Begin or continue making payments towards any court-ordered restitution;
- Complete and submit for approval a phase report that reflects on progress in the program and sets goals for the next phase; and
- Maintain sobriety for at least three consecutive months prior to moving to Phase Three.

Phase Three – Relapse Prevention Planning

Phase Length: Approximately three months

Goals: Participants secure long-term recovery needs and develop and finalize a relapse prevention plan.

Expectations for Participants:

- Abstain from use of all mood- or mind-altering drugs or alcohol, even if those substances are legally available;
- Do not commit any crimes or acquire any criminal charges;
- Comply with all bond or supervised release conditions;
- Attend BRIDGE Program court hearings once per month;
- Participate in substance abuse treatment as directed;
- Attend at least three self-help meetings weekly and submit verification;
- Submit to drug and alcohol testing as ordered by the presiding judge or as deemed appropriate by supervising probation officer;
- Submit to community and/or home visits as deemed appropriate by the supervising probation officer;
- Maintain full-time employment or community service commitments or full-time student status;
- Continue weekly personal wellness activity;
- Complete any court-ordered restitution;
- Complete and submit for approval a relapse-prevention plan which includes continued recovery goals; and
- Maintain sobriety for at least five consecutive months prior to moving graduating from the BRIDGE Program.

VIII. DRUG COURT HEARINGS

In advance of the regularly-scheduled drug court hearings, the supervising probation officer and court staff prepare and distribute progress reports to the BRIDGE Program Team. These reports describe both successes and problems experienced on supervision, which may be treatment related, or otherwise. At staff meetings held before each drug court hearing, the BRIDGE Program Team reviews the progress reports for each participant and discusses each participant's progress. The entire team provides recommendations to the presiding judge as to how the participants' problems and successes should be addressed.

Participants and the BRIDGE Program Team assemble at the regularly-scheduled drug court hearings. Participants report on their progress and team members comment on the participants' successes or failures. Any BRIDGE Program, bond, or supervised release violations are addressed by the presiding judge. The presiding judge rewards or sanctions participants as appropriate.

IX. INCENTIVES AND REWARDS

Participation in the BRIDGE Program offers many rewards. Most importantly, participants receive substance abuse treatment and regain hope for a sober and crime-free life. Pretrial defendants who successfully complete the BRIDGE Program can expect the United States Attorney's Office to, in its own discretion, move for downward departure, reduce the charges to a lesser offense, recommend a non-guideline sentence, refer the participant to Pretrial Diversion, or dismiss the charges entirely. Post-conviction defendants who successfully complete the BRIDGE Program can expect to have their supervised release or probation terms reduced by one year.

As participants advance through the program, they may receive additional rewards during the drug court hearings. These rewards may include, but are not limited to:

- Applause and verbal praise;
- Written recognition or certificates of achievement;
- Reduced frequency of court appearances;
- Reduced drug testing;
- Elimination of curfew, home detention, or location monitoring;
- Token gifts such as neckties and snacks;
- Vouchers or gift cards;
- Promotion to next phase;
- Recovery materials; and
- A graduation certificate upon program completion.

X. VIOLATIONS AND SANCTIONS

Sanctions are imposed on participants who engage in misconduct as a way of deterring future misconduct. Sanctions are imposed with progressive severity. Misconduct and resulting sanctions may be addressed in the regularly-scheduled drug court hearings or at separate status conferences held by the presiding judge.

The following is a non-exhaustive list of behavior that the BRIDGE Program Team considers to be sanctionable misconduct:

- Dishonesty with members of the BRIDGE Program Team, including the presiding judge, supervising probation officer, and treatment provider;
- Unexcused absence from court hearings, meetings with the supervising probation officer, or meetings with the treatment provider;
- Positive alcohol or drug test results;
- Missed alcohol or drug test or refusal to submit to urinalysis testing;
- Submission or attempted submission of an adulterated urine sample;
- Failure to maintain employment, community service, or student status as directed;
- Failure to comply with conditions of bond or supervised release;
- New arrest; and
- Failure to comply with court-ordered restitution.

The following is a non-exhaustive list of sanctions that the presiding judge may impose in response to sanctionable misconduct:

- Verbal or written reprimands;
- Increased frequency of attendance at drug court hearings;
- Increased meetings with supervising probation officer and/or treatment provider;
- Increased drug and alcohol testing;
- Increased length of phase;
- Community service hours;
- Curfew or home confinement with or without location monitoring;
- Transdermal alcohol monitoring;
- Placement in a residential re-entry center, halfway house, or sober house;
- Placement in an in-patient or out-patient addiction treatment program;
- Days spent in custody of the U.S. Marshal's Service;
- Incarceration of varying length, generally no more than seven days;
- Revocation of bond; and
- Termination from the program.

XI. TERMINATION

There are four different ways in which participants are terminated from the BRIDGE Program.

Successful Termination: Successful termination occurs when a participant completes the program successfully. Successful termination is marked with a graduation ceremony.

Unsuccessful Termination With Return to Regular Supervision: This type of unsuccessful termination occurs when the participant has not committed a serious violation of program rules, but is not succeeding in the program. The participant may also have become a threat to public safety or program integrity. The participant is transferred back to supervision without a violation.

Unsuccessful Termination With a Formal Violation: This type of unsuccessful termination occurs when the participant has committed a serious violation of the program rules and the presiding judge determines that participation in the BRIDGE Program is no longer possible. The participant may also have become a threat to public safety or program integrity. The participant is returned to traditional supervision and generally faces a violation hearing before a magistrate judge or district judge.

The following is a non-exhaustive list of the types of misconduct that may result in unsuccessful termination with a formal violation:

- Criminal conduct;
- Repeated drug use;
- Repeated failure to cooperate with the supervising probation officer;
- Repeated failure to cooperate with the treatment provider;
- Failure to comply with sanctions ordered by the presiding judge; and
- Repeated failure to comply with the program's rules, orders from the presiding judge, and/or directions given by the supervising probation officer.

It is the policy of the U.S. Probation Office not to allege as a formal violation for conduct that has already been addressed within the BRIDGE Program. After the criminal defendant has been terminated from the program with a formal violation, however, the U.S. Probation Office will advise the judge presiding over the violation hearing of all conduct that has taken place during the period of supervision, including successes, failures, and sanctions that occurred while the defendant participated in the BRIDGE Program.

Administrative Discharge: Administrative discharge occurs when participation in the BRIDGE Program is no longer practical for reasons such as long-term illness. This type of termination is considered neither successful nor unsuccessful. Participants are returned to their traditional supervision, but may be permitted to return to the program at a later date.

Appendix 1

Expanded Eligibility Criteria

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF SOUTH CAROLINA

BRIDGE Program

Expanded Eligibility Criteria

This document provides expanded guidance regarding the eligibility criteria included in the BRIDGE Program's ***Mission Statement & Policies***. The following criteria are considered by the BRIDGE Program Team when determining whether to admit an individual to the program. No single consideration is necessarily dispositive. No combination or quantity of favorable and disfavorable factors will be determinative.

Criminal defendants with a history of violent crime, sex offenses, or severe mental health conditions are not eligible for the program. Juveniles are not eligible for the program.

PROGRAM ELIGIBILITY CRITERIA

Verified evidence or history of current substance abuse and/or addiction: The team may consider whether or not the pending federal offense was motivated by the defendant's substance abuse and/or addiction.

Unrelated pending criminal cases, active warrants, or active capias: The presence of such other pending federal, state, or local cases or warrants may disqualify a candidate from participation in the program.

Mental health comorbidities and their severity: The team may consider the severity of condition or disorder as well as any relevant treatment and medicinal demands.

Desire to enter the program as well as willingness and ability to comply with requirements:
The team may consider:

- Whether or not the defendant is a citizen of the United States or is otherwise lawfully present here;
- Whether the defendant is an adult or a juvenile;
- Any prior substance abuse treatment failures; and
- Whether the defendant can otherwise fully participate in and comply with the requirements of the program.

revised July 2016

Nature of pending charge, criminal history, and danger posed to the community: The team may consider:

- The drug quantity involved in the offense that is the subject of the pending federal charge;
- Whether the pending federal charge involved death or bodily injury to another person;
- Whether the defendant used violence or credible threats of violence or possessed a firearm, dangerous weapon, or body armor (or induced another to do so) in connection with the offense that is the subject of the pending federal charge;
- Whether the defendant engaged in obstruction of justice, intimidation or retaliation against a potential witness in the context of the pending federal offense;
- The nature and kind of the defendant's involvement in any alleged conspiracy;
- Whether or not the defendant was an organizer, leader, manager, or supervisor of others in the offense that is the subject of the pending federal charge;
- The degree of sentencing exposure;
- The presence of prior convictions for a serious violent offense, including but not limited to, any offense that has as an element the use, attempted use, or threatened use of physical force against another person;
- Whether the defendant is a member of a criminal street gang; and
- Whether the defendant is a member of any group espousing violence against the United States.

History of sex offense convictions or charges: The team may consider relevant pending or prior convictions, including but not limited to convictions for:

- Stalking;
- Child pornography; and
- Any offense involving any conduct codified in 18 U.S.C. §§ 109A, 109B, 110, and 110A.

Reliable transportation: The team may consider whether the defendant has the ability to attend the program's many required events, including court hearings, self-help meetings, appointments with treatment providers, and drug testing.

Appendix 2

Initial Referral Form

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF SOUTH CAROLINA

BRIDGE Program

Initial Referral Form

Date: _____

To: Tremaine Sumter, United States Probation Office
Tremaine_Sumter@scp.uscourts.gov
Office: (843) 579-1528
Fax: (843) 579-1519

From: _____

Email: _____

Phone: _____

Fax: _____

Subject: **BRIDGE Program Referral**

I hereby refer the following defendant to the BRIDGE Program.

Name: _____ Phone: _____

Case Number: _____

Defense Attorney: _____ Phone:_____

AUSA: _____ Phone:_____

BASIS FOR REFERRAL:

Please include any pertinent information that will assist in determining if this individual is a suitable BRIDGE Program referral, including: (1) whether he or she has reliable transportation for regular treatment appointments, court hearings, and self-help meetings; (2) any prior or current treatment for substance abuse; and (3) his or her commitment to drug treatment and the program's strict demands.

revised July 2016

Appendix 3

Participant Agreement

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF SOUTH CAROLINA

Bridge Program

Participant Agreement

I, _____, wish to participate in the District of South Carolina's Bridge Program, a federal drug court. I understand that if I am accepted into the Bridge Program, I must fully comply with all program requirements, all other court orders, and any orders that govern the conditions of my bond or supervised release. I understand that failure to comply with the terms of this agreement, other Bridge Program requirements, or court orders may result in the imposition of sanctions or, ultimately, in my termination from the Bridge Program. I also understand that any misconduct I may commit while I am a Bridge Program participant could result in the revocation of my bond, probation, or supervised release.

_____ I agree that I will not violate any federal, state, or local laws, and I acknowledge that I may be immediately terminated from the Bridge Program if I am charged with any such violations.

_____ I agree that I will not use any mood- or mind-altering drugs or alcohol, even if those substances are legally available.

_____ If I am placed on bond before or during my participation in the Bridge Program, I agree that participation in the Bridge Program is a condition of my bond.

_____ If I am placed on supervised release before or during my participation in the Bridge Program, I agree that participation in the Bridge Program is a condition of my supervision.

_____ I agree that I will be honest and candid with the Bridge Program's presiding judge, my supervising U.S. Probation Officer(s), and other members of the Bridge Program Team.

_____ I agree to obey all instructions and orders given to me by the Bridge Program's presiding judge and by my supervising U.S. Probation Officer(s).

_____ I agree to report to my supervising U.S. Probation Officer(s), as soon as possible but in no event later than 24 hours, every contact I have with law enforcement personnel, including arrests, questioning, or traffic stops.

_____ I agree to notify my supervising U.S. Probation Officer(s), as soon as possible but in no event later than 24 hours, of changes in any of the following: my home address; my phone number(s); my employment; and my educational pursuits.

_____ I agree to notify my supervising U.S. Probation Officer(s), as soon as possible but in no event later than 24 hours, if I lose my mobile telephone.

_____ I agree to submit to drug testing as directed by the Bridge Program's presiding judge or my supervising U.S. Probation Officer(s).

_____ I agree to immediately enroll in a substance abuse treatment program as directed by the Bridge Program's presiding judge or my supervising U.S. Probation Officer(s). I further agree to abide by the rules and regulations of that program until I am discharged from that program.

_____ I agree that I will participate in Alcoholics Anonymous, Narcotics Anonymous, or another court-approved self-help program as directed by the Bridge Program's presiding judge or my supervising U.S. Probation Officer(s).

_____ I agree to execute release forms that allow my supervising U.S. Probation Officer(s) to access any and all of my financial records, including but not limited to records maintained by banks, credit unions, credit reporting services, and the Social Security Administration.

_____ I agree to allow my supervising U.S. Probation Officer(s) to access and monitor any and all of my social networking accounts, including but not limited to Facebook, My Space, Twitter, and Instagram.

_____ I agree to allow my supervising U.S. Probation Officer(s) to access and monitor my educational records, including any online accounts that allow me to check my interim and final grades.

_____ I agree to execute release forms that allow my supervising U.S. Probation Officer(s) to access any and all of my health records, including but not limited to records held by physicians, nurses, hospitals, emergency rooms, urgent care providers and pharmacies.

_____ I agree to notify all health care providers, including but not limited to, physicians, nurses, hospitals, emergency rooms and urgent care providers, of the specifics of my substance abuse addiction, particularly before those health care providers prescribe any medication to me.

_____ I agree to report to my supervising U.S. Probation Officer(s), as soon as possible but in no event later than 24 hours, every contact I have with health care providers, including but not limited to visits with physicians, nurses, hospitals, emergency rooms, and urgent care providers.

_____ I agree to report to my supervising U.S. Probation Officer(s), as soon as possible but in no event later than 24 hours, any and all medication that has been prescribed to me.

_____ I agree that I will use prescription medication only in the manner in which it has been prescribed to me. I agree that I will use over-the-counter medication only in keeping with that medication's directions. If my health care provider prescribes alternate instructions for using over-the-counter medication, I will report those directions to my supervising U.S. Probation Officer(s) as soon as possible, but in no event later than 24 hours.

_____ I agree to undergo record checks for up to three (3) years following the termination of my term of supervision only for purposes of the Bridge program evaluation.

_____ I will not associate with any Bridge Program participants outside of the status hearings, drug treatment sessions, and self-help meetings, unless my supervising U.S. Probation Officer(s) expressly permits me to do so.

_____ I will not associate with any persons engaged in criminal activity and shall not associate with any person convicted of a felony, unless my supervising U.S. Probation Officer(s) expressly permits me to do so.

_____ I understand that information provided during Bridge Program hearings may not be protected by any privilege, and could be used against me in future court proceedings.

_____ I understand that should I fail to appear for any of the Bridge Program's status hearings, a warrant may be issued for my arrest only for purposes of the Bridge program evaluation.

_____ I understand that the United States Attorney's Office may petition – at any time – for my termination from the Bridge Program. I understand that the decision regarding termination rests in the sole discretion of the Bridge Program's presiding judge.

_____ I have not been promised any particular outcome with regards to the resolution of the federal charges or supervised release violation that I am currently facing. I understand that if I successfully complete the Bridge Program, the U.S. Attorney's Office – in its sole discretion – may move for downward departure regarding my sentence, reduce or dismiss my charges, recommend a non-guideline sentence, refer me to Pretrial Diversion, or move for reduction in the term of my supervised release or probation.

_____ I understand that, upon my successful completion of the Bridge Program, the program's presiding judge may recommend that I attend up to twelve bi-monthly counseling sessions as part of an after-care program for Bridge graduates. I agree that the district judge presiding over my sentencing, bond hearing, or supervision hearing may, in his or her sole discretion, order me to attend these counseling sessions. These counseling sessions, if required, will be provided at no or low cost to me.

_____ I understand that, upon my successful completion of the Bridge Program, the district judge presiding over my sentencing, bond hearing, or supervision hearing may, in his or her sole discretion, order me to perform a specified amount of community service, and/or attend a specified number of self-help meetings, and/or be present for a specified number of BRIDGE hearings.

_____ I have read and understand the District of South Carolina's Bridge Program Drug Testing Participant Contract (see addendum).

I have read the Participant Overview and the Participant Agreement, or they have been read to me, and I understand the terms and conditions of my participation in the Bridge Program. I agree to fully comply with these terms and conditions. By agreeing to participate in the Bridge Program, I consent to the disclosure of my confidential information to Bridge Program team members; I also consent to the disclosure of confidential information during Bridge Program hearings as appropriate. I understand that this is a voluntary program. By agreeing to participate in the Bridge Program, I agree that I will abide by all of the program's rules.

_____ _____
Participant Date

I have advised my client of all of the Bridge Program's terms and conditions. I believe that my client fully understands those terms and conditions, and that he or she knowingly and voluntarily seeks permission to participate in the Bridge Program.

_____ _____
Attorney for Participant Date

I recommend the above-named individual for participation in the Bridge Program.

_____ _____
U.S. Probation Officer, District of South Carolina Date

I approve the above-named individual for participation in the Bridge Program.

_____ _____
Bruce H. Hendricks Date
United States District Judge, District of South Carolina

I further understand that the Federal Public Defender may be appointed to represent me for the purposes of the BRIDGE Program only.

☐ I consent to the appointment of the Federal Public Defender to represent me for the purposes of the BRIDGE Program only. I understand that my defense attorney of record will continue to represent me in all matters arising in my underlying criminal case.

☐ I do not consent to the appointment of the Federal Public Defender to represent me for the purposes of the BRIDGE Program. I understand that my defense attorney of record will represent me for the purposes of the BRIDGE Program as well as in all matters arising in my underlying criminal case.

☐ The Federal Public Defender has previously been appointed to represent me in my criminal case and will also represent me for purposes of the BRIDGE Program.

_____	_____
Participant	Date
_____	_____
Attorney for Participant	Date
_____	_____
Assistant Federal Public Defender	Date

Bridge Program Drug Testing Participant Contract

Fact Sheet Regarding Creatinine

Urine specimens below 90° F, above 100° F, or that have a creatinine level below 20 mg/dL will be presumed to be diluted or fraudulent.

a) Normal human creatinine levels will vary during the day based upon fluid intake–healthy individuals will rarely produce urine samples with creatinines of less than 20 mg/dL

b) Incidence of creatinines less than 20 mg/dL in a "normal" population is approximately 1%

c) Urine with less than 20 mg/dL of creatinines are considered "dilute" and often do not reflect an accurate picture of recent drug use

d) Continued diluted drug tests will be treated as a compliance/dishonesty issue, but not a positive drug test. Dishonesty is the most severe misconduct and will be addressed significantly and appropriately. Participants that produce repeated diluted tests may be required to undergo testing with a nephrologist or other relevant physician at the participant's expense.

Sanctions: Sanctions listed below are in no particular order and may include, but are not limited to:

- Verbal warning
- Community service
- Write thinking report
- Increased meetings with supervising probation officer and/or treatment provider
- Increased drug testing
- Loss of privileges
- Jail time
- Termination from the program

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF SOUTH CAROLINA

Bridge Program

Drug Testing Participant Contract

1) Drug and alcohol testing will be performed frequently and on a random basis throughout your enrollment in the Drug Court. You will be placed on the United States Probation Office color code system. You will be required to call in daily to determine if you are to report to a specific location for testing. Additional testing will be conducted by the United States Probation Office and your substance abuse treatment provider as deemed appropriate.

2) I understand that it is my responsibility to report to the assigned location at the time given for the test.

3) Drug and alcohol testing may be performed on weekends and holidays.

4) Additional drug and alcohol testing will be performed by a laboratory or program approved by the Drug Court.

5) Because cannabinoids (a byproduct of marijuana) may persist in the body for several days, marijuana users have a two-week grace period following enrollment during which no sanctions will be given for positive cannabinoid test results. However, after two weeks positive cannabinoid tests will be presumed to reflect new marijuana use. Participants bear the burden of establishing a convincing alternative explanation for such results. After you have had two consecutive cannabinoid-negative urine specimens, the Drug Court will presume that subsequent positive cannabinoid results reflect new use.

6) Failure to provide a test specimen or providing an insufficient volume of urine for analysis is an infraction of the rules of the program and will be sanctioned accordingly. You will be given a sufficient time (up to one hour) to deliver a urine specimen and allowed to drink up to 8 ounces of water in the presence of staff.

7) I have been informed that the ingestion of excessive amounts of fluids can result in a diluted urine sample, and I understand that my urine sample will be tested to ensure the sample is not diluted.

8) You have the right to challenge the results of a screening test and to request proof that an adequate chain of custody was established for your specimen. The Drug Court will rely on the results of an instrumented or laboratory-based test in confirming whether substance use has occurred. You may be charged the cost of the confirmation test if a screening test is confirmed.

9) You will be sanctioned for providing diluted, adulterated, or substituted test specimens. Urine specimens below 90° F, above 100° F, or that have a creatinine level below 20 mg/dL will be presumed to be diluted or fraudulent.

   a) Normal human creatinine levels will vary during the day based upon fluid intake–healthy individuals will rarely produce urine samples with creatinines of less than 20 mg/dL

   b) Incidence of creatinines less than 20 mg/dL in a "normal" population is approximately 1%

   c) Urine with less than 20 mg/dL of creatinines are considered "dilute" and often do not reflect an accurate picture of recent drug use

   d) Continued diluted drug tests will be treated as a compliance/dishonesty issue, but not a positive drug test. Dishonesty is the most severe misconduct and will be addressed significantly and appropriately. Participants that produce repeated diluted tests may be required to undergo testing with a nephrologist or other relevant physician at the participant's expense.

      Sanctions: Sanctions listed below are in no particular order and may include, but are not limited to:

      - Verbal warning
      - Community service
      - Write thinking report
      - Increased meetings with supervising probation officer and/or treatment provider
      - Increased drug testing
      - Loss of privileges
      - Jail time
      - Termination from the program

10) You will be sanctioned for associating with other people who are engaged in substance use or for exposing yourself to passive inhalation or secondhand smoke.

11) I understand that substituting, altering or attempting to substitute/alter my specimen for the purpose of changing drug testing result will be considered noncompliance. Such conduct may result in sanctioning and may be grounds for immediate termination from drug court.

I have read the Drug Testing Participant Contract and the Fact Sheet Regarding Creatinine, or they have been read to me, and I understand the terms and conditions or my participation in the Bridge Program. I agree to fully comply with these terms and conditions. By agreeing to participate in the Bridge Program, I consent to the disclosure of my confidential information to Bridge Program team members; I also consent to the disclosure of confidential information during Bridge Program hearings as appropriate. I understand that this is a voluntary program. By agreeing to participate in the Bridge Program, I agree that I will abide by all of the program's rules and this Drug Testing Participant Contract.

I understand and agree that it is my responsibility to produce a valid sample upon every request for testing. Failure to do so will be treated as an offense for possible sanction.

_____ _____

Participant Date

_____ _____

U.S. Probation Officer, District of South Carolina

Appendix 4

Participant Overview

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF SOUTH CAROLINA

BRIDGE Program

Participant Overview

revised July 2016

I. INTRODUCTION

As members of the BRIDGE Program Team, we would like to congratulate you on your selection for participation in the BRIDGE Program, South Carolina's federal drug court. The recommendation process is not an easy one and your very referral to the program speaks to our belief in your ability to successfully complete it. This packet is designed to help you decide whether or not you would like to accept the referral and, if so, what you should expect while a participant in the program.

The BRIDGE Program is difficult. It will often be inconvenient and will demand discipline and sacrifice. Changing old habits is never simple or pain free. Regaining control of your life, in body and mind, is worth your hard work and sacrifice. That we can promise. And your path through the program will be supported by people who not only care about your future but have the expertise to help you change it.

You should know that the BRIDGE Program is completely voluntary. You can accept or decline participation in it. However, if you agree enter the program, you must abide by its rules, including its termination procedures. As will be explained, the BRIDGE Program both helps you change your lifestyle provides an opportunity to lessen the consequences you may otherwise face as a result of your criminal charges. Declining or quitting the program makes it more likely that you will have to face those consequences in the context of a criminal prosecution.

Lastly, the BRIDGE Program is built on trust and credibility. Your success in the program is tied directly to your commitment to candor and honesty. We expect that you will make mistakes during your time in the BRIDGE Program. However, even when you make mistakes, you always can control your own truthfulness. The presiding judge's harshest sanctions are often reserved for those times when participants fail to tell the truth. Accepting responsibility for your mistakes *is* changing your life; hiding your mistakes will only hold you back.

We hope you choose to join the BRIDGE Program.

II. TEAM MEMBERS

The BRIDGE Program Team consists of the presiding judge, court staff, a treatment provider, defense counsel, and representatives from the U.S. Attorney's Office, the Federal Public Defender's Office, and the U.S. Probation Office. All team members play important roles, as outlined below.

Presiding Judge: The presiding judge's job is to encourage you in your progress through the BRIDGE Program. You will appear before him or her on a regular basis to discuss your efforts in the Program. The presiding judge will give you encouragement and reward when you have made good choices, and will advise and sanction you when you make mistakes.

Supervising Probation Officer: The supervising probation officer is an important part of the BRIDGE Program team. He or she will coordinate and manage your participation in various

rehabilitation and treatment programs and will be responsible for reporting to the presiding judge and the team about your progress. The supervising probation officer will meet with you at both regularly scheduled and unscheduled times during your time in the program. He or she is your greatest resource. As with the presiding judge, if you are honest with the supervising probation officer, you have a great chance of making a change in your life for the better.

Assistant U.S. Attorney: The assistant U.S. attorney assigned to the BRIDGE Program plays an active part of your rehabilitation. He or she believes that you can be successful. As part of the team, he or she will offer insight into ways the program can work best for you.

Assistant Federal Public Defender or Defense Counsel: Many participants who join the BRIDGE Program opt to be represented by the assistant federal public defender for purposes of drug court only. If you choose this option, the assistant federal public defender assigned to the BRIDGE Program will represent you in drug court, while your current attorney will continue to represent you in all matters relating to your criminal case. Whether you are represented by the assistant federal public defender or by your current attorney, you will have an attorney who looks out for you best legal and personal interests. He or she works closely with the rest of the BRIDGE Program Team to ensure that you receive the help that you need.

Treatment Providers: During the BRIDGE Program, you may be required to attend counseling sessions, substance abuse programs, job training, self-help meetings, personal money management programs, community service activities, and more. The treatment providers who staff these activities are experts in providing the help you need and are trained to help you make better choices.

Court Staff: Members of the courthouse staff support the BRIDGE Program in a number of ways. They work closely with the rest of the BRIDGE Program Team to ensure that you receive the help that you need.

III. PROGRAM OVERVIEW

The BRIDGE Program is designed to last at least one year. Participants who struggle in treatment, but remain dedicated to recovery, may be given extensions to complete their term of treatment. Prior to being accepted into the BRIDGE Program, applicants must attend a BRIDGE Program hearing, participate in an interview with the supervising probation officer, and undergo a substance abuse assessment. Once accepted into the BRIDGE Program, participants are under the supervision of the United States Probation Officer assigned to the BRIDGE Program. Participants take part in all recommended treatment. Participants set goals for themselves and strive to achieve these individualized goals. Participants also submit to drug testing as directed by the supervising probation officer or the presiding judge. In addition to actively engaging in treatment, participants must comply with the general conditions of supervision.

The BRIDGE Program is made up of three phases. The phases are designed to allow each participant to establish a sober and law-abiding lifestyle. The phases encourage participants to develop an understanding of their substance abuse or dependence by recognizing patterns of use,

factors that influence use, and the impact of use on themselves, their families, and their communities. While each phase has a specific purpose with distinct and achievable goals, the participants work throughout toward the development of a community-based sober support system. Each participant must successfully complete all levels in order to graduate from the program.

Phase One – Early Recovery

Phase Length: Approximately four months

Goals: Participants abstain from drug and alcohol use, engage in treatment and stabilize in the appropriate level of treatment services. Participants develop an understanding of addiction, patterns of use, and factors that influence use. Participants establish early recovery tools and a foundation of support for recovery.

Expectations for Participants:

- Abstain from use of all mood- or mind-altering drugs or alcohol, even if those substances are legally available;
- Do not commit any crimes or acquire any criminal charges;
- Comply with all bond or supervised release conditions;
- Attend all BRIDGE Program court hearings, which occur semimonthly;
- Participate in substance abuse treatment as directed;
- Attend at least three self-help meetings weekly and submit verification;
- Submit to drug and alcohol testing as ordered by the presiding judge or as deemed appropriate by the supervising probation officer;
- Submit to community and/or home visits as deemed appropriate by the supervising probation officer;
- Develop a plan to comply with any court-ordered restitution and, if possible, begin making payments;
- Complete and submit for approval a phase report that reflects on progress in the program and sets goals for the next phase; and
- Maintain sobriety for at least two consecutive months prior to moving into Phase Two.

Phase Two – Primary Treatment & Continued Care

Phase Length: Approximately five months

Goals: Participants begin to identify and understand adverse consequences of drug/alcohol use and take responsibility for same. Participants continue abstinence and continue to build a sober support network in the community.

Expectations for Participants:

- Abstain from use of all mood- or mind-altering drugs or alcohol, even if those substances are legally available;
- Do not commit any crimes or acquire any criminal charges;
- Comply with all bond or supervised release conditions;
- Attend all BRIDGE Program court hearings, which occur semimonthly;
- Participate in substance abuse treatment as directed;
- Attend at least three self-help meetings weekly and submit verification;
- Submit to drug and alcohol testing as ordered by the presiding judge or as deemed appropriate by supervising probation officer;
- Submit to community and/or home visits as deemed appropriate by the supervising probation officer;
- Seek and secure full-time employment/community service or enroll in and attend a full-time educational or vocational program;
- If offered and deemed necessary, participate in the U.S. Probation Office's Makin' It Work Program;
- If offered and deemed necessary, participate in the U.S. Probation Office's Money Smart Program;
- Identify personal wellness activity and begin weekly participation;
- Begin or continue making payments towards any court-ordered restitution;
- Complete and submit for approval a phase report that reflects on progress in the program and sets goals for the next phase; and
- Maintain sobriety for at least three consecutive months prior to moving to Phase Three.

Phase Three – Relapse Prevention Planning

Phase Length: Approximately three months

Goals: Participants secure long-term recovery needs and develop and finalize a relapse prevention plan.

Expectations for Participants:

- Abstain from use of all mood- or mind-altering drugs or alcohol, even if those substances are legally available;
- Do not commit any crimes or acquire any criminal charges;
- Comply with all bond or supervised release conditions;
- Attend BRIDGE Program court hearings once per month;
- Participate in substance abuse treatment as directed;
- Attend at least three self-help meetings weekly and submit verification;
- Submit to drug and alcohol testing as ordered by the presiding judge or as deemed appropriate by supervising probation officer;
- Submit to community and/or home visits as deemed appropriate by the supervising probation officer;
- Maintain full-time employment or community service commitments or full-time student status;
- Continue weekly personal wellness activity;
- Complete any court-ordered restitution;
- Complete and submit for approval a relapse-prevention plan which includes continued recovery goals; and
- Maintain sobriety for at least five consecutive months prior to moving graduating from the BRIDGE Program.

IV. PROGRAM GOALS

Your primary goal and your motivation for participation in the BRIDGE Program should be your personal sobriety. It is the reason you were selected for the program, and no other meaningful change can happen in your life until you get your addiction to drugs and alcohol under control. We will work very hard in the early phases of the program to ensure effective sobriety before advancing you to the next phase. Once you are living sober, important things like a job, education, and health will be more realistic goals.

V. DRUG COURT HEARINGS

Participants regularly appear before the presiding judge to evaluate their progress. Every effort is made to ensure that the time of the appearance does not conflict with employment or treatment. At BRIDGE Program hearings, both the supervising probation officer and other team members report on the participant's progress. These reports describe both successes and problems experienced on supervision, which may be treatment related or otherwise.

VI. INCENTIVES AND REWARDS

Participation in the BRIDGE Program offers many rewards. Most importantly, participants receive substance abuse treatment and regain hope for a sober and crime-free life. Pretrial defendants who successfully complete the BRIDGE Program can expect the United States Attorney's Office to, in its own discretion, move for downward departure, reduce the charges to a lesser offense, recommend a non-guideline sentence, refer the participant to Pretrial Diversion, or dismiss the charges entirely. Post-conviction defendants who successfully complete the BRIDGE Program can expect to have their supervised release or probation terms reduced by one year.

As participants advance through the program, they may receive additional rewards during the drug court hearings. These rewards may include, but are not limited to:

- Applause and verbal praise;
- Written recognition or certificates of achievement;
- Reduced frequency of court appearances;
- Reduced drug testing;
- Elimination of curfew, home detention, or location monitoring;
- Token gifts such as neckties and snacks;
- Vouchers or gift cards;
- Promotion to next phase;
- Recovery materials; and
- A graduation certificate upon program completion.

VII. VIOLATIONS AND SANCTIONS

Misconduct by participants results in sanctions. Violations and sanctions will ordinarily be handled at the regularly scheduled BRIDGE Program hearing. Additionally, the sanctions and modifications regarding treatment may be handled on an expedited basis. Factors which will influence the type of sanction imposed include the participant's honesty about the misconduct, the seriousness of the violation, and the participant's history of good or bad conduct throughout

the course of the program. In addition, an important factor will be whether participants voluntarily disclose the violation. Any dishonesty may result in enhanced sanctions, including termination from the program. The following is a non-exclusive list of sanctionable misconduct:

- Dishonesty with members of the BRIDGE Program Team, including the presiding judge, supervising probation officer, and treatment provider;
- Unexcused absence from court hearings, meetings with the supervising probation officer, or meetings with the treatment provider;
- Positive alcohol or drug test results;
- Missed alcohol or drug test or refusal to submit to urinalysis testing;
- Submission or attempted submission of an adulterated urine sample;
- Failure to maintain employment, community service, or student status as directed;
- Failure to comply with conditions of bond or supervised release;
- New arrest; and
- Failure to comply with court-ordered restitution.

The following is a non-exhaustive list of sanctions that may be imposed by the presiding judge:

- Verbal or written reprimands;
- Increased frequency of attendance at drug court hearings;
- Increased meetings with supervising probation officer and/or treatment provider;
- Increased drug and alcohol testing;
- Increased length of phase;
- Community service hours;
- Curfew or home confinement with or without location monitoring;
- Transdermal alcohol monitoring;
- Placement in a residential re-entry center, halfway house, or sober house;
- Placement in an in-patient or out-patient addiction treatment program;
- Days spent in custody of the U.S. Marshal's Service;
- Incarceration of varying length, generally no more than seven days;
- Revocation of bond; and
- Termination from the program.

VIII. TERMINATION

There are four different ways in which participants are terminated from the BRIDGE Program.

Successful Termination: Successful termination occurs when a participant completes the program successfully. Successful termination is marked with a graduation ceremony. As noted above, pretrial defendants who successfully complete the BRIDGE Program can expect the United States Attorney's Office to, in its own discretion, move for downward departure, reduce the charges to a lesser offense, recommend a non-guideline sentence, refer the participant to Pretrial Diversion, or dismiss the charges entirely. Post-conviction defendants who successfully complete the BRIDGE Program can expect to have their supervised release or probation terms reduced by one year.

Unsuccessful Termination With Return to Regular Supervision: This type of unsuccessful termination occurs when the participant has not committed a serious violation of program rules, but is not succeeding in the program. The participant may also have become a threat to public safety or program integrity. The participant is transferred back to supervision without a violation.

Unsuccessful Termination With a Formal Violation: This type of unsuccessful termination occurs when the participant has committed a serious violation of the program rules and the presiding judge determines that participation in the BRIDGE Program is no longer possible. The participant may also have become a threat to public safety or program integrity. The participant is returned to traditional supervision and generally faces a violation hearing before a magistrate judge or district judge.

The following is a non-exhaustive list of the types of misconduct that may result in unsuccessful termination with a formal violation:

- Criminal conduct;
- Repeated drug use;
- Repeated failure to cooperate with the supervising probation officer;
- Repeated failure to cooperate with the treatment provider;
- Failure to comply with sanctions ordered by the presiding judge; and
- Repeated failure to comply with the program's rules, orders from the presiding judge, and/or directions given by the supervising probation officer.

It will be policy of the U.S. Probation Office not to allege as a formal violation for conduct that has already been addressed within the BRIDGE Program. After the criminal defendant has been terminated from the program with a formal violation, however, the U.S. Probation Office will advise the judge presiding over the violation hearing of all conduct that has taken place during the period of supervision, including successes, failures, and sanctions that occurred while the defendant participated in the BRIDGE Program.

Administrative Discharge: Administrative discharge occurs when participation in the BRIDGE Program is no longer practical for reasons such as long-term illness. This type of termination is considered neither successful nor unsuccessful. Participants are returned to their traditional supervision, but may be permitted to return to the program at a later date.

THE RISE PROGRAM

U.S. District Court **District of Massachusetts**
U.S. Probation & Pretrial Services **2015**

Purpose:

The RISE Program is designed for individuals who have pled guilty and are under pretrial supervision prior to sentencing. These individuals must apply for admission to the program and be accepted into the program by the Court. Goals of the program include:

- Promoting rehabilitation
- Promoting productive behavior
- Participants' accepting responsibility for offense(s) of conviction and their consequences
- Reducing recidivism
- Managing taxpayer funds/resources wisely

Eligibility Criteria:

Individuals meeting all three of the following criteria will be considered for the RISE Program:

- Individual is on pretrial release;
- Individual satisfies either of the following two conditions:
  a) Serious history of substance abuse or addiction as reflected in information available to Probation, which abuse or addiction substantially contributed to the commission of the charged offense; or
  b) History reflects significant deficiencies in full-time productive activity, decision making (i.e., criminal thinking in addition to charged offenses), or prosocial peer networks, as a result of which the defendant would benefit substantially from a structured pretrial program under the close supervision of the Court and Probation. The program requires a tailored combination of full-time productive activity (school, employment or community service), cognitive behavioral therapy to address criminal thinking (e.g., MRT program), development of new social or peer networks and removing other barriers to a sober, employed, law-abiding life (e.g., health insurance, driver's license, child support, financial literacy, parenting skills etc.);
- Nothing in history or pending charges makes the individual ineligible for the program such as (but not limited to) ineligibility for necessary or appropriate supervision or treatment programs or a pending sex offender charge.

Individuals will attend a RISE Program Court session each month and will complete the program by satisfying all identified goals and participating in the program successfully for a period of up to 12 months. Individuals who successfully complete the RISE Program are entitled to no specific or guaranteed benefit other than that the Court will consider all aspects of the defendant's participation in the RISE Program at sentencing. In other words, successful completion may be considered favorably at sentencing.

USDC – MASSACHUSETTS RISE PROGRAM

I. Overview

This RISE Program is a program created by the United States District Court for the District of Massachusetts and its Probation Office. In the course of developing the program, the Court has consulted with the United States Attorney's Office, the Federal Public Defender Office, members of the Criminal Justice Act panel and treatment providers.

For eligible defendants whose participation the assigned district judge approves at the prompt plea hearing, the RISE Program offers closer supervision, establishes higher expectations for a defendant's conduct, requires participation in treatment and delays the defendant's sentencing to permit participation. The Program aims to promote productive behavior by the defendants in the program, promote rehabilitation, increase acceptance of responsibility for the offense(s) of conviction as well as their consequences, manage wisely taxpayer funds, and reduce recidivism.

Defendants successfully completing the RISE Program are entitled to no specific or guaranteed benefit other than that the Court will consider all aspects of the defendant's participation in the RISE Program at sentencing. We anticipate that successful completion will be considered favorably at sentencing.

This document will be interpreted to advance the purposes of the RISE Program. It is not meant to be construed as a law, statute or regulation. Rather it is meant to be a tool for District Judges in the exercise of their broad individual discretion in addressing supervision and sentencing matters. Accordingly, nothing in this document establishes an enforceable legal right. Nor should any of the form of words in the document be the subject of additional written submissions unless the individual judge determines that the exercise of informed discretion would be assisted by such written submissions and expressly solicits them.

The Court approved the RISE Program as a three year pilot commencing on July 1, 2015, with annual review by the Court, and automatic expiration at the end of the three years absent an express decision by the Court to continue the RISE Program.

II. Identification of Participants

Each month Probation will identify those defendants, released the prior month, meeting the eligibility requirements for the Program. A Committee consisting of the Chair of the Court's Committee on Reentry, Diversion and Alternatives to Incarceration, the RISE Magistrate Judge, representatives of the Probation Office, a representative from the United States Attorney's Office, a representative of the Federal Public Defender's Office and such other judicial officers or persons designated by the Chief

Judge will review the released defendants for possible participation in the RISE Program.[1] The Committee will endeavor to reach consensus on all the recommendations it makes; however, the decision as to whether a defendant may participate as well as the terms governing the defendant's participation rests with the district judge to whom the defendant's case is assigned.

Defendants meeting all three of the following criteria will be considered for the RISE Program:

(a) Defendant is on pretrial release;
(b) Defendant satisfies either of the following two conditions
    a. Defendant has a serious history of substance abuse or addiction as reflected in the information available to Probation which abuse or addiction substantially contributed to the commission of the charged offense; or
    b. Defendant's history reflects significant deficiencies in full-time productive activity, decision making (i.e. criminal thinking in addition to the charged offenses), or pro-social peer networks as a result of which the defendant would benefit substantially from a structured pretrial program under the close supervision of the Court and Probation requiring a tailored combination of full-time productive activity (school, employment or community service), cognitive behavioral therapy to address criminal thinking (e.g. Probation's MRT program), development of new social or peer networks and resolving other barriers to a sober, employed law abiding life (e.g. health insurance, driver's license, child support, financial literacy, parenting skills etc.)[2];
(c) Nothing in the defendant's history or pending charges makes the person ineligible for the program such as (but not limited to) ineligibility for necessary or appropriate supervision or treatment programs or a pending sex offender charge.

---

[1] For each defendant not represented by the FPD, in advance of the meeting, Probation will seek the consent of each defendant's attorney to the FPD representative reviewing the material regarding the defendant (e.g. bail report and criminal record) solely for the purpose of considering the defendant's participation in the program. Ordinarily, Probation will do this by emailing defense counsel a description of the RISE Program along with a consent form. In the event counsel does not consent, then the FPD will not review the materials regarding that defendant or participate in any discussion.

[2] The "white collar defendants" whose history reflects substantial work history, education, and resources are, by the criteria established in text, ineligible for participation.

The Committee anticipates that some successful defendants will receive probation in lieu of a jail sentence, others may receive a shorter sentence of imprisonment and occasionally the USAO might determine a dismissal or reduction to a misdemeanor is appropriate. However, successful participation carries with it no guaranteed or promised result.

For each defendant identified as eligible, the Committee will create an individualized specific list of supplemental release conditions and program requirements tailored to the needs of the defendant. Both the CARE type and RESTART types of defendants shall complete both Probation's MRT program and restorative justice activities that (a) foster an appreciation for the harm caused by the charged offense(s) and (b) repair, at least in part, the harm from the offense(s). In addition, CARE type defendants, shall submit to drug testing, at a minimum, at a frequency similar to that applicable in CARE, drug treatment, and, for successful completion of the program, a minimum of twelve months of successful participation with seven months of consecutive sobriety concluding the participation. For RESTART type defendants, the list shall include, at a minimum, a list of objectives to accomplish and, for successful completion of the program, a minimum of twelve months of full-time productive activity.

Within seven days after the Committee makes a recommendation for participation, Probation will notify the assigned district judge and both counsel of the defendant's eligibility as well as the specific requirements for this defendant. The Court will not punish a defendant for electing not to participate. Defendants' electing to participate in the program must, within ninety days of arraignment, file a motion requesting the Court schedule a Rule 11 hearing. The Motion must also state that the defendant elects to participate in the RISE Program, whether the Committee recommended (or not) the defendant's participation and whether the Government assents, objects or takes no position on the defendant's participation. Unless the Committee has recommended defendant's participation, the defendant shall have the opportunity to explain the basis for its position before the assigned district judge renders a decision. Unless the Government assents, it shall have the opportunity to explain the basis for its position before the assigned district judge renders a decision. The assigned district judge shall state his or her decision approving or rejecting the defendant's participation prior to taking the defendant's plea. There is no requirement to do so; however, before the plea hearing. A delay in filing the motion for plea hearing and stating the defendant's election shall not preclude the defendant's participation, provided the defendant sought, from the assigned district judge, an extension in the ninety day deadline, before its expiration, due to the delay in receipt of substantial automatic discovery materials or an equivalent basis. Early participation in the RISE Program will promote successful results; however, the defendant must also receive a reasonable period of time to evaluate the discovery

before making the election to participate and the ninety day period ordinarily accomplishes both objectives.

After taking a plea[3] in the case of a defendant whose participation in the RISE Program the assigned district judge approves, the Court will not schedule a sentencing date, but rather note the defendant's referral to the RISE Program. The district judge will also (1) amend the defendant's release conditions to include the requirement of "Successful Participation in the RISE Program including compliance with all Program Rules" and (2) reassign the defendant's case, solely for purposes of the RISE Program and supervision of release conditions to the RISE Magistrate Judge, from the previously assigned Magistrate Judge. The RISE Magistrate Judge will provide a brief update to each district judge regarding the status of each of the judge's defendants in the RISE Program every April 1st, August 1st and December 1st.

Probation will commence the preparation of the PSR, in the ordinary course, up to the point of disclosure to the parties. Upon the defendant's conclusion of the RISE Program, Probation will require five weeks until sentencing during which time it will release the draft PSR including a summary of defendant's participation, receive and respond to objections and disclose the final PSR.

Defendants may not begin formal participation in the program until after pleading guilty; however, defendants may, prior to plea, observe the RISE Court session and otherwise begin to perform under the plan developed for the defendant. However, the required 12 month periods do not commence until formal participation in the program begins.

III. The Program

Probation will supervise the defendant's release including all of the additional conditions and requirements.

Each month the RISE Magistrate Judge will convene a RISE Court session. At each session, each defendant must report on his or her performance the prior month discussing each of the tasks/objectives/requirements applicable to this defendant including a recommendation as to whether or not he/she satisfied any of the objectives or

[3] Unsuccessful participation in (or a failure to complete) the RISE Program is neither a basis to withdraw a plea the Court has accepted nor a basis to oppose acceptance of a plea previously offered. The prompt acceptance of responsibility and the prompt final resolution of the pending charges are important purposes served by the requirement that the defendant plead guilty within the ninety day deadline.

earned credit for the month in terms of sobriety or gainful full-time activity. Probation will advise the Court of any additional applicable information and make its own recommendation. The Court will review with the defendant his/her performance and determine which, if any, requirements are satisfied and whether the month qualifies as a sober or employed month. Sanctions in the form of program requirements, e.g. essays, no credit, redo a requirement, etc may be imposed in the Court session without further process. Adjustments of bail conditions including temporary or permanent revocation of release, imposition of a curfew, a period in the half way house etc will occur only in a formal bail review hearing pursuant to Title 18 and the Federal Rules of Criminal Procedure which may occur during the monthly session or at another time as determined by the RISE Magistrate Judge. The USAO representative and FPD representative on the Committee will ordinarily attend each monthly session. While the FPD representative will raise potential Fifth Amendment or other issues of concern possibly affecting an individual defendant, the FPD representative does not appear as a counsel for any defendant.

The RISE Magistrate Judge may, in consultation with the Committee adjust the required objectives for the defendant in the course of his participation in the program, provided the assigned district judge approves.

In the event of misconduct warranting a possible immediate adjustment to a defendant's release conditions, e.g. a positive drug test, a failure to engage in productive activity as required or another similar matter in Probation's judgment, Probation may (a) secure defendant's agreement to an adjustment of the bail conditions, provided counsel for the defendant agrees and the RISE Magistrate Judge approves or (b) seek an adjustment to the defendant's release conditions by requesting from the Court a bail modification or revocation hearing.

IV. Completion of or Termination from the Program

A defendant completes the program successfully by satisfying all of his/her goals and completing the minimum period of sobriety or productive activity after which the RISE Magistrate Judge will notify the assigned district judge and request the scheduling of sentencing pursuant to the ordinary schedule. Probation will proceed to prepare the PSR. The defendant will continue to participate in the RISE Program until his actual sentencing.

The RISE Magistrate Judge may recommend to the assigned district judge the defendant's termination from the RISE Program whenever, in the judgment of the RISE Magistrate Judge, further participation in the program by the defendant is not warranted. The defendant may object to this recommendation. The assigned district

judge terminates the defendant's participation by accepting the recommendation, scheduling sentencing pursuant to the ordinary scheduling and notifying Probation to prepare the PSR.

Either the Government or Probation may seek the defendant's termination at any time in which case the RISE Magistrate Judge will either issue the recommendation described above or issue a recommendation of continued participation noting the objection of Probation and/or the Government. The assigned district judge will either reject the objection to continued participation or terminate the defendant's participation by proceeding as described above.

The assigned district judge may, at any time, terminate the defendant's participation in the RISE Program by scheduling the sentencing and directing Probation to complete the PSR.

Any party or Probation may provide the assigned district judge any information regarding the decision to terminate or not a defendant's continued participation.

A defendant may withdraw or quit the RISE Program at any time by requesting the assigned district judge to proceed to sentencing. The Court shall not punish the defendant for the decision to withdraw or quit.

Neither a defendant's unsuccessful participation in or a failure to complete the RISE Program is a basis to withdraw a plea the Court has accepted nor a basis to oppose acceptance of a plea previously offered.

The Court may consider all facts regarding the defendant's participation in the RISE Program at sentencing.

V. The RISE Program and Sentencing

Upon the conclusion of the defendant's participation in the RISE Program, the assigned district judge will schedule sentencing no less than five weeks from completion of the program to allow for disclosure of the draft PSR and the objection period.

The USAO will consider the significance of the defendant's participation and performance in the RISE Program in making its sentencing recommendations to the Court and in determining whether to make any different charging decisions after the conclusion of the defendant's participation in the RISE Program. Nothing about the RISE Program or a defendant's participation in it creates any obligations upon the USAO or requires any reports from the USAO beyond the ordinary statements and filings it makes as part of a sentencing process in any event.

At sentencing, the assigned district judge will consider the defendant's participation in the program giving it the appropriate weight under the applicable law and in light of any factual determinations made by the Court.

Presumably, successful participation in the program may result in a more favorable disposition for the defendant than had the defendant not participated at all; however, participation entitles the defendant to no particular benefit.

THE RISE PROGRAM

U.S. District Court **District of Massachusetts**
U.S. Probation & Pretrial Services **2015**

I, _____, have received a copy of the RISE Program description. In addition, the program has been explained to me by a Probation Officer. I have spoken to my attorney about the program.

I would like to be considered for acceptance into the program. I understand that the Program Selection Committee will look at my application and decide whether to accept me. The Program Selection Committee includes the Chair of the Court's Committee on Reentry, Diversion and Alternatives to Incarceration, the U.S. Magistrate Judge assigned to RISE, representatives of the Probation Office, a representative from the U.S. Attorney's Office, a representative of the Federal Public Defender Office and other persons designated by the Chief Judge to be on the committee.

I agree that a representative from the Federal Public Defender Office can review material regarding me for the purpose of considering my participation in the program. I understand that the Federal Public Defender representative will be excused from reviewing my application if conflicts are identified.

I understand that as part of the application process to be admitted into the program, I am required to participate in risk assessment and drug use assessments administered by the Probation Office. I understand that the results of these risk assessments will be reviewed by the Court and Probation Office when the committee is reviewing my application.

I understand that my acceptance into the program is not guaranteed.

_____ _____

Defendant Date

_____ _____

Counsel Date

PUBLIC HEARING ON
ALTERNATIVE TO INCARCERATION
COURT PROGRAMS AND SYNTHETIC DRUGS
MARCH 15, 2017
WASHINGTON, DC

Panel I. Alternatives to Incarceration: Design and Study

Vanessa Price
Director
National Drug Court Institute
National Association of Drug Court Professionals

Dr. Shannon Carey, Ph.D.
Co-President and Senior Research Associate
NCP Research

Dr. Faye Taxman, Ph.D.
Professor, Criminology, Law and Society Department
Director, Center for Advancing Correctional Excellence
George Mason University

Vanessa E. Price
Director
National Drug Court Institute
National Association of Drug Court Professionals

Vanessa E. Price is the Director of the National Drug Court Institute, which is the primary training and technical assistance division of the National Association of Drug Court Professionals. Prior to this, Ms. Price was a police officer with the City of Oklahoma City from 1990 through 2012, where she was an Inspector and Drug Court Liaison Officer. From 1998 through September 2009, she worked with the Oklahoma County Drug Court and was instrumental in the development of the program. Ms. Price has provided training to numerous drug court programs nationwide and abroad, on topics related to substance abuse, drug testing, recovery related services, and program training, development, and implementation. She received her Associates degree from Oklahoma State University in Applied Police Science and her Bachelor of Arts degree from the University of Central Oklahoma in Criminal Justice.

Good morning. My name is Vanessa Price. I am the director of the National Drug Court Institute at the National Association of Drug Court Professionals. Prior to assuming my role as director, I retired after 22 years in law enforcement, most recently as an inspector in the Oklahoma City Police Department, where I had the privilege of being the department's primary liaison to the Oklahoma County Drug Court team. In my nearly two decades of participation on drug court teams and training hundreds of courts nationally and internationally, I have found no other method as effective at reducing crime and saving valuable resources by ending the revolving door of those with substance use and co-occurring disorders entering and re-entering the justice system.

The United States is in the midst of an opioid epidemic. Americans from all areas, ages and socio-economic backgrounds are being affected by the serge of opioid misuse. In fact, according to the Centers for Disease Control and Prevention, at least 91 Americans die each day from an opioid overdose, accounting for more than 60 percent of drug overdose deaths in the United States today.

But this is hardly the first time our country has faced a drug epidemic. In the 1980s, crack cocaine was infecting the streets in cities across America, sparking policymakers nationwide to adopt policies viewed as "tough on crime." These policies, coupled with the now infamous "War on Drugs," emphasized harsh punishment for any type of drug-related crime. But quite simply, it didn't work.

Nowhere in the country was this more evident than in Miami, Florida. Crack cocaine was king, and those falling victim to its rapid spread were finding themselves in and out of a justice system powerless to do little more than try to incarcerate its way out of a public health crisis. Fed up with a backlog of cases involving people with serious substance use disorders and overcrowded, overspent jails, a group of professionals in the county justice system decided to come up with a solution.

In 1989, under the supervision of Judge Stanley Goldstein, Miami-Dade County opened the first program of what would come to be known as drug court. In sharp contrast to the standard practice of the day, emphasis in this court was placed not in providing the maximum amount of jail time, but in treatment and accountability. In drug court, the judge, prosecutor, defense attorney, law enforcement and probation officers worked as a team along with clinicians, case managers and treatment providers to ensure each program participant received an individualized, evidence-based treatment plan. In this new court, participants were capable of overcoming their addiction and not seen as societal castoffs whose only place in the world was behind bars.

And it was working.

Soon, jurisdictions across the country in search of their own solutions to the growing drug crisis started adopting this experimental model from Miami. Courts from Rochester, New York to Kansas City, Missouri to Portland, Oregon were finding drug court was not only saving lives, but saving thousands in taxpayer dollars, making it an easier sell to local and state governments.

As the 1990s progressed, courts began operating in more and more jurisdictions across the country. But even as drug courts received federal authorization in the 1994 Crime Bill, sending the number of drug courts in the United States skyrocketing, the movement lacked a clearly defined model. This changed in 1997, when the newly formed National Association of Drug Court Professionals, with the Bureau of Justice Assistance, published *Defining Drug Courts: The Key Components*. Known in the field as the Ten Key Components, this early publication of NADCP would become the core framework of the drug court

model, setting the stage for best practices and the expansion of the model to serve other populations, including repeat DWI offenders, tribal communities, families, veterans and others.

As more communities turned to drug courts in the 21st century to help reduce crime and lower rising criminal justice costs, the body of research continued to expand, making drug court the most researched intervention in the justice system. The first wave of research confirmed that drug courts effectively reduce drug use and crime while saving money. With this, researchers then turned their focus to determining why drug court works and what elements of the model are most critical to success. We now know that the effectiveness of drug courts depends largely on their adherence to the Ten Key Components. Courts that ignore or even only loosely adopt the components see lower graduation rates and higher recidivism, all resulting in lower cost savings.

Going beyond simply validating the broad principles of the Ten Key Components, the research gave them life, cementing them in our field as the standard for practice. Armed with this research, NADCP recognized the need to provide drug courts with guidance on how to operationalize the components and ensure fidelity to the drug court model.

We now know that drug court is most effective for those at the highest risk for recidivism and the highest need of treatment for a substance use disorder. Moreover, we know outcomes are further improved for participants if they complete 200 or more hours of drug treatment counseling, take advantage of medication-assisted treatment when applicable and have access to a wide range of complementary social services, including housing assistance, family counseling and educational services.

Knowing these and other critical elements, NADCP developed the *Adult Drug Court Best Practice Standards*. The standards incorporate more than a quarter-century of research defining appropriate practice for drug courts across a spectrum of highly researched principles, including target populations, team member roles, equity and inclusion, evaluation and others.

Since their release, the effect of the standards on the drug court field has been profound. New drug courts are using the standards as the foundation for building a successful program, and existing courts are using them to adopt new policies or retool old ones. Already, 22 states have either adopted the NADCP best practice standards or are incorporating them into their own standards. Last year, the White House Office of National Drug Control Policy awarded NADCP with funding to aid states in the implementation of the standards in their jurisdictions.

The ten standards outlined in two volumes were carefully chosen based on research showing they unequivocally improve outcomes in drug court. Of course, there are other essential practices that courts perform designed to answer the unique needs of their communities not addressed by the standards. The drug court field has always and will continue to follow the research, so we fully expect the standards will continue to evolve with time, and future volumes will be released as new research continues to validate other essential practices.

The standards are applied to other models of treatment courts outside of adult drug court. However, when applying the standards to other models, such as DWI courts or veterans treatment courts, consideration must be given to the population served and whether the body of research supports that population.

In conclusion, what started in Miami as a bold plan to reduce recidivism in 1989 is today an international movement dedicated to a smarter, economical and more effective approach to substance use and mental health disorders in the justice system. There are now more than 3,000 treatment courts in the United States covering every state and territory and serving a variety of populations, including adults, juveniles, veterans, federal offenders, tribal communities and many more.

I am honored to testify before you today about these lifesaving programs. Thank you for your time, and I welcome your questions.

U.S. Department of Justice
Office of Justice Programs
Drug Courts Program Office

OJP
Drug Courts
Program Office

Defining Drug Courts: The Key Components

January 1997

Defining Drug Courts: The Key Components

January 1997

The National Association of Drug Court Professionals

Drug Court Standards Committee

This project is supported by Grant No. 96-DC-MX-K001, awarded by the Drug Courts Program Office, Office of Justice Programs, U.S. Department of Justice. Points of view in this document are those of the authors and do not necessarily represent the official positions or policies of the U.S. Department of Justice.

Contents

Acknowledgments 1

Preface

Purpose 3
How to Use This Document 4

Introduction

Background 5
What Is a Drug Court? 7
The Planning Process 7

Key Component #1: Drug courts integrate alcohol and other drug treatment services with justice system case processing 9

Key Component #2: Using a nonadversarial approach, prosecution and defense counsel promote public safety while protecting participants' due process rights 11

Key Component #3: Eligible participants are identified early and promptly placed in the drug court program 13

Key Component #4: Drug courts provide access to a continuum of alcohol, drug, and other related treatment and rehabilitation services 15

Key Component #5: Abstinence is monitored by frequent alcohol and other drug testing 21

Key Component #6: A coordinated strategy governs drug court responses to participants' compliance 23

Key Component #7: Ongoing judicial interaction with each drug court participant is essential 27

Key Component #8: Monitoring and evaluation measure the achievement of program goals and gauge effectiveness 29

Key Component #9: Continuing interdisciplinary education promotes effective drug court planning, implementation, and operations 35

Key Component #10: Forging partnerships among drug courts, public agencies, and community-based organizations generates local support and enhances drug court effectiveness 37

Appendix 1: Drug Court Standards Committee 39

Appendix 2: Resource List 41

Acknowledgments

Appreciation is extended to the many individuals who took the time to offer comments and suggestions on the field review draft. Every suggestion was considered and most were incorporated, improving the document and making it truly reflect the drug court field's best thinking.

The Drug Court Standards Committee members donated their time and attention to this task, receiving no compensation except our deep gratitude for an excellent job. Special thanks are extended to the committee's chairman, Judge Bill Meyer of the Denver Drug Court, whose vision, enthusiasm, and good humor provided direction and momentum to the project.

The staff of the National Association of Drug Court Professionals and their consultant, Jody Forman, are commended for convening the committee and providing effective and expert support.

The production of this document was a joint effort of a dedicated group of drug court professionals and the Drug Courts Program Office, Office of Justice Programs, U.S. Department of Justice. It is my hope that this process and result will be the model for many successful cooperative projects.

Marilyn McCoy Roberts
Director, Drug Courts Program Office
Office of Justice Programs

Preface

Purpose

Defining Drug Courts: The Key Components was produced by a diverse group of drug court practitioners and other experts from across the country, brought together by the National Association of Drug Court Professionals. The committee includes representatives from courts, prosecution, public defense, treatment, pretrial services, case management, probation, court administration, and academia and others with drug court experience. (See appendix 1.)

The committee intends for the benchmarks presented in this publication to be inspirational, describing the very best practices, designs, and operations of drug courts for adults with alcohol and other drug problems. The committee recognizes that juveniles present different legal, social, educational, and treatment issues. Although the document may be useful in developing a juvenile drug court, its focus is on adults. The committee also acknowledges that local resources, political, and operational issues will not permit every local adult drug court to adopt all aspects of the guidelines.

The benchmarks offered here are not intended as a certification or regulatory checklist because the field is still too new to codify policies, procedures, and operations. Because drug courts are evolving, the committee decided that the field would benefit most from general, practical guidance on how to get established, what to consider, whom to include, and how to proceed. The benchmarks are meant to serve as a practical, yet flexible framework for developing effective drug courts in vastly different jurisdictions and to provide a structure for conducting research and evaluation for program accountability.

With over 200 drug courts in the United States, examples could be cited for almost every concept in this document. It was a difficult decision, but the committee decided that citing examples would make the document too large and its organization unwieldy. Also, since the examples would describe current drug court operations in a developing field, the material would be time sensitive and would render the document dated almost as soon as it was published.

In such a new field, the best practices of today will, doubtless, change tomorrow. For this reason, a resource list is privided in appendix 2. This document should be considered a starting point in the process of compiling the knowledge and experiences of others on how to best design and implement drug courts.

How to Use This Document

Over 200 drug courts coordinate treatment delivery with judicial oversight; these are considered bona fide drug courts. Many other programs named "drug courts" have sprung up across the country in the past several years in response to expanding court dockets, clogged with drug—related offenses. They may look similar, but they may not provide the orientation toward treatment and judicial supervision described in this document. Some programs focus on expediting case processing. Others try to intervene before trial but do not use judicial oversight, immediate treatment intervention, or alcohol and drug testing. Adherence to the key components and benchmarks detailed here distinguish treatment-based, multidiscipline, full-range drug courts from other programs.

This document is organized around 10 key components, which describe the basic elements that define drug courts. The purpose of each key component is explained, followed by several performance benchmarks that give guidance for implementing each key component.

Introduction

Insanity is doing the same thing over and over again and expecting different results.
Anonymous

Background

For several decades, drug use has shaped the criminal justice system. Drug and drug-related offenses are the most common crime in nearly every community.[1] Drug offenders move through the criminal justice system in a predictable pattern: arrest, prosecution, conviction, incarceration, release. In a few days, weeks, or months, the same person may be picked up on a new charge and the process begins again.

The segment of society using drugs between 1950 and 1970 expanded with the crack cocaine epidemic of the mid-1980's, and the number of drug arrests skyrocketed.[2] Early efforts to stem the tide only complicated the situation. Initial legislation redefined criminal codes and escalated penalties for drug possession and sales. These actions did little to curtail the illicit use of drugs and alcohol. As law enforcers redoubled their efforts, America's prisons were filled,[3] compromising Federal and State correction systems' abilities to house violent and career felons.[4] Some States scrambled to "build out" of the problem, spending hundreds of millions of dollars on new prisons, only to find that they could not afford to operate or maintain them.[5]

Other jurisdictions, encouraged and supported by the Federal Government, developed Expedited Drug Case Management systems and were the first to adopt the term "drug court." These early efforts sped up drug case processing by reducing the time between arrest and conviction. Existing resources were used more efficiently, and serious drug trafficking cases were processed more rapidly. However, these efforts did little to address the problems of habitual drug use and simply sped up the revolving door from court to jails and prisons and back again.

As offenders flooded the criminal justice system, many were not identified as having problems

---

[1]Drug Strategies, Keeping Score 1996: What are we getting for our federal drug control dollars. pp. 9–10, Washington, DC: Drug Strategies,1996.
[2]Drugs, Crime and the Criminal Justice System: A National Report. (NCJ133652), Washington, DC: U.S. Department of Justice, Bureau of Justice Statistics, 1992. pp. 26, 61.
[3]Drugs and Crime Facts 1994. (NCJ154053). Washington, DC: U.S. Department of Justice, Bureau of Justice Statistics, 1995.
[4]National Drug Control Strategy: Reclaiming Our Communities From Drugs and Violence.Washington, DC: The White House, February 1994.
Currie, E. Reckoning. New York: Hill & Wang,1995 p.15.
[5]National Directory of Corrections Construction, 1993 Supplement. (NCJ142525). Washington, DC: U.S. Department of Justice, Office of Justice Programs, National Institute of Justice and the Bureau of Justice Assistance, July 1993. Currie, p.151.

with alcohol and other drugs or were released to the community without referral to treatment. When they were identified, attempts by judges to refer them to treatment often yielded meager gains, either because the few alcohol and other drug (AOD) abuse treatment programs were full and waiting lists were long or because cooperative working relationships between criminal justice agencies and AOD treatment providers were inadequate or nonexistent. In addition, the majority of drug abusers ordered by judges to participate in treatment did not remain involved in the process long enough to develop behaviors and skills for long-term abstinence.

The traditional adversarial system of justice, designed to resolve legal disputes, is ineffective at addressing AOD abuse. Moreover, many features of the court system actually contribute to AOD abuse instead of curbing it: Traditional defense counsel functions and court procedures often reinforce the offender's denial of an AOD problem. The offender may not be assessed for AOD use until months after arrest, if at all. Moreover, the criminal justice system is often an unwitting enabler of continuing drug use because few immediate consequences for continued AOD use are imposed. When referrals to treatment are made, they can occur months or years after the offense and there is little or no inducement to complete the program.

In response, a few forward-thinking and innovative jurisdictions began to reexamine the relationship between criminal justice processing and AOD treatment services. Several commonsense improvements sprang up spontaneously throughout the Nation. It became increasingly apparent that treatment providers and criminal justice practitioners shared common goals: stopping the illicit use and abuse of all addictive substances and curtailing related criminal activity. Each system possessed unique capabilities and resources that could complement the other and enhance the effectiveness of both if combined in partnership. Thus, the concept of treatment-oriented drug courts was born.

Drug courts were first implemented in the late 1980's, but they did not develop in a vacuum. They are an outgrowth of the continuing development of community-based team-oriented approaches that have their roots in innovative programs developed by pretrial, probation, and parole agencies, as well as treatment-based partnerships such as TASC (Treatment Alternative to Street Crime) and law enforcement innovations such as community policing programs.

Nor are drug courts the culmination or focal point of this evolution in community-based court programs. "Community courts," encouraged by the success of drug courts, have emerged over the past several years to include domestic violence courts, DUI (driving under the influence) courts, juvenile and family drug courts, neighborhood courts, and even "deadbeat dad" courts. These courts are designed to reflect community concerns and priorities, access community

resources, include community organizations in policymaking decisions, and seek general community participation and support.

Drug courts and other new and innovative community-based court programs making up the community court field are, in turn, part of the "community justice" field. Along with community policing, community prosecution, and community corrections, these programs are evolving fast, gaining momentum, and spreading across the country. As the community justice field evolves into the 21st century, so too will drug courts.

What Is a Drug Court?

The mission of drug courts is to stop the abuse of alcohol and other drugs and related criminal activity. Drug courts offer a compelling choice for individuals whose criminal justice involvement stems from AOD use: participation in treatment. In exchange for successful completion of the treatment program, the court may dismiss the original charge, reduce or set aside a sentence, offer some lesser penalty, or offer a combination of these.

Drug courts transform the roles of both criminal justice practitioners and AOD treatment providers. The judge is the central figure in a team effort that focuses on sobriety and accountability as the primary goals. Because the judge takes on the role of trying to keep participants engaged in treatment, providers can effectively focus on developing a therapeutic relationship with the participant. In turn, treatment providers keep the court informed of each participant's progress so that rewards and sanctions can be provided.

Drug courts create an environment with clear and certain rules. The rules are definite, easy to understand, and most important, compliance is within the individual's control. The rules are based on the participant's performance and are measurable. For example, the participant either appears in court or does not, attends treatment sessions or does not; the drug tests reveal drug use or abstinence. The participant's performance is immediately and directly communicated to the judge, who rewards progress or penalizes noncompliance. A drug court establishes an environment that the participant can understand—a system in which clear choices are presented and individuals are encouraged to take control of their own recovery.

The Planning Process

Drug courts require a coordinated, systemic approach to the drug offender. Comprehensive and inclusive planning is critical. Planning begins with a vision of what will be achieved when the drug court succeeds. A mission statement evolves from this vision, giving rise to goals and objectives that create form and function. Clearly defined goals and objectives should be measurable and provide accountability for State and local funding agencies and policymakers who ultimately will ensure the continuation of the court.

Planning must be detailed, and thorough and must include as many perspectives as possible. A myriad of issues must be addressed, including offender identification and eligibility criteria; treatment methods, expectations, and support service availability; organizational coordination; formal policies and procedures; contractual and budgetary agreements; ongoing supervision; and process and outcome evaluation.

The judge, court administrator, clerk, prosecutor, defender, and other staff are particularly important to the planning process. The initial planning group should also include representatives from State and local treatment provider agencies, law enforcement, pretrial services, jails, probation services, and other community-based organizations. This core group develops a work plan addressing the operational, coordination, resource, information management, and evaluation needs of the program. The work plan should be specific, describing roles and responsibilities of each program component. For example, eligibility criteria, screening, and assessment procedures must be established. Both court and treatment case management procedures and information systems must be developed. Graduated responses to both participant compliance and noncompliance must be defined. Treatment requirements and expectations need to be understood and agreed to by the planning group.

Drug court programs should have the capacity to demonstrate tangible outcomes and cost—effectiveness. It is unlikely that drug courts will thrive without demonstrating reductions in AOD use, decreases in criminal behavior, and improvements in the employability and educational levels of participants.

As the planning process continues, additional challenges will arise. Once the drug court begins, what isn't working will quickly become apparent and must be adjusted or modified. Key personnel will change over time. Experience will bring growth and expansion. Mechanisms must already be in place to address these challenges.

Although the plan may never be perfect, the time allotted for planning should be sufficient to consider all of the critical issues, but short enough to implement while enthusiasm for the new endeavor is high.

Key Component #1

Drug courts integrate alcohol and other drug treatment services with justice system case processing.

Purpose: The mission of drug courts is to stop the abuse of alcohol and other drugs and related criminal activity. Drug courts promote recovery through a coordinated response to offenders dependent on alcohol and other drugs. Realization of these goals requires a team approach, including cooperation and collaboration of the judges, prosecutors, defense counsel, probation authorities, other corrections personnel, law enforcement, pretrial services agencies, TASC programs, evaluators, an array of local service providers, and the greater community. State-level organizations representing AOD issues, law enforcement and criminal justice, vocational rehabilitation, education, and housing also have important roles to play. The combined energies of these individuals and organizations can assist and encourage defendants to accept help that could change their lives.

The criminal justice system has the unique ability to influence a person shortly after a significant triggering event such as arrest, and thus persuade or compel that person to enter and remain in treatment. Research indicates that a person coerced to enter treatment by the criminal justice system is likely to do as well as one who volunteers.[6]

Drug courts usually employ a multiphased treatment process, generally divided into a stabilization phase, an intensive treatment phase, and a transition phase. The stabilization phase may include a period of AOD detoxification, initial treatment assessment, education, and screening for other needs. The intensive treatment phase typically involves individual and group counseling and other core and adjunctive therapies as they are available (see Key Component 4). The transition phase may emphasize social reintegration, employment and education, housing services, and other aftercare activities.

Performance Benchmarks:

1. Initial and ongoing planning is carried out by a broad-based group, including persons representing all aspects of the criminal justice system, the local treatment delivery system, funding agencies, the local community other key policymakers.
2. Documents defining the drug court's mission, goals, eligibility criteria, operating

[6]Hubbard, R., Marsden, M., Rachal, J., Harwood, H., Cavanaugh, E., and Ginzburg, H. Drug Abuse Treatment: A National Study of Effectiveness. Chapel Hill: University of North Carolina Press, 1989.

Pringle G., Impact of the criminal justice system on substance abusers seeking professional help, Journal of Drug Issues. Summer, pp. 275–283, vol 12, no. 3, 1982.

procedures, and performance measures are collaboratively developed, reviewed, and agreed upon.

3. Abstinence and law-abiding behavior are the goals, with specific and measurable criteria marking progress. Criteria may include compliance with program requirements, reductions in criminal behavior and AOD use, participation in treatment, restitution to the victim or to the community, and declining incidence of AOD use.

4. The court and treatment providers maintain ongoing communication, including frequent exchanges of timely and accurate information about the individual participant's overall program performance.[7]

5. The judge plays an active role in the treatment process, including frequently reviewing of treatment progress. The judge responds to each participant's positive efforts as well as to noncompliant behavior.

6. Interdisciplinary education is provided for every person involved in drug court operations to develop a shared understanding of the values, goals, and operating procedures of both the treatment and justice system components.

7. Mechanisms for sharing decisionmaking and resolving conflicts among drug court team members, such as multidisciplinary committees, are established to ensure professional integrity.

[7] All communication about an individual's participation in treatment must be in compliance with the provisions of 42 CFR, Part 2 (the federal regulations governing confidentiality of alcohol and drug abuse patient records), and with similar State and local regulations.

Key Component #2

Using a nonadversarial approach, prosecution and defense counsel promote public safety while protecting participants' due process rights.

Purpose: To facilitate an individual's progress in treatment, the prosecutor and defense counsel must shed their traditional adversarial courtroom relationship and work together as a team. Once a defendant is accepted into the drug court program, the team's focus is on the participant's recovery and law-abiding behavior—not on the merits of the pending case.

The responsibility of the prosecuting attorney is to protect the public's safety by ensuring that each candidate is appropriate for the program and complies with all drug court requirements. The responsibility of the defense counsel is to protect the participant's due process rights while encouraging full participation. Both the prosecuting attorney and the defense counsel play important roles in the court's coordinated strategy for responding to noncompliance.

Performance Benchmarks:

1. Prosecutors and defense counsel participate in the design of screening, eligibility, and case-processing policies and procedures to guarantee that due process rights and public safety needs are served.

2. For consistency and stability in the early stages of drug court operations, the judge, prosecutor, and court-appointed defense counsel should be assigned to the drug court for a sufficient period of time to build a sense of teamwork and to reinforce a nonadversarial atmosphere.

3. The prosecuting attorney

   - reviews the case and determines if the defendant is eligible for the drug court program;
   - files all necessary legal documents;
   - participates in a coordinated strategy for responding to positive drug tests and other instances of noncompliance;
   - agrees that a positive drug test or open court admission of drug possession or use will not result in the filing of additional drug charges based on that admission; and

- makes decisions regarding the participant's continued enrollment in the program based on performance in treatment rather than on legal aspects of the case, barring additional criminal behavior.

4. The defense counsel

   - reviews the arrest warrant, affidavits, charging document, and other relevant information, and reviews all program documents (e.g., waivers, written agreements),

   - advises the defendant as to the nature and purpose of the drug court, the rules governing participation, the consequences of abiding or failing to abide by the rules, and how participating or not participating in the drug court will affect his or her interests;

   - explains all of the rights that the defendant will temporarily or permanently relinquish;

   - gives advice on alternative courses of action, including legal and treatment alternatives available outside the drug court program, and discusses with the defendant the long-term benefits of sobriety and a drug-free life;

   - explains that because criminal prosecution for admitting to AOD use in open court will not be invoked, the defendant is encouraged to be truthful with the judge and with treatment staff, and informs the participant that he or she will be expected to speak directly to the judge, not through an attorney.

Key Component #3

Eligible participants are identified early and promptly placed in the drug court program.

Purpose: Arrest can be a traumatic event in a person's life. It creates an immediate crisis and can force substance abusing behavior into the open, making denial difficult. The period immediately after an arrest, or after apprehension for a probation violation, provides a critical window of opportunity for intervening and introducing the value of AOD treatment. Judicial action, taken promptly after arrest, capitalizes on the crisis nature of the arrest and booking process.

Rapid and effective action also increases public confidence in the criminal justice system. Moreover, incorporating AOD concerns into the case disposition process can be a key element in strategies to link criminal justice and AOD treatment systems overall.

Performance Benchmarks:

1. Eligibility screening is based on established written criteria. Criminal justice officials or others (e.g., pretrial services, probation, TASC) are designated to screen cases and identify potential drug court participants.

2. Eligible participants for drug court are promptly advised about program requirements and the relative merits of participating.

3. Trained professionals screen drug court—eligible individuals for AOD problems and suitability for treatment.

4. Initial appearance before the drug court judge occurs immediately after arrest or apprehension to ensure program participation.

5. The court requires that eligible participants enroll in AOD treatment services immediately.

Key Component #4

Drug courts provide access to a continuum of alcohol, drug, and other related treatment and rehabilitation services.

Purpose: The origins and patterns of AOD problems are complex and unique to each individual. They are influenced by a variety of accumulated social and cultural experiences. If treatment for AOD is to be effective, it must also call on the resources of primary health and mental health care and make use of social and other support services.[8]

In a drug court, the treatment experience begins in the courtroom and continues through the participant's drug court involvement. In other words, drug court is a comprehensive therapeutic experience, only part of which takes place in a designated treatment setting. The treatment and criminal justice professionals are members of the therapeutic team.

The therapeutic team (treatment providers, the judge, lawyers, case managers, supervisors, and other program staff) should maintain frequent, regular communication to provide timely reporting of a participant's progress and to ensure that responses to compliance and noncompliance are swift and coordinated. Procedures for reporting progress should be clearly defined in the drug court's operating documents.

While primarily concerned with criminal activity and AOD use, the drug court team also needs to consider co-occurring problems such as mental illness, primary medical problems, HIV and sexually-transmitted diseases, homelessness; basic educational deficits, unemployment and poor job preparation; spouse and family troubles—especially domestic violence—and the long-term effects of childhood physical and sexual abuse. If not addressed, these factors will impair an individual's success in treatment and will compromise compliance with program requirements. Co-occurring factors should be considered in treatment planning. In addition, treatment services must be relevant to the ethnicity, gender, age, and other characteristics of the participants.

Longitudinal studies have consistently documented the effectiveness of AOD treatment in reducing criminal recidivism and AOD use.[9] A study commissioned by the Office of National Drug Control Policy found AOD treatment is significantly more cost-effective than domestic law

[8] Treatment-Based Drug Court Planning Guide and Checklist, Combining Alcohol and Other Drug Abuse Treatment With Diversion for Juveniles in the Justice System, TIP #21, Treatments Drug Courts: Integrating Substance Abuse Treatment With Legal Case Processing, TIP #23. Rockville, MD: Center for Substance Abuse Treatment, 1996.
[9] The Effectiveness of Treatment for Drug Abusers Under Criminal Justice Supervision. Lipton, D., Washington, DC: National Institute of Justice, Research Report, November 1995.

enforcement, interdiction, or "source-country control" in reducing drug use in the United States[10]

Research indicates that the length of time an offender spends in treatment is related to the level of AOD abuse and criminal justice involvement.[11] A comprehensive study conducted by the State of California indicates that AOD treatment provides a $7 return for every $1 spent on treatment. The study found that outpatient treatment is the most cost-effective approach, although residential treatment, sober living houses, and methadone maintenance are also cost-effective.[12] Comprehensive studies conducted in California[13] and Oregon[14] found that positive outcomes associated with AOD treatment are sustained for several years following completion of treatment.

For the many communities that do not have adequate treatment resources, drug courts can provide leadership to increase treatment options and enrich the availability of support services. Some drug courts have found creative ways to access services, such as implementing treatment readiness programs for participants who are on waiting lists for comprehensive treatment programs. In some jurisdictions, drug courts have established their own treatment programs where none existed. Other drug courts have made use of pretrial, probation, and public health treatment services.

Performance Benchmarks:

1. Individuals are initially screened and thereafter periodically assessed by both court and treatment personnel to ensure that treatment services and individuals are suitably matched:

    - An assessment at treatment entry, while useful as a baseline, provides a time specific "snapshot" of a person's needs and may be based on limited or unreliable information. Ongoing assessment is necessary to monitor progress, to change the treatment plan as necessary, and to identify relapse cues.

[10] Rydell, P., Everingham, S. Controlling Cocaine: Supply Versus Demand Programs. Santa Monica, CA: RAND Corporation, Office of National Drug Control Policy, Policy Research Center, 1994.
[11] Field, G. Oregon prison drug treatment programs. In C. Leukefeld and F. Tims (eds.), Drug Abuse Treatment in Prisons and Jails. Research monograph series #108. Rockville, MD: National Institute on Drug Abuse, 1992. Wexler, H., Falkin, G., and Lipton, D. Outcome evaluation of a prison therapeutic community for substance abuse treatment. Criminal Justice and Behavior, 17, pp 71-92, 1990.
[12] Evaluating Recovery Services: The California Drug and Alcohol Treatment Assessment (CALDATA) General Report. Sacramento, CA: California Department of Alcohol and Drug Programs, April 1994.
[13] Ibid.
[14] Societal Outcomes and Cost Savings of Drug and Alcohol Treatment in the State of Oregon. Salem, OR: Office of Alcohol and Drug Abuse Programs, Oregon Department of Human Resources, February 1996.

- If various levels of treatment are available, participants are matched to programs according to their specific needs. Guidelines for placement at various levels should be developed.

- Screening for infectious diseases and health referrals occurs at an early stage.

2. Treatment services are comprehensive:

   - Services should be available to meet the needs of each participant.

   - Treatment services may include, but are not limited to; group counseling; individual and family counseling; relapse prevention; 12-step self-help groups; preventive and primary medical care; general health education; medical detoxification; acupuncture for detoxification, for control of craving, and to make people more amenable to treatment; domestic violence programs; batterers' treatment; and treatment for the long-term effects of childhood physical and sexual abuse.

   - Other services may include housing; educational and vocational training; legal, money management, and other social service needs; cognitive behavioral therapy to address criminal thinking patterns; anger management; transitional housing; social and athletic activities; and meditation or other techniques to promote relaxation and self-control.

   - Specialized services should be considered for participants with co-occurring AOD problems and mental health disorders. Drug courts should establish linkages with mental health providers to furnish services (e.g., medication monitoring, acute care) for participants with co-occurring disorders. Flexibility (e.g., in duration of treatment phases) is essential in designing drug court services for participants with mental health problems.

   - Treatment programs or program components are designed to address the particular treatment issues of women and other special populations.

   - Treatment is available in a number of settings, including detoxification, acute residential, day treatment, outpatient, and sober living residences.

   - Clinical case management services are available to provide ongoing assessment of participant progress and needs, to coordinate referrals to services in addition to primary treatment, to provide structure and support for individuals who typically

have difficulty using services even when they are available, and to ensure communication between the court and the various service providers.

3. Treatment services are accessible:

   - Accommodations are made for persons with physical disabilities, for those not fluent in English, for those needing child care, and/or for persons with limited literacy.

   - Treatment facilities are accessible by public transportation, when possible.

4. Funding for treatment is adequate, stable, and dedicated to the drug court:

   - To ensure that services are immediately available throughout a participant's treatment, agreements are made between courts and treatment providers. These agreements are based on firm budgetary and service delivery commitments.

   - Diverse treatment funding strategies are developed based on both government and private sources at national, State and local levels.

   - Health care delivered through managed care organizations is encouraged to provide resources for the AOD treatment of member participants.

   - Payment of fees, fines, and restitution is part of treatment.

   - Fee schedules are commensurate with an individual's ability to pay. However, no one should be turned away solely because of an inability to pay.

5. Treatment services have quality controls:

   - Direct service providers are certified or licensed where required, or otherwise demonstrate proficiency according to accepted professional standards.

   - Education, training, and ongoing clinical supervision are provided to treatment staff.

6. Treatment agencies are accountable:

   - Treatment agencies give the court accurate and timely information about a participant’s progress. Information exchange complies with the provisions of 42 CFR, Part 2 (the Federal regulations governing confidentiality of AOD abuse patient records) and with applicable State statutes.

- Responses to progress and noncompliance are incorporated into the treatment protocols.

7. Treatment designs and delivery systems are sensitive and relevant to issues of race, culture, religion, gender, age, ethnicity, and sexual orientation.

Key Component #5

Abstinence is monitored by frequent alcohol and other drug testing.

Purpose: Frequent court-ordered AOD testing is essential. An accurate testing program is the most objective and efficient way to establish a framework for accountability and to gauge each participant's progress. Modern technology offers highly reliable testing to determine if an individual has recently used specific drugs. Further, it is commonly recognized that alcohol use frequently contributes to relapse among individuals whose primary drug of choice is not alcohol.

AOD testing results are objective measures of treatment effectiveness, as well as a source of important information for periodic review of treatment progress. AOD testing helps shape the ongoing interaction between the court and each participant. Timely and accurate test results promote frankness and honesty among all parties.

AOD testing is central to the drug court's monitoring of participant compliance. It is both objective and cost-effective. It gives the participant immediate information about his or her own progress, making the participant active and involved in the treatment process rather than a passive recipient of services.

Performance Benchmarks:

1. AOD testing policies and procedures are based on established and tested guidelines, such as those established by the American Probation and Parole Association. Contracted laboratories analyzing urine or other samples should also be held to established standards.

2. Testing may be administered randomly or at scheduled intervals, but occurs no less than twice a week during the first several months of an individual's enrollment. Frequency thereafter will vary depending on participant progress.

3. The scope of testing is sufficiently broad to detect the participant's primary drug of choice as well as other potential drugs of abuse, including alcohol.

4. The drug-testing procedure must be certain. Elements contributing to the reliability and validity of a urinalysis testing process include, but are not limited to,

    - Direct observation of urine sample collection;

    - Verification temperature and measurement of creatinine levels to determine the

extent of water loading;

- Specific, detailed, written procedures regarding all aspects of urine sample collection, sample analysis, and result reporting;
- A documented chain of custody for each sample collected;
- Quality control and quality assurance procedures for ensuring the integrity of the process; and
- Procedures for verifying accuracy when drug test results are contested.

5. Ideally, test results are available and communicated to the court and the participant within one day. The drug court functions best when it can to respond immediately to noncompliance; the time between sample collection and availability of results should be short.

6. The court is immediately notified when a participant has tested positive, has failed to submit to AOD testing, has submitted the sample of another, or has adulterated a sample.

7. The coordinated strategy for responding to noncompliance includes prompt responses to positive tests, missed tests, and fraudulent tests.

8. Participants should be abstinent for a substantial period of time prior to program graduation.

Key Component #6

A coordinated strategy governs drug court responses to participants' compliance.

Purpose: An established principle of AOD treatment is that addiction is a chronic, relapsing condition. A pattern of decreasing frequency of use before sustained abstinence from alcohol and other drugs is common. Becoming sober or drug free is a learning experience, and each relapse to AOD use may teach something about the recovery process.

Implemented in the early stages of treatment and emphasized throughout, therapeutic strategies aimed at preventing the return to AOD use help participants learn to manage their ambivalence toward recovery, identify situations that stimulate AOD cravings, and develop skills to cope with high-risk situations. Eventually, participants learn to manage cravings, avoid or deal more effectively with high-risk situations, and maintain sobriety for increasing lengths of time.

Abstinence and public safety are the ultimate goals of drug courts, but many participants exhibit a pattern of positive urine tests within the first several months following admission. Because AOD problems take a long time to develop and because many factors contribute to drug use and dependency, it is rare that an individual ceases AOD use as soon as he or she enrolls in treatment. Even after a period of sustained abstinence, it is common for individuals to occasionally test positive.

Although drug courts recognize that individuals have a tendency to relapse, continuing AOD use is not condoned. Drug courts impose appropriate responses for continuing AOD use. Responses increase in severity for continued failure to abstain.

A participant's progress through the drug court experience is measured by his or her compliance with the treatment regimen. Certainly cessation of drug use is the ultimate goal of drug court treatment. However, there is value in recognizing incremental progress toward the goal, such as showing up at all required court appearances, regularly arriving at the treatment program on time, attending and fully participating in the treatment sessions, cooperating with treatment staff, and submitting to regular AOD testing.

Drug courts must reward cooperation as well as respond to noncompliance. Small rewards for incremental successes have an important effect on a participant's sense of purpose and accomplishment. Praise from the drug court judge for regular attendance or for a period of clean drug tests, encouragement from the treatment staff or the judge at particularly difficult times, and ceremonies in which tokens of accomplishment are awarded in open court for completing a

particular phase of treatment are all small but very important rewards that bolster confidence and give inspiration to continue.

Drug courts establish a coordinated strategy, including a continuum of responses, to continuing drug use and other noncompliant behavior. A coordinated strategy can provide a common operating plan for treatment providers and other drug court personnel. The criminal justice system representatives and the treatment providers develop a series of complementary, measured responses that will encourage compliance. A written copy of these responses, given to participants during the orientation period, emphasizes the predictability, certainty, and swiftness of their application.

Performance Benchmarks:

1. Treatment providers, the judge, and other program staff maintain frequent, regular communication to provide timely reporting of progress and noncompliance and to enable the court to respond immediately. Procedures for reporting noncompliance are clearly defined in the drug court's operating documents.

2. Responses to compliance and noncompliance are explained verbally and provided in writing to drug court participants before their orientation. Periodic reminders are given throughout the treatment process.

3. The responses for compliance vary in intensity.

    - Encouragement and praise from the bench;
    - Ceremonies and tokens of progress, including advancement to the next treatment phase;
    - Reduced supervision;
    - Decreased frequency of court appearances;
    - Reduced fines or fees;
    - Dismissal of criminal charges or reduction in the term of probation;
    - Reduced or suspended incarceration; and
    - Graduation.

4. Responses to or sanctions for noncompliance might include

    - Warnings and admonishment from the bench in open court;
    - Demotion to earlier program phases;
    - Increased frequency of testing and court appearances;
    - Confinement in the courtroom or jury box;
    - Increased monitoring and/or treatment intensity;
    - Fines;

- Required community service or work programs;
- Escalating periods of jail confinement (However, drug court participants remanded to jail should receive AOD treatment services while confined); and
- Termination from the program and reinstatement of regular court processing.

Key Component #7

Ongoing judicial interaction with each drug court participant is essential.

Purpose: The judge is the leader of the drug court team, linking participants to AOD treatment and to the criminal justice system. This active, supervising relationship, maintained throughout treatment, increases the likelihood that a participant will remain in treatment and improves the chances for sobriety and law-abiding behavior. Ongoing judicial supervision also communicates to participants—often for the first time—that someone in authority cares about them and is closely watching what they do.

Drug courts require judges to step beyond their traditionally independent and objective arbiter roles and develop new expertise. The structure of the drug court allows for early and frequent judicial intervention. A drug court judge must be prepared to encourage appropriate behavior and to discourage and penalize inappropriate behavior. A drug court judge is knowledgeable about treatment methods and their limitations.

Performance Benchmarks:

1. Regular status hearings are used to monitor participant performance:

    - Frequent status hearings during the initial phases of each participant's program establish and reinforce the drug court's policies, and ensure effective supervision of each drug court participant. Frequent hearings also give the participant a sense of how he or she is doing in relation to others.

    - Time between status hearings may be increased or decreased, based on compliance with treatment protocols and progress observed.

    - Having a significant number of drug court participants appear at a single session gives the judge the opportunity to educate both the offender at the bench and those waiting as to the benefits of program compliance and consequences for noncompliance.

2. The court applies appropriate incentives and sanctions to match the participant's treatment progress.

3. Payment of fees, fines and/or restitution is part of the participant's treatment. The court supervises such payments and takes into account the participant's financial ability to fulfill these obligations. The court ensures that no one is denied participation in drug courts solely because of inability to pay fees, fines, or restitution.

Key Component #8

Monitoring and evaluation measure the achievement of program goals and gauge effectiveness.

Purpose: Fundamental to the effective operation of drug courts are coordinated management, monitoring, and evaluation systems. The design and operation of an effective drug court program result from thorough initial planning, clearly defined program goals, and inherent flexibility to make modifications as necessary.

The goals of the program should be described concretely and in measurable terms to provide accountability to funding agencies and policymakers. And, since drug courts will increasingly be asked to demonstrate tangible outcomes and cost-effectiveness, it is critical that the drug court be designed with the ability to gather and manage information for monitoring daily activities, evaluating the quality of services provided, and producing longitudinal evaluations.

Management and monitoring systems provide timely and accurate information about program operations to the drug court's managers, enabling them to keep the program on course, identify developing problems, and make appropriate procedural changes. Clearly defined drug court goals shape the management information system, determine monitoring questions, and suggest methods for finding information to answer them.

Program management provides the information needed for day-to-day operations and for planning, monitoring, and evaluation. Program monitoring provides oversight and periodic measurements of the program's performance against its stated goals and objectives.

Evaluation is the institutional process of gathering and analyzing data to measure the accomplishment of the program's long-term goals. A process evaluation appraises progress in meeting operational and administrative goals (e.g., whether treatment services are implemented as intended). An outcome evaluation assesses the extent to which the program is reaching its long-term goals (e.g., reducing criminal recidivism). An effective design for an outcome evaluation uses a comparison group that does not receive drug court services.

Although evaluation activities are often planned and implemented simultaneously, process evaluation information can be used more quickly in the early stages of drug court implementation. Outcome evaluation should be planned at the beginning of the program as it requires at least a year to compile results, especially if past participants are to be found and interviewed.

Evaluation strategies should reflect the significant coordination and the considerable time required to obtain measurable results. Evaluation studies are useful to everyone, including funding agencies and policymakers who may not be involved in the daily operations of the program. Information and conclusions developed from periodic monitoring reports, process evaluation activities, and longitudinal evaluation studies may be used to modify program procedures, change therapeutic interventions, and make decisions about continuing or expanding the program.

Information for management, monitoring, and evaluation purposes may already exist within the court system and/or in the community treatment or supervision agencies (e.g., criminal justice data bases, psychosocial histories, and formal AOD assessments). Multiple sources of information enhance the credibility and persuasiveness of conclusions drawn from evaluations.

Performance Benchmarks:

1. Management, monitoring, and evaluation processes begin with initial planning. As part of the comprehensive planning process, drug court leaders and senior managers should establish specific and measurable goals that define the parameters of data collection and information management. An evaluator can be an important member of the planning team.

2. Data needed for program monitoring and management can be obtained from records maintained for day-to-day program operations, such as the numbers and general demographics of individuals screened for eligibility; the extent and nature of AOD problems among those assessed for possible participation in the program; and attendance records, progress reports, drug test results, and incidence of criminality among those accepted into the program.

3. Monitoring and management data are assembled in useful formats for regular review by program leaders and managers.

4. Ideally, much of the information needed for monitoring and evaluation is gathered through an automated system that can provide timely and useful reports. If an automated system is not available, manual data collection and report preparation can be streamlined. Additional monitoring information may be acquired by observation and through program staff and participant interviews.

5. Automated and manual information systems must adhere to written guidelines that protect against unauthorized disclosure of sensitive personal information about individuals.

6. Monitoring reports need to be reviewed at frequent intervals by program leaders and senior managers. They can be used to analyze program operations, gauge effectiveness, modify procedures when necessary, and refine goals.

7. Process evaluation activities should be undertaken throughout the course of the drug court program. This activity is particularly important in the early stages of program implementation.

8. If feasible, a qualified independent evaluator should be selected and given responsibility for developing and conducting an evaluation design and for preparing interim and final reports. If an independent evaluation is unavailable the drug court program designs and implements its own evaluation, based on guidance available through the field.

   - Judges, prosecutors, the defense bar, treatment staff, and others design the evaluation collaboratively with the evaluator.

   - Ideally, an independent evaluator will help the information systems expert design and implement the management information system.

   - The drug court program ensures that the evaluator has access to relevant justice system and treatment information.

   - The evaluator maintains continuing contact with the drug court and provides information on a regular basis. Preliminary reports may be reviewed by drug court program personnel and used as the basis for revising goals, policies, and procedures as appropriate.

9. Useful data elements to assist in management and monitoring may include, but are not limited to,

   - The number of defendants screened for program eligibility and the outcome of those initial screenings;

   - The number of persons admitted to the drug court program;

   - Characteristics of program participants, such as age, sex, race/ethnicity, family status, employment status, and educational level, current charges; criminal justice history; AOD treatment or mental health treatment history; medical needs (including detoxification); and nature and severity of AOD problems;

- Number and characteristics of participants (e.g., duration of treatment involvement, reason for discharge from the program);
- Number of active cases;
- Patterns of drug use as measured by drug test results;
- Aggregate attendance data and general treatment progress measurements;
- Number and characteristics of persons who graduate or complete treatment successfully;
- Number and characteristics of persons who do not graduate or complete the program;
- Number of participants who fail to appear at drug court hearings and number of bench warrants issued for participants;
- Re-arrests during involvement in the drug court program and type of arrest(s); and
- Number, length, and reasons for incarcerations during and subsequent to involvement in the drug court program.

10. When making comparisons for evaluation purposes, drug courts should consider the following groups:

    - Program graduates;
    - Program terminations;
    - Individuals who were referred to, but did not appear for, treatment; and
    - Individuals who were not referred for drug court services.

11. At least six months after exiting a drug court program, comparison groups (listed above) should be examined to determine long-term effects of the program. Data elements for follow-up evaluation may include

    - Criminal behavior/activity;
    - Days spent in custody on all offenses from date of acceptance into the program;

- AOD use since leaving the program;
- Changes in job skills and employment status;
- Changes in literacy and other educational attainments;
- Changes in physical and mental health;
- Changes in status of family relationships;
- Attitudes and perceptions of participation in the program; and
- Use of health care and other social services.

12. Drug court evaluations should consider the use of cost-benefit analysis to examine the economic impact of program services. Important elements of cost-benefit analysis include

- Reductions in court costs, including judicial, counsel, and investigative resources;
- Reductions in costs related to law enforcement and corrections;
- Reductions in health care utilization; and
- Increased economic productivity.

Key Component #9

Continuing interdisciplinary education promotes effective drug court planning, implementation, and operations.

Purpose: Periodic education and training ensures that the drug court's goals and objectives, as well as policies and procedures, are understood not only by the drug court leaders and senior managers, but also by those indirectly involved in the program. Education and training programs also help maintain a high level of professionalism, provide a forum for solidifying relationships among criminal justice and AOD treatment personnel, and promote a spirit of commitment and collaboration.

All drug court staff should be involved in education and training, even before the first case is heard. Interdisciplinary education exposes criminal justice officials to treatment issues, and treatment staff to criminal justice issues. It also develops shared understandings of the values, goals, and operating procedures of both the treatment and the justice system components. Judges and court personnel typically need to learn about the nature of AOD problems and the theories and practices supporting specific treatment approaches. Treatment providers typically need to become familiar with criminal justice accountability issues and court operations. All need to understand and comply with drug testing standards and procedures.

For justice system or other officials not directly involved in the program's operations, education provides an overview of the mission, goals, and operating procedures of the drug court.

A simple and effective method of educating new drug court staff is to visit an existing court to observe its operations and ask questions. On-site experience with an operating drug court provides an opportunity for new drug court staff to talk to their peers directly and to see how their particular role functions.

Performance Benchmarks:

1. Key personnel have attained a specific level of basic education, as defined in staff training requirements and in the written operating procedures. The operating procedures should also define requirements for the continuing education of each drug court staff member.

2. Attendance at education and training sessions by all drug court personnel is essential. Regional and national drug court training provide critical information on innovative developments across the Nation. Sessions are most productive when drug court

personnel attend as a group. Credits for continuing professional education should be offered, when feasible.

3. Continuing education institutionalizes the drug court and moves it beyond its initial identification with the key staff who may have founded the program and nurtured its development.

4. An education syllabus and curriculum are developed, describing the drug court's goals, policies, and procedures. Topics might include

   - Goals and philosophy of drug courts;
   - The nature of AOD abuse, its treatment and terminology;
   - The dynamics of abstinence and techniques for preventing relapse;
   - Responses to relapse and to noncompliance with other program requirements;
   - Basic legal requirements of the drug court program and an overview of the local criminal justice system's policies, procedures, and terminology;
   - Drug testing standards and procedures;
   - Sensitivity to racial, cultural, ethnic, gender, and sexual orientation as they affect the operation of the drug court;
   - Interrelationships of co-occurring conditions such as AOD abuse and mental illness (also known as “dual diagnosis”); and
   - Federal, State, and local confidentiality requirements.

Key Component #10

Forging partnerships among drug courts, public agencies, and community-based organizations generates local support and enhances drug court program effectiveness.

Purpose: Because of its unique position in the criminal justice system, a drug court is especially well suited to develop coalitions among private community-based organizations, public criminal justice agencies, and AOD treatment delivery systems. Forming such coalitions expands the continuum of services available to drug court participants and informs the community about drug court concepts.

The drug court is a partnership among organizations—public, private, and community-based—dedicated to a coordinated and cooperative approach to the AOD offender. The drug court fosters systemwide involvement through its commitment to share responsibility and participation of program partners. As a part of—and as a leader in—the formation and operation of community partnerships, drug courts can help restore public faith in the criminal justice system.

Performance Benchmarks:

1. Representatives from the court, community organizations, law enforcement, corrections, prosecution, defense counsel, supervisory agencies, treatment and rehabilitation providers, educators, health and social service agencies, and the faith community meet regularly to provide guidance and direction to the drug court program.

2. The drug court plays a pivotal role in forming linkages between community groups and the criminal justice system. The linkages are a conduit of information to the public about the drug court, and conversely, from the community to the court about available community services and local problems.

3. Partnerships between drug courts and law enforcement and/or community policing programs can build effective links between the court and offenders in the community.

4. Participation of public and private agencies, as well as community-based organizations, is formalized through a steering committee. The steering committee aids in the acquisition and distribution of resources. An especially effective way for the steering committee to operate is through the formation of a nonprofit corporation structure that includes all the principle drug court partners, provides policy guidance, and acts as a conduit for fundraising and resource acquisition.

5. Drug court programs and services are sensitive to and demonstrate awareness of the populations they serve and the communities in which they operate. Drug courts provide opportunities for community involvement through forums, informational meetings, and other community outreach efforts.

6. The drug court hires a professional staff that reflects the population served, and the drug court provides ongoing cultural competence training.

Appendix 1: Drug Court Standards Committee

Bill Meyer, Chairman Judge, Denver Drug Court Denver, CO	Carlos J. Martinez Assistant Public Defender Law Offices of Bennett H. Brummer Miami, FL
Ed Brekke Administrator Civil & Criminal Operations Los Angeles Superior Court Los Angeles, CA	Roger Peters Associate Professor University of South Florida Florida Mental Health Institute Department of Mental Health Law and Policy Tampa, FL
Frank Tapia Probation Officer Oakland, CA	Molly Merrigan Assistant Prosecutor Jackson County Drug Court Kansas City, MO
Jay Carver Director, District of Columbia Pretrial Services Agency Washington, DC	John Marr CEO Choices Unlimited Las Vegas, NV
Caroline Cooper Director OJP Drug Court Clearinghouse and Technical Assistance Project American University Washington, DC	Ana Oliveira Director Samaritan Village Briarwood, NY
Barry Mahoney President The Justice Management Institute Denver, CO	Jane Kennedy Executive Director TASC of King County Seattle, WA
U.S. Department of Justice **Office of Justice Programs Representatives** Marilyn McCoy Roberts Director, Drug Courts Program Office Office of Justice Programs	Susan Tashiro Program Manager Office of Justice Programs

National Association of Drug Court Professionals Judge Jeffrey S. Tauber President Marc Pearce Chief of Staff	**Writer and Coordinator** Jody Forman The Dogwood Institute Charlottesville, VA

Appendix 2: Resource List

Federal Organizations and Agencies Providing Information and Guidance on Drug Courts:

The White House
Office of National Drug Control Policy (ONDCP)
Executive Office of the President
The White House
Washington, DC 20500
Tel: 202/395-6700

U.S. Department of Justice

Bureau of Justice Assistance
Office of Justice Programs
U.S. Department of Justice
633 Indiana Avenue NW
Washington, DC 20531
Tel: 202/307-6185
Fax: 202/305-1367

Drug Courts Program Office
Office of Justice Programs
U.S. Department of Justice
633 Indiana Avenue NW
Washington, DC 20531
Tel: 202/616-5001
Fax: 202/307-2019

National Criminal Justice Reference Service
P. O. Box 6000
Rockville, MD 20849-6000
Tel: 800/688-4252 or 301/251-5500

Federal Agencies and Organizations Providing Information on AOD Treatment:

U.S. Department of Health and Human Services

Alcoholism and Substance Abuse Branch
Indian Health Service
5600 Fishers Lane, Room 5A-20
Rockville, MD 20857
Tel: 301/443-7623

Center for Substance Abuse Treatment
Substance Abuse and Mental Health Services Administration, Public Health Service
5515 Security Lane
Rockville, MD 20852
Tel: 301/443-5700

National Clearinghouse for Alcohol and Drug Information
11426 Rockville Pike, Suite 200
Rockville, MD 20852
Tel: 800-729-6686

National Institute on Alcohol and Alcoholism
Substance Abuse and Mental Health Services Administration, Public Health Service
Willco Bldg., Suite 400-MSC7003
6000 Executive Blvd.
Bethesda, MD 20892
Tel: 301/443-3851

National Institute on Drug Abuse
Substance Abuse and Mental Health Services Administration, Public Health Service
5600 Fishers Lane, Room 18-49
Rockville, MD 20857
Tel: 301/443-0107

Organizations Providing Information on Drug Courts:

Drug Court Clearinghouse and Technical Assistance Project
American University
Justice Programs Office
Brandywine, Suite 660
4400 Massachusetts Avenue, NW
Washington, DC 20016-8159
Tel: 202/885-2875
Fax: 202/885-2885

Justice Management Institute
1900 Grant St., Suite 815
Denver, CO 80203
Tel: 303/831-7564
Fax: 303/831-4564

National Association of Drug Court Professionals
901 North Pitt St, Suite 300
Alexandria, VA 22314
Tel: 800/542-2322 or 703/706-0576
Fax: 703/706-0565

State Justice Institute
1650 King St., Suite 600
Alexandria, VA 22314
Tel: 703/684-6100
Fax: 703/684-7618

Private Organizations Providing Information on AOD Treatment:

American Society of Addiction Medicine, Inc.
Upper Arcade, Suite 101
4601 North Park Avenue
Chevy Chase, MD 20815
Tel: 301/656-3920

Guidepoints: Acupuncture in Recovery
(Information on innovative treatment of addictive and mental disorders)
7402 NE 58th St.
Vancouver, WA 98662
Tel: 360/254-0186

National Acupuncture

Join Together
441 Stuart Street, 6th Floor
Boston, MA 02116
Tel: 617/437-1500

Partnership for a Drug Free America
State Alliance Program
405 Lexington Ave., 16th Floor
New York, NY 10174
Tel: 212/922-1560

Dr. Shannon Carey, Ph.D.
Co-President and Senior Research Associate
NCP Research

Dr. Shannon Carey is Co-President and Senior Research Associate at NPC Research. She has worked in the areas of criminal justice and substance abuse treatment for over 15 years, specifically focusing on evaluating the costs and effectiveness of drug court programs. Dr. Carey has extensive experience managing, designing, and implementing evaluations of substance abuse prevention and treatment programs within the adult criminal and juvenile systems. She has published and presented extensively on best practices in the development and evaluation of court intervention programs. Dr. Carey has also led efforts to create and provide web-based tools for drug courts to analyze their own costs and benefits. She is a faculty member at the National Drug Court Institute and is a member of the American Evaluation Association, the Oregon Program Evaluators Network, the National Association of Drug Court Professionals, and the American Society of Criminology. Dr. Carey earned her Ph.D. from Portland State University in Systems Science and Applied Psychology.

Written Statement for U.S. Sentencing Commission
For Hearing on March 15, 2017
Shannon Carey, Ph.D.

Drug Court Program Design and Eligibility Criteria

Drug courts are designed to guide defendants identified as drug- or alcohol-addicted into treatment that will reduce substance dependence and improve the quality of life for the defendants and their families. Benefits to society take the form of reductions in crime, decreased use of emergency health care services, decreased child welfare involvement, and increased employment, resulting in reduced costs to taxpayers and increased public safety.

In the typical drug court program, participants are closely supervised by a judge who is supported by a team of agency representatives operating both within and outside of their traditional roles. The team typically includes a drug court coordinator, case managers, substance abuse treatment providers, prosecuting attorneys, defense attorneys, law enforcement officers, and probation officers who work together to provide needed services to drug court participants. Prosecuting and defense attorneys modify their traditional adversarial roles to collaborate in support of the treatment and supervision needs of program participants. Drug courts blend the resources, expertise and interests of a variety of jurisdictions and agencies.

Drug courts are complex programs designed to deal with some of the most challenging problems that communities face. These courts bring together multiple and traditionally adversarial roles plus stakeholders from different agencies and systems with different training, professional language, and approaches. They take on groups of clients that have serious substance abuse treatment needs. Adults with substance abuse issues involved in the criminal justice system must be seen within an ecological context; that is, within the environment that has contributed to their attitudes and behaviors. This environment includes their neighborhoods, families, friends, and formal or informal economies through which they support themselves. The drug court must understand the various social, economic, mental health and cultural factors that affect their participants.

Drug courts have been shown to be effective in reducing criminal recidivism (GAO, 2005), improving the psycho-social functioning of participants (Kralstein, 2010), and reducing taxpayer costs due to positive outcomes for drug court participants (including fewer re-arrests, less time in jail and less time in prison) (Kissick, Waller & Carey 2013; Carey & Waller, 2011; Carey, Finigan, Waller, Lucas, & Crumpton, 2005). Some drug courts have been shown to cost less to operate than processing defendants through business-as-usual in the court system (Carey & Finigan, 2004; Carey et al., 2005). Multiple meta-analyses have also shown that drug courts

consistently show positive outcomes for their participants, particularly when they engage in known, research-based best practices.

The **eligibility criteria** for drug court participation in any particular jurisdiction should be based on an assessment of the criminal justice population in that jurisdiction to help focus the program on the specific needs the program intends to address. For example, if there are large numbers of defendants with property crimes that are fueled by their drug use, then it would be appropriate for a program to specifically target property crimes as eligible charges.

In addition, drug court programs have the biggest impact on individuals who are high risk (i.e., they are likely to fail on traditional probation and likely to continue to commit new crimes) and high need (specifically, they are diagnosed with moderate to severe substance use disorder). However, drug courts can also have substantial impacts on individuals that are high-risk/low-need and low risk/high need. (Low-risk/low-need individuals should not go to a drug court programs and should be redirected out of the criminal justice system as quickly as possible.) It is recommended that drug court programs either focus on high-risk/high-need participants, or that they create separate tracks in their program to treat the unique risk and need levels of each of their participants.

Absolutely key in the eligibility process is the use of **standardized risk and need assessment** instruments that are validated for the specific population of participants. Risk assessments and clinical needs assessments are also crucial in determining the appropriate level of supervision as well as the appropriate type and level of substance abuse and other treatment provided by the drug court program for each participant. Individuals who receive less treatment than they need get worse. Individuals who get more treatment than they need also get worse.

Please see NADCP's Adult Best Practice Standards Volume I, Standard I (2013) for more information on drug court participants and eligibility criteria.

Drug Court Evaluation

Evaluation of drug courts can include process, outcome and cost evaluation. A **process evaluation** considers a program's policies and procedures and examines whether the program is meeting its goals and objectives. Process evaluations generally determine whether programs have been implemented as intended and are delivering planned services to target populations. To do this the evaluator must have criteria or standards to apply to the program being studied. In the case of drug treatment courts, some nationally recognized guidelines have been established and used to assess drug court program processes. Standards have been established by the National Association of Drug Court Professionals through a thorough review of the extant research on drug courts. Two volumes of the Adult Best Practice Standards were published in 2013 and 2015. In addition, there is a seminal article on the fundamental model defining drug courts called the "10 Key Components of Drug Courts" (NADCP, 1997). Good process evaluation should provide useful information about program functioning related to

known best practices in ways that can contribute to program improvement. The main benefit of a process evaluation is improving program practices with the intention of increasing program effectiveness for its participants. Program improvement leads to better outcomes and impacts and in turn, increased cost-effectiveness and cost-savings.

The purpose of an **outcome evaluation** is to determine whether the program has improved participant outcomes. In other words, did the program achieve its intended goals for its participants? An outcome evaluation can examine short-term outcomes that occur while a participant is still in the program. For drug courts, this includes whether the program is delivering the intended amount of services, whether participants are receiving the right services, whether participants are successfully completing the program in the intended amount of time, whether drug use is reduced and what factors lead to participants successfully completing the program. An outcome evaluation can also measure longer term outcomes (sometimes called an "impact evaluation") including participant outcomes after program completion. In the case of drug court programs, one of the main impacts of interest is recidivism. Are program participants avoiding the criminal justice system "revolving door?" How often are participants being re-arrested, and spending time on probation and in jail? Does participation in the program result in reduced criminal justice recidivism? Other outcomes of interest include reduced emergency room visits, reduced involvement in child welfare, increased likelihood of employment and paying taxes and increased education.

In order to determine whether a drug court program is effective in reducing recidivism and having other positive outcomes it is necessary to have a **comparison group**. The question is, "Is recidivism reduced compared to what?" To answer this question, it is necessary to compare the program to a condition with no program. This is accomplished through developing a comparison group of individuals who did not participate in the program but are otherwise as similar as possible to those who did participate. There are many strategies for gaining this type of comparison group and there are benefits and drawbacks to each.

The "gold standard" for a comparison group in research is a randomized design where individuals who are eligible for the program are randomly assigned to either participate or receive the traditional court process. However, this is generally not practical in drug court research for several reasons. Two main reasons are that: (1) It requires the agreement of the drug court Judge and the team to randomly assign eligible individuals who they believe would benefit from the program to NOT receive drug court services; and (2) It requires a very long study period since after individuals are assigned to the drug court or traditional court, we must wait for the participants to go through the course of the program and then allow further time for outcomes AFTER program participation.

Other, non-random, study designs are called "quasi-experimental." These strategies can include a quite rigorous research design while still being practical for the program under study. One strategy is to use a group of individuals who were found eligible for drug court but who chose not to participate. This has the benefit of ensuring that the comparison group is equivalent to

the drug court participants, at least in terms of criminal history and other possible eligibility requirements, but is commonly criticized for the possibility that those individuals who choose against drug court are not as motivated to change their lives and stop using drugs.

A second strategy involves identifying eligible individuals who were never offered the program for various reasons, such as issues with the ability of the referring agencies to find and refer all eligible individuals, capacity issues, or because the program was not yet implemented. In our previous research in multiple drug courts we have found that eligible individuals have "slipped through the cracks." The most ideal comparison group is similar clients who cannot be served by the drug court because the court has reached its capacity for enrollment. Another possible comparison group are those individuals who would have been eligible for program but whose "eligible," or recent, charge happened prior to program implementation and therefore could not be offered the program. For the most part, both these options have the benefit of avoiding the issue of motivational differences, although the latter is subject to potential "historical" differences in the community context (e.g., policy changes, variability in treatment resources, etc., that might change over time regardless of the program). Selecting these comparison groups generally involves obtaining a list of people with the same charges as program-eligible participants and then examining certain key characteristics of each possible comparison group member to determine whether he or she fits the program's eligibility criteria. However, the one unavoidable drawback to this approach is if the program eligibility criteria include a measurement of addiction severity and/or mental health issues, it is nearly impossible to be certain that the group is truly equivalent, since this measurement is not generally done for people as a part of the traditional court process. However, we have found in our prior research that the vast majority of the time drug court staff very rarely exclude participants who have been referred and are legally eligible for their programs. Therefore, identifying eligible individuals who were never offered the program is generally the most valid as well as practical approach to gaining a comparison group.

Once the comparison group is identified then propensity score matching or weighting can be performed to "match" the drug court participant group and the comparison group. The use of propensity scores is a statistical method that mimics random assignment and can be used to match the groups on as many background characteristics as possible (e.g., age, gender, race/ethnicity, risk level, substance use issues, marital status, criminal history). It is crucial that the drug court participant group and the comparison group match as closely as possible to increase the certainty that any differences in outcomes for the two groups can be attributed to participation in the drug court rather than some other existing difference. For example, research has shown that older individuals are less likely to engage in new crime than younger individuals so if the drug court participant group was older than the comparison group, any reduction in recidivism could be due to the age of the participants rather than due to the drug court.

Finally, to conduct an outcome evaluation it is important to have **sufficient numbers** of participants to perform valid statistical analysis. With larger programs (e.g., those that take at least 50 participants per year) this is not a concern. However, some drug court programs are quite small. In these instances it might be necessary to wait for several years until enough

participants have been through the program to increase the sample size. Alternatively, small programs can at the very least participate in a process evaluation to ensure that they are engaging in known best practices that will result in positive outcomes for their participants.

As mentioned earlier, there are three main types of evaluation, process, outcome and cost. In **cost evaluation** there is an important distinction between the meaning of the term "cost-effective" and the term "cost-benefit." A *cost-effectiveness* analysis calculates the cost of a program and then examines whether the program led to its intended positive outcomes. For example, a cost-effectiveness analysis of drug courts would determine the investment cost of the drug court program and then look at whether the number of re-arrests were reduced by the amount the program intended (e.g., a 50% reduction in re-arrests compared to those who did not participate in the program).

A *cost-benefit* evaluation calculates the cost of the program and also the cost of the outcomes, resulting in a cost-benefit ratio. For example, the cost of the program is compared to the cost-savings due to the reduction in re-arrests. In some drug court programs, for every dollar spent on the program, over $10 is saved due to positive outcomes.[1] A *cost-benefit* analysis provides a greater detail of cost information

A cost-benefit evaluation is designed to address the following study questions:

1. How much does the program cost?
2. What is the cost impact on the criminal justice system of sending offenders through drug court compared to traditional court processing?
3. What is the cost impact on the criminal justice system (or other systems of interest such as health care and child welfare) of participation in drug court compared to the impact without drug court?
4. Is there a cost benefit in terms of monetary or resource savings due to participation in the program?

A cost-benefit methodology developed specifically for drug courts is called is called Transactional and Institutional Cost Analysis (TICA). The TICA approach views an individual's interaction with publicly funded agencies as a set of transactions in which the individual utilizes resources contributed from multiple agencies. Transactions are those points within a system where resources are consumed and/or change hands. In the case of drug courts, when a drug court participant appears in court or has a drug test, resources such as judge time, defense attorney time, court facilities, and urine sample cups are used. Court appearances and drug tests are transactions. In addition, the TICA approach recognizes that these transactions take place within multiple organizations and institutions that work together to create the program of interest. These organizations and institutions contribute to the cost of each transaction that

[1] See drug court cost-benefit studies at http://www.npcresearch.com/projects_drug_courts.php

occurs for program participants. TICA is an intuitively appropriate approach to conducting costs assessment in an environment such as a drug court, which involves complex interactions among multiple taxpayer-funded organizations.

In order to maximize a cost evaluation's benefit to policymakers, a "cost-to-taxpayer" approach is used. This focus helps define which cost data should be collected (costs and avoided costs involving public funds) and which cost data should be omitted from the analyses (e.g., costs to the individual participating in the program).

The central core of the cost-to-taxpayer approach in calculating benefits (avoided costs) for drug courts specifically is the fact that untreated substance abuse will cost tax dollar-funded systems money that could be avoided or diminished if substance abuse were treated. In this approach, any cost that is the result of untreated substance abuse and that directly impacts a citizen (through tax-related expenditures) is used in calculating the benefits of substance abuse treatment.

The TICA cost approach looks at publicly funded costs as "opportunity resources." The concept of opportunity cost from the economic literature suggests that system resources are available to be used in other contexts if they are not spent on a particular transaction. The term opportunity resource describes these resources that are now available for different use. For example, if substance abuse treatment reduces the number of times that a client is subsequently incarcerated, the local sheriff may see no change in his or her budget, but an opportunity resource will be available to the sheriff in the form of a jail bed that can now be filled by another person, who, perhaps, possesses a more serious criminal justice record than does the individual who has received treatment and successfully avoided subsequent incarceration. Therefore, any "cost savings" reported in this type of cost evaluation may not be in the form of actual monetary amounts, but may be available in the form of a resource (such as a jail bed, or a police officer's time) that is available for other uses.

A cost evaluation involves calculating the costs of the program and the costs of outcomes (or impacts) after program entry (or the equivalent for the comparison group). To determine if there are any benefits (or avoided costs) due to program participation, it is necessary to determine what the participants' outcome costs would have been had they not participated in the drug court. One of the best ways to do this is to compare the costs of outcomes for drug court participants to the outcome costs for similar individuals who were eligible for the drug court but did not participate.

There are six key steps in the TICA methodology. Step 1 is to determine the program process through process evaluation; Step 2 is to identify the program transactions such as court hearings, various types of services, drug tests and case management; Step 3 is to identify the agencies involved with each transaction; Step 4 is to determine the resources used (such as staff time and materials) by each agency in performing each transaction; Step 5 is to determine

the cost of the resources (e.g., staff salaries, the cost of urine cups for drug testing); and Step 6 is to calculate the cost results which involves calculating the cost of each transaction and multiplying this cost by the number of transactions. For example, to calculate the cost of drug testing the unit cost per drug test is multiplied by the average number of drug tests per person. All the transactional costs for each individual are added to determine the overall cost per drug court participant/comparison group individual. This is reported as an average cost per person for the program, and outcome/impact costs due to re-arrests, jail time and other recidivism costs, as well as any other service usage, such as substance abuse treatment. Cost data is divided into program costs and outcome costs. The program costs, calculated only for those in drug court, are those associated with activities performed within the program such as court hearings, case management, drug tests, substance abuse treatment, and any other unique services provided by the program to participants. The outcome costs, calculated for both drug court and comparison groups, include criminal justice involvement (e.g., new arrests, subsequent court cases, jail/prison days, probation/parole days), treatment events that were not specifically a part of the drug court program, as well as other events that occur such as victimizations or emergency room visits. Finally, the outcome costs for the drug court group are subtracted from the cost of the comparison group, the resulting difference shows either the savings (if the drug court group costs less than the comparison) or the loss (if the drug court group costs more.

For more information on drug court evaluation, please see NADCP's best practice Standards Volume II Standard X.

Research Based Best Practices of Drug Court

The standards developed by NADCP combine the vast majority of existing good quality drug court research into some clear best practices (see attached documents – Volume I and II of the Adult Best Practice Standards). In addition, studies conducted by a private research and evaluation firm called NPC Research examined differences in practice across 100 different drug courts and determined over 50 best practices that were correlated with reduced recidivism and reduced cost (i.e., cost savings) in drug court programs (see two documents attached – the article describing the best practice research and a table listing the majority of known best practices).

The judge's role is key in the drug court process. Indeed, if no judge is presiding over a drug court program, then by definition, it cannot be considered a "drug court." Best practice research has shown that when judges preside over a drug court program for longer periods, participant recidivism decreases. Indeed, more than one study has shown that when a new judge takes the bench in a drug court program, participant recidivism increases significantly, and then recidivism decreases in the second year, as the judge learns the myriad amount of information to effectively run a drug court program. For this reason, best practice is that judges should be assigned to the a drug court for at least two years if not indefinitely. There is a steep

learning curve for new drug court team members, including the judge. To effectively participate in these program the judge and other team members need to understand addiction and the impact it has on individuals' brains. They need to understand behavior modification as the main purpose of a drug court program is to change participant behavior away from drug use and criminal activities to behaving as a law abiding, contributing citizen. The judge needs to learn about drug testing, substance abuse treatment, social services available in the community and motivational interviewing. Best practice research shows that when drug court team members receive training in all these areas, participant recidivism decreases and taxpayer savings increase.

Best practices also show that participant outcomes are significantly better when judges spend at least three minutes talking with each participant in court hearings, when the judge sees the participant in court at least once every two weeks, and when the judge chooses to sit on the drug court bench voluntarily rather than being assigned the role.

Research on Federal Problem Solving Courts

There have been a small number of research or evaluation studies in federal problem solving courts in both "front-end" drug courts (where participant go directly into the drug court without being incarcerated) and reentry courts (where participants are released from federal prison into the program).

Two outcome studies have been completed in the last few years:

1. A 2014 study of the federal drug court in the Eastern District of N.Y. about federal problem-solving courts: https://img.nyed.uscourts.gov/files/local_rules/EDNY-TWOYEARREPORT-ATI_Programs_April-2014.pdf and;
2. A 2016 study by the Federal Judicial Center (Rauma, 2016) of federal reentry courts in various districts.

Both studies found little impact of the programs on participant outcomes. Unfortunately, both studies were also poorly designed and there was little evidence that the programs involved were following known research based best practices and therefore, these studies cannot be used to make any definitive decisions around whether problem-solving courts (when properly implemented) can be effective in the federal system.

There are two studies currently underway on federal problem-solving courts, both scheduled to be completed before the end of 2017 and both being conducted by NPC Research. One is an outcome study of two reentry courts in the District of Oregon, one of which is following best practices for drug courts (i.e., adhering to the drug court model) and one that is using other reentry practices but not following many drug court specific best practices. This study should provide some evidence for whether the use of the drug court model in reentry courts in the federal system is effective. The second study is an outcome and cost study of a "front end" drug court in the District of Columbia operated by Pre-Trial Services (so participants are referred to and enter the program before conviction). This program was operating for several years

without adhering to the drug court model and following best practices. In more recent years the program implemented many of the drug court best practices and is now adhering fairly well to the drug court model. This study will examine participant outcomes both before and after the program implemented best practices. This study should provide some information on whether “front end” drug courts are effective in the federal system as an alternative to incarceration, and whether adherence to the model is important for positive outcomes to occur.

Best Practices by Drug Court Key Component

Key Component #1: Drug courts integrate alcohol and other drug treatment services with justice system case processing	
1.1	Program has a Memorandum of Understanding (MOU) in place between the drug court team members (and/or the associated agencies) a. MOU specifies team member roles b. MOU specifies what information will be shared
1.2	Program has a written policy and procedure manual
1.3	All key team members attend staffing (Judge, prosecutor, defense attorney, treatment, program coordinator, and probation)
1.4	All key team members attend court sessions/status review hearings (Judge, prosecutor, defense attorney, treatment, program coordinator, and probation)
1.5	Law enforcement (e.g., police, sheriff) is a member of the drug court team
1.6	Law enforcement attends drug court team meetings (staffings)
1.7	Law enforcement attends court sessions (status review hearings)
1.8	Treatment communicates with court via email
Key Component #2: Using a non-adversarial approach, prosecution and defense counsel promote public safety while protecting participants' due process rights	
2.1	A prosecuting attorney attends drug court team meetings (staffings)
2.2	A prosecuting attorney attends court sessions (status review hearings)
2.3	The defense attorney attends drug court team meetings (staffings)
2.4	The defense attorney attends court sessions (status review hearings)
Key Component #3: Eligible participants are identified early and promptly placed in the drug court program.	
3.1	The time between arrest and program entry is 50 days or less
3.2	Current program caseload/census (number of individuals actively participating at any one time) is less than 125
3.3	The drug court allows other charges in addition to drug charges
3.4	The drug court accepts offenders with serious mental health issues, as long as appropriate treatment is available
3.5	The drug court accepts offenders who are using medications to treat their drug dependence
3.6	Program uses validated, standardized assessment to determine eligibility
3.7	Participants are given a participant handbook upon entering the program
Key Component #4: Drug courts provide access to a continuum of alcohol, drug and other treatment and rehabilitation services	
4.1	The drug court works with two or fewer treatment agencies or has a treatment representative that oversees and coordinates treatment from all agencies

4.2	The drug court requires participants to meet individually with a treatment provider or clinical case manager weekly in the first phase of the program
4.3	The drug court offers a continuum of care for substance abuse treatment (detoxification, outpatient, intensive outpatient, day treatment, residential)
4.4	Program uses validated, standardized assessment to determine level or type of services needed
4.5	Treatment providers administer evidence-based, manualized behavioral or cognitive-behavioral treatments
4.6	The drug court offers gender specific services
4.7	The drug court offers mental health treatment
4.8	The drug court offers parenting classes
4.9	The drug court offers family/domestic relations counseling
4.10	The drug court offers residential treatment
4.11	The drug court offers health care
4.12	The drug court offers dental care
4.13	The drug court offers anger management classes
4.14	The drug court offers housing assistance
4.15	The drug court offers trauma-related services
4.16	The drug court offers a criminal thinking intervention
4.17	The drug court provides relapse prevention services for all participants
4.18	The drug court provides services to participant's children
4.19	The drug court provides childcare while participants are in treatment or in court (or participating in other drug court requirements)
4.20	Program provides (or partners with service providers who provide) participants with legally prescribed psychotropic or addiction medication (MAT)
4.21	The minimum length of the drug court program is 12 months or more
4.22	Treatment providers are licensed or certified to deliver substance abuse treatment
4.23	Treatment providers have training and/or experience working with a criminal justice population
4.24	Caseloads for probation/supervision officers do not exceed 30 active participants (up to 50 if mix of low risk and no other caseloads/responsibilities)
4.25	Caseloads for clinicians providing case management and treatment do not exceed 30 active participants (up to 40 if only counseling OR 50 if only case management)
Key Component #5: Abstinence is monitored by frequent alcohol and other drug testing	
5.1	Drug testing is random/unpredictable
5.2	Drug testing occurs on weekends/holidays
5.3	Collection of test specimens is witnessed directly by staff
5.4	Staff that collect drug testing specimens are trained in appropriate collection protocols
5.5	Drug test results are back in 2 days or less
5.6	Drug tests are collected at least 2 times per week

5.7	Participants are expected to have greater than 90 days clean (negative drug tests) before graduation
Key Component #6: A coordinated strategy governs drug court responses to participants' compliance	
6.1	Program has incentives for graduation, including avoiding a criminal record, avoiding incarceration, or receiving a substantially reduced sentence
6.2	Sanctions are imposed immediately after non-compliant behavior (e.g., drug court will impose sanctions in advance of a client's regularly scheduled court hearing)
6.3	Team members are given a written copy of the incentive and sanction guidelines
6.4	Program has a range of sanction options (including less severe sanctions such as writing assignments and community services and more severe sanctions such as jail time)
6.5	In order to graduate participants must have a job or be in school
6.6	In order to graduate participants must have a sober housing environment
6.7	In order to graduate participants must have pay all court-ordered fines and fees (e.g., fines, restitution)
6.8	Participants are required to pay court fees
6.9	The drug court reports that the typical length of jail sanctions is 6 days or less
6.10	The drug court retains participants with new possession charges (new possession charges do not automatically prompt termination)
Key Component #7: Ongoing judicial interaction with each participant is essential	
7.1	Participants have status review sessions every 2 weeks, or once per week, in the first phase
7.2	Judge spends an average of 3 minutes or greater per participant during status review hearings
7.3	The judge's term is as least 2 years or indefinite
7.4	The judge was assigned to drug court on a voluntary basis
7.5	In the final phase of drug court, the clients appear before the judge in court at least once per month
Key Component #8: Monitoring and evaluation measure the achievement of program goals and gauge effectiveness	
8.1	The results of program evaluations have led to modifications in drug court operations
8.2	Review of program data and/or regular reporting of program statistics has led to modifications in drug court operations
8.3	The drug court maintains data that are critical to monitoring and evaluation in an electronic database (rather than paper files)
Key Component #9: Continuing interdisciplinary education promotes effective drug court planning, implementation, and operations	
9.1	All new hires to the drug court complete a formal training or orientation
9.2	All members of the drug court team are provided with training in the drug court model
9.3	Drug court staff members receive ongoing cultural competency training

Key Component #10: Forging partnerships among drug courts, public agencies, and community-based organizations generates local support and enhances drug court program effectiveness
10.1 The drug court has an advisory committee that includes community members
10.2 The drug court has a steering committee or policy group that meets regularly to review policies and procedures

DRUG COURT REVIEW

Volume VIII, Issue 1

Special Issue

BEST PRACTICES IN DRUG COURTS

NATIONAL DRUG COURT INSTITUTE
ALEXANDRIA, VIRGINIA

SPECIAL ISSUE

DRUG COURT REVIEW **VOLUME VIII, ISSUE 1**

NATIONAL DRUG COURT INSTITUTE

C. West Huddleston, III, Chief Executive Officer
Carolyn D. Hardin, MPA., Senior Director
1029 N. Royal Street, Suite 201
Alexandria, Virginia 22314
Tel. (703) 575-9400, Fax (703) 575-9402
www.ndci.org

The National Drug Court Institute (NDCI) is the Professional Services Branch of the National Association of Drug Court Professionals (NADCP). NDCI is grateful to the Office of National Drug Control Policy of the Executive Office of the President and the Bureau of Justice Assistance within the Office of Justice Programs at the U.S. Department of Justice for the support that made this publication possible.

This project was supported by Grant No. 2010-DC-BX-K081 awarded by the Bureau of Justice Assistance. The Bureau of Justice Assistance is a component of the Office of Justice Programs, which also includes the Bureau of Justice Statistics, the National Institute of Justice, the Office of Juvenile Justice and Delinquency Prevention, the SMART Office, and the Office for Victims of Crime. Points of view or opinions in this document are those of the author and do not represent the official position or policies of the U.S. Department of Justice.

Printed in the United States of America.

Drug Courts perform their duties without manifestation, by word or conduct, of bias or prejudice, including, but not limited to, bias or prejudice based upon race, gender, national origin, disability, age, sexual orientation, language, or socioeconomic status.

THE DRUG COURT REVIEW

Published annually, the *Drug Court Review's* goal is to keep the Drug Court practitioner abreast of important new developments in the Drug Court field. Drug Courts demand a great deal of time and energy of the practitioner, allowing little opportunity to read lengthy evaluations or keep up with important research in the field. Yet, the ability to marshal scientific and research information and "argue the facts" can be critical to a program's success and ultimate survival.

The *Drug Court Review* builds a bridge between law, science, and clinical communities, providing a common tool to all. A headnote indexing system allows access to evaluation outcomes, scientific analysis, and research on Drug Court related areas. Scientific jargon and legalese are interpreted for the practitioner in common language.

Although the *Drug Court Review's* emphasis is on scholarship and scientific research, it also provides commentary from experts in the Drug Court and related fields on important issues to Drug Court practitioners.

The *Drug Court Review* invites submission of articles relevant to the Drug Court field. This would include but not be limited to drug testing, case management, cost analysis, program evaluation, legal issues, application of incentives and sanctions, and treatment methods.

For complete submission guidelines, please visit http://www.ndci.org.

THE NATIONAL DRUG COURT INSTITUTE

The *Drug Court Review* is a project of the National Drug Court Institute (NDCI). NDCI was established under the auspices of the National Association of Drug Court Professionals with support from the Office of National Drug Control Policy, Executive Office of the President, and the Bureau of Justice Assistance, U.S. Department of Justice.

NDCI's mission is to promote education, research, and scholarship to the Drug Court field and other court-based intervention programs.

Since its inception in December 1997, NDCI has emerged as the preeminent source of cutting-edge training and technical assistance to the Drug Court field, providing research-driven solutions to address the changing needs of treating substance-abusing offenders. NDCI launched five separate team-oriented Drug Court training programs, eight comprehensive, discipline-specific training programs, and five separate subject matter training programs.

NDCI developed a research division responsible for creating a scientific agenda and publication dissemination strategy for the field. NDCI has published a monograph series, fact sheets, and legal issues publications on relevant issues to Drug Court to help maintain fidelity to the Drug Court model and expansion.

For additional information about NDCI and its training programs, visit http://www.ndci.org.

ACKNOWLEDGMENTS

I wish to thank all those who have contributed to this issue of the *Drug Court Review*: the Office of National Drug Control Policy, Executive Office of the President, and the Bureau of Justice Assistance, U.S. Department of Justice, for the leadership, support, and collaboration that these agencies have offered to the National Drug Court Institute.

For their contributions as authors, I would like to thank Dr. Shannon Carey, Mr. Mitchell Downey, Dr. Karen Dugosh, Dr. David Festinger, Dr. Michael Finigan, Dr. Christine Lindquist, Dr. Juliette Mackin, Dr. Douglas Marlowe, Dr. Gerald Melnick, Dr. David Metzger, Dr. John Roman, Ms. Shelli Rossman, Mr. Michael Tobin, Dr. Harry Wexler, Mr. Mark Zehner, and Dr. Janine Zweig.

Finally, I would like to thank the peer reviewers, Fred Cheesman, Jim Egar, David Festinger, Kirstin Frescoln, Scott Henggeler, Norma Jaeger, Kevin Knight, Elizabeth Letourneau, Michael McCart, Roger Peters, Josiah Rich, Hon. Robert Russell, Rick Schwermer, Jennifer Shackelford, and Jeff Thoma.

C. West Huddleston, III
Chief Executive Officer
National Association of Drug Court Professionals
National Drug Court Institute

CONTENTS

INTRODUCTION:
Special Issue on Best Practices in Drug Courts **1**
Douglas B. Marlowe

INVITED SUBMISSION:
What Works? The Ten Key Components of Drug Court: Research-Based Best Practices **6**
Shannon M. Carey — Juliette R. Mackin — Michael W. Finigan

Drug Court Policies and Practices: How Program Implementation Affects Offender Substance Use and Criminal Behavior Outcomes **43**
Janine M. Zweig — Christine Lindquist
P. Mitchell Downey — John K. Roman — Shelli B. Rossman

Improving Drug Court Operations: NIATx Organizational Improvement Model **80**
Harry K. Wexler — Mark Zehner — Gerald Melnick

PRACTICE COMMENTARY:
Participation of Defense Attorneys in Drug Courts **96**
Michael Tobin

The Prevalence of HIV Risk Behaviors among Felony Drug Court Participants **131**
David S. Festinger — Karen L. Dugosh
David S. Metzger — Douglas B. Marlowe

Headnotes Index **147**

INTRODUCTION

SPECIAL ISSUE ON BEST PRACTICES IN DRUG COURTS

Douglas B. Marlowe, JD, PhD

THE FIRST GENERATION of research on most programs addresses the basic question of whether the program can be effective under typical conditions. Studies compare the effects of the program to no treatment or to alternative programs addressing the same condition and determine whether, on average, it significantly outperforms the alternatives. These so-called horse races are necessary to decide whether continuing to invest time and effort in the intervention is justifiable, but they do not grapple with the more important questions of who the program is most effective for (i.e., its target population), how to make it most efficient and cost-effective, and how to avoid any negative side effects it might produce.

The second generation of research delves beyond the average effects of an intervention to identify the factors that distinguish effective programs from those that are ineffective or even harmful. This is referred to as research on *best practices*. The most common approach is for evaluators to compare the characteristics of programs that have significant positive outcomes with those that have poor or insignificant outcomes. Presumably, services that are provided by effective programs and not provided by ineffective programs are likely to be important ingredients of an effective intervention. Of course, one cannot place full confidence in the reliability of such findings because the services were not under experimental control. Programs may have differed, simply by chance, on dimensions that were not in fact responsible for the differences in outcomes. Nevertheless, in the absence of definitive evidence from controlled research studies, it makes logical sense to emulate the practices of effective programs and avoid the practices of ineffective or harmful programs.

Drug Courts have decidedly entered into the second generation of research on best practices. No longer preoccupied with the answered question of whether they work, Drug Courts are now focusing their attention on characterizing the attributes of exemplary programs. In the process, they are also identifying the attributes that are lacking in a small subgroup of poorly performing Drug Courts. These so-called outlier programs have the potential to give the Drug Court field a black eye, and provide fodder for critics who may be opposed to the Drug Court model on purely philosophical or attitudinal grounds.

This special issue of the *Drug Court Review* fills critical gaps in the literature on best practices in Drug Courts, and offers concrete guidance for Drug Court practitioners to enhance their operations and improve their outcomes. In the first invited article, Drs. Shannon Carey, Juliette Mackin, and Michael Finigan compare the programmatic policies and procedures, services offered, and outcomes produced from a large sample of sixty-nine Drug Courts in several states. Each of their studies employed a parallel methodology that permitted the researchers to examine common factors influencing effectiveness and cost-effectiveness across all or most of the jurisdictions. The results lent substantial support to many of the key components of the Drug Court model. For example, substantially greater reductions in crime and lower societal costs were produced by Drug Courts that had multidisciplinary team involvement in their court hearings and team meetings, held more frequent judicial status reviews, performed intensive urine drug testing, and administered gradually escalating incentives and sanctions. The best Drug Courts ensured their teams attended timely training events and engaged in ongoing performance monitoring of their operations and outcomes.

In the second article, Drs. Janine Zweig, Christine Lindquist, P. Mitchell Downey, John Roman and Ms. Shelli Rossman review findings from the Multisite Adult Drug Court Evaluation (MADCE). Funded by the National Institute of Justice (NIJ), this groundbreaking study compared outcomes for more than 1,000 participants in twenty-three adult Drug Courts located in seven geographic regions around the country to those of a carefully matched comparison sample. Not only did the findings confirm that the Drug Courts reduced crime and

drug abuse and improved the participants' psychosocial functioning, but, more importantly, they also revealed a number of practices that were associated with better results. Again, the findings confirmed many of the core tenets of the Drug Court model. Better outcomes were produced, for example, by Drug Courts that had moderately predictable sanctioning schedules, exercised greater leverage over their participants, and had judges with more positive interactional styles.

In the third article, Dr. Harry Wexler, Mr. Mark Zehner, and Dr. Gerald Melnick report on their application of the NIATx (Network for the Improvement of Addiction Treatment) process improvement model in ten Drug Courts. Funded by the Center for Substance Abuse Treatment (CSAT), NIATx has been proven to improve client access to and retention in substance abuse treatment, but had not heretofore been applied in the justice system. The results revealed that relatively simple and modest adjustments to the Drug Courts' organizational and administrative processes substantially reduced wait times and no-shows for appointments and increased admission rates and participant engagement in treatment. If Drug Courts intend to "go to scale" and make meaningful contributions to the justice system, they must learn new ways to improve their recruitment rates and streamline their operations to serve more people more efficiently. The NIATx model shows considerable promise for helping Drug Courts in this critical challenge.

In the fourth article, Mr. Michael Tobin, a highly experienced public defender, offers suggestions to help defense attorneys recognize and resolve ethical challenges in Drug Courts. Among many issues, Mr. Tobin offers practical suggestions for advising clients about the anticipated benefits and burdens of participating in Drug Court, advocating for fair and effective procedures in the program, educating the defense bar about the Drug Court option, and protecting client confidentiality and due process. Most importantly, he addresses the important issue of avoiding role conflicts when exercising the functions of adversarial counsel as opposed to membership on a multidisciplinary Drug Court team. Although the recommendations do not necessarily represent the unanimous opinion of the defense bar or

NADCP policy, they reflect the considered wisdom of an experienced defense expert who has carefully thought through these issues for decades.

Finally, in the fifth article, Drs. David Festinger, Karen Dugosh, David Metzger, and Douglas Marlowe report outcomes from a study examining HIV risk behaviors among participants in a felony Drug Court in Philadelphia. Funded by the National Institute on Drug Abuse (NIDA), the study revealed that sexual risk behaviors, including unprotected sex with multiple partners, were prevalent. Many of the Drug Court participants lived in geographic zones of the city characterized by high HIV seroconversion rates and a high prevalence of persons living with HIV/AIDS, thus heightening the probability of exposure to the virus. The criminal justice system, especially jails and prisons, has long been recognized as a major vector for the spread of HIV and a critical juncture for launching prevention and early detection efforts. The results of this study suggest Drug Courts should be playing a much more active role in administering HIV prevention and detection protocols.

In summary, the articles in this special issue address critical issues pertaining to best practices in Drug Courts that can optimize outcomes and make the most efficient use of scarce resources. Defining best practices is especially critical as Drug Courts go to scale and address the full scope of our nation's drug problem. The appalling figures are well known: 1 out of every 100 American citizens is behind bars with the burden borne disproportionately by minorities and the poor (Pew Center on the States, 2008). Our prisons are overcrowded with nonviolent offenders charged with drug-related offenses and our budgets are buckling under the weight of enormous correctional expenditures, yet, crime rates and drug-use initiation rates are barely budging or are merely shifting in character. Drug Courts have been credited with helping to "bend the curve" of incarceration downward, especially for racial minority citizens (Mauer, 2009). But Drug Courts still serve only a small fraction of the roughly 1.5 million adults arrested each year in the U.S. who are at risk for substance abuse or dependence (Bhati, Roman, & Chalfin, 2008). Drug Courts need to treat every American in need, and that requires them to optimize their ser-

vices, take advantage of economies of scale, and instill greater efficiencies in their operations. Best practice standards reflect the hard-won knowledge of the Drug Court field garnered from more than two decades of earnest labor and honest self-appraisal. As more and more Drug Courts come on line, it is essential they benefit from this institutional memory and avoid relearning the painful lessons of the past.

REFERENCES

Bhati, A.S., Roman, J.K., & Chalfin, A. (2008). *To treat or not to treat: Evidence on the prospects of expanding treatment to drug-involved offenders.* Washington, DC: The Urban Institute.

Mauer, M. (2009, April). *The changing racial dynamics of the War on Drugs.* Washington, DC: The Sentencing Project.

Pew Center on the States. (2008). *One in 100: Behind Bars in America 2008*. Washington, DC: Author.

INVITED SUBMISSION

WHAT WORKS? THE TEN KEY COMPONENTS OF DRUG COURT: RESEARCH-BASED BEST PRACTICES

Shannon M. Carey — Juliette R. Mackin
Michael W. Finigan

[1] Best Practices in Drug Courts—*Studies of 69 Drug Courts revealed significantly better outcomes for programs that followed the Ten Key Components.*

[2] Characteristics of Effective Drug Courts—*The most effective and cost-effective Drug Courts worked collaboratively as a team, provided structure and accountability, offered wraparound services, trained team members, and monitored performance and outcomes.*

[3] Characteristics of Cost-Effective Drug Courts—*Investments in treatment and supervision services, staff training, program evaluation, and management information systems were recouped by greater improvements in outcome costs to the taxpayer.*

DRUG COURT PROGRAMS VARY tremendously in how they operationalize the Ten Key Components (NADCP, 1997). Although research clearly shows that adult Drug Courts can significantly improve treatment outcomes and reduce recidivism, outcomes vary considerably across participants and programs (e.g., Lowencamp, Holsinger, & Latessa, 2005; Mackin et al, 2009; Carey & Waller, 2011). Thus, we must not only examine the effectiveness of the nation's Drug Courts, but get inside the "black box" to determine which practices lead to better participant and program outcomes such as reduced criminal recidivism and lower costs (i.e., greater savings).

For this study, we determined Drug Court practices related to lower recidivism and lower costs in sixty-nine Drug Courts nationally. The

analysis builds on a previous study of eighteen Drug Courts in four states and one U.S. territory (Carey, Finigan, & Pukstas, 2008).

RESEARCH ON DRUG COURT EFFECTIVENESS

Drug Courts use the coercive authority of the criminal justice system to provide treatment to addicts in lieu of incarceration. This model of linking the resources of the criminal justice system and substance treatment programs has proven effective for increasing treatment participation, decreasing criminal recidivism, and reducing use of the health care system (Carey & Finigan, 2004; Gottfredson, Najaka, & Kearley, 2003; Finigan, 1998).

In a 2001 review for the National Drug Court Institute, Belenko summarized Drug Court research, both published and unpublished, conducted between 1999 and 2001. Conclusions from his review indicated that Drug Courts were relatively successful in reducing drug use and criminal activity while participants were in the program. Program completion rates nationally were (and remain) around 47 percent. Belenko (1998, 2001) noted that the research on long-term outcomes was less definitive. In his report, he called for more research into the services that Drug Court participants receive while in the program as well as the long-term impact of Drug Courts. A myriad of research on Drug Courts has answered his call since this important review.

A 2005 review by the Government Accountability Office (GAO), looking at six New York State Drug Court programs found a significant reduction in crime in five of those programs. New arrests leading to a conviction one year postprogram decreased by 6–13 percentage points.

Adding to this evidence, a 2006 meta-analysis of sixty Drug Court outcome evaluations showed that postadjudication Drug Courts reduced recidivism by an average of 10%, and preadjudication courts averaged a 13% reduction (Shaffer, 2006).

Another study found twenty-four Oregon Drug Court programs reduced recidivism (measured as number of rearrests) on average by 44% (Carey & Waller, 2011). Finally, the National Institute of Jus-

tice's (NIJ's) Multisite Adult Drug Court Evaluation (MADCE) of twenty-three Drug Courts found an average reduction in recidivism of 16% (Rempel & Zweig, 2011).

Research has also shown that Drug Court programs are cost beneficial in local criminal justice systems with cost-benefit ratios ranging $3–$27 for every one dollar invested in the program (Carey & Finigan, 2004; Carey, Finigan, et al., 2006; Carey & Waller, 2011; Crumpton et al., 2004; Fomby & Rangaprasad, 2002; Marchand, Waller, & Carey, 2006a and 2006b). More limited research has shown that Drug Courts also fiscally benefit other publicly supported services, such as child welfare, physical health care, mental health care, and employment security (Finigan, 1998; Crumpton, Worcel, & Finigan, 2003; Carey, Sanders, et al., 2010a and 2010b). Studies show some Drug Courts cost less to operate than standard court processing of offenders (Carey & Finigan, 2004; Carey, Finigan, et al., 2006). The overall findings continue to show that Drug Courts are effective in many areas. The question as to *why* has fueled another body of research on Drug Courts.

Since Belenko's report, more Drug Court research has focused on identifying the characteristics of an effective Drug Court program and profiling the ideal participant. To this end, Marlowe and colleagues found that high-risk participants graduated at higher rates, provided more drug-negative urine specimens at six months after program admission, and reported significantly less drug use and alcohol intoxication at six months when they were matched to hearings held every other week as compared with the usual less frequent schedule (Marlowe et al., 2007). Many Drug Courts are working toward identifying and enrolling high-risk/high-need offenders into their programs as their target population.

In research on characteristics of an effective program (defined as a program that significantly reduced recidivism), Shaffer (2006) found that a program length between eight and sixteen months provided the best recidivism outcomes. Programs that lasted less than eight or more than sixteen months were significantly less effective. Also, program requirements such as restitution and education were associated with program effectiveness. Finally, Drug Courts that had

internal treatment providers were more effective than Drug Courts that had external treatment providers. Shaffer suggests this may be because of the direct control a Drug Court would enjoy with an internal provider. NIJ's MADCE study indicated drug testing, judicial supervision, and the threat of jail or prison upon termination were important contributing factors as to why Drug Courts work (Rempel & Zweig, 2011). Many of Shaffer's and the MADCE findings are supported by the promising practices research described below (Carey, Finigan, & Pukstas, 2008) and by the research presented in this paper.

PROMISING PRACTICES RELATED TO POSITIVE OUTCOMES IN DRUG COURTS

Results from previous Drug Court research in eighteen Drug Courts in four states and one U.S. territory (Carey, Finigan, & Pukstas, 2008) as well as other research in California (Carey, Pukstas, et al., 2008; Carey, Waller, & Weller, 2010; Carey, Finigan, et al., 2006) and Oregon (Carey & Waller, 2011; Finigan, Carey, and Cox, 2007) have shown several promising practices within the framework of the Ten Key Components. Carey and colleagues collected data on over 200 practices engaged in by twenty-five California Drug Courts and twenty-four Oregon Drug Courts. In all three of these studies, analyses were run to determine which practices related to higher graduation rates, lower recidivism, and greater cost savings. The studies found the following themes related to the best outcomes:

- *Team Engagement*—All team members (judge, attorneys, coordinator, probation, treatment, law enforcement) should attend case staffings and court sessions.
- *Wraparound Services*—Participants need additional support services such as anger management, educational assistance, and relapse prevention.
- *Drug Testing*—Programs should drug test two to three times per week, obtain test results back within forty-eight hours, and require participants to have no positive drug tests for at least ninety days before graduation.

- *Responses to Participant Behavior (Incentives and Sanctions)*—Team members should receive written rules or guidelines regarding sanctions and incentives and require participants to pay program fees and complete community service in order to graduate.
- *Drug Court Hearings and the Judge's Role*—Participants should be required to attend Drug Court hearings once every two weeks and the judge should spend at least three minutes per participants on average at court hearings.
- *Data Collection and Monitoring*—Data should be maintained electronically and programs should participate in evaluation and use program statistics to make program improvements.
- *Training*—Staff should participate in training prior to program implementation, judges should receive formal training, and all team members should be trained as soon as possible.

Volumes of research has been conducted on Drug Courts during the over twenty years of their existence. One can find journal articles written on almost any aspect of Drug Courts, from racial differences in Drug Court graduation rates (McKean & Warren-Gordon, 2011) to the effect of faith on program success (Duvall et al., 2008). Moreover, Drug Court best practices continue to be identified and taught at national Drug Court training conferences. Using a larger sample, this article further supports this previous research by confirming, updating, and adding to the research findings about specific Drug Court practices that relate to significantly better outcomes.

METHODS

Between 2000 and 2010, NPC Research conducted over 125 evaluations of adult Drug Court program operations. For this study, we selected sixty-nine of these evaluations because they used consistent methods for collecting detailed process information, included recidivism and cost analyses using the same methodology, and had sufficient sample sizes (total $n \geq 100$) for valid analysis. All process evaluations were designed to assess how and to what extent the Drug Court programs had implemented the Ten Key Components. The Drug Courts represented diverse geographic areas in Oregon, California, Indiana, Maryland, Michigan, Vermont, and Guam. In total, this

study included 32,719 individuals (16,317 Drug Court participants and 16,402 comparison group members).[1]

Participation by the Drug Court programs in these evaluations was voluntary. These courts either directly contracted with NPC Research for evaluation services as part of their own quality improvement initiatives or collaborated with NPC Research as part of larger state or federal grant initiatives.

Data Collection

The data used in these analyses were collected as a part of process, outcome, and cost evaluations performed by NPC Research between 2000 and 2010. A brief description of the process, outcome, and cost data collection methodology is summarized below.[2]

Process Data Collection

For the process evaluations, the team relied on a multi-method approach. This strategy included a combination of site visit observations, key informant interviews, focus groups, and document reviews. This broad approach allowed the team greater access to descriptive program data than would have been available using any single method. A standard methodology was applied at each site to provide comparable data.

Key informant interviews were conducted with the Drug Court coordinator, judge, prosecutor, defense attorney, treatment providers, and probation and law enforcement representatives. Frequently, representatives from other involved agencies were also interviewed. NPC Research developed a standardized Drug Court typology interview guide and online survey to provide a consistent method for collecting structure and process information. The topics for the survey and typology interview guide were based on the Ten Key Components

[1] See http://www.npcresearch.com/Files/Appendix_A_Adult_drug_courts_participating_in_this_research.pdf for the programs included in this analysis.

[2] Detailed descriptions of the methodology and data collection performed for each Drug Court's full evaluation can be found in the program site-specific reports at www.npcresearch.com.

(NADCP, 1997) and were chosen from three main sources: the evaluation team's extensive Drug Court experience, the American University Drug Court Survey, and a published paper by Longshore and colleagues (2001) describing a conceptual framework for Drug Courts. The survey and typology interview guide covered many areas including specific Drug Court characteristics, structure, processes, and organization.

Outcome Data Collection

For the Drug Court participant sample, NPC Research identified individuals at each Drug Court who enrolled in the programs over a specified time period (at least a 2-year period). These individuals were selected using a Drug Court database or paper files listing Drug Court participants. To create a comparison group, NPC Research identified similarly situated individuals who were eligible for Drug Court but did not participate and received traditional court processing. Both groups were examined through existing administrative databases for a period of at least two years following entry. When databases were not available, data were gathered from paper files maintained by the program and other agencies involved with the offender population. The evaluation team utilized county and statewide data sources on criminal activity and treatment utilization to determine how Drug Court participants and the individuals from comparison groups differed in court processing and subsequent recidivism-related events (e.g., rearrests, new court cases, new probation, and incarceration).

Cost Data Collection

NPC Research performed the cost studies in these Drug Court programs using an approach called transaction and institutional cost analysis (TICA) (Crumpton, Carey, & Finigan, 2004). The TICA approach views an individual's interaction with publicly funded agencies as a set of transactions in which the individual utilizes resources contributed from multiple agencies. Transactions are those points within a system where resources are consumed or change hands. In the case of Drug Courts, when a Drug Court participant appears in court or has a drug test, resources such as judge time, public defender

time, court facilities, and urine cups are used. Court appearances and drug tests are transactions. In addition, the TICA approach recognizes that these transactions take place within multiple organizations and institutions that work together to create the program. These organizations and institutions contribute to the cost of each transaction with program participants. TICA is a practical approach to conducting cost assessment in an environment such as a Drug Court, which involves complex interactions among multiple taxpayer-funded organizations.

In order to maximize the study's benefit to policymakers, a cost-to-taxpayer approach was used in these evaluations. This focus helps define which cost data should be collected (costs and avoided costs involving public funds) and which cost data are omitted from the analyses (e.g., costs to the individual participating in the program). In this approach, any criminal-justice-related cost incurred by the Drug Court or comparison group participant that directly impacts a citizen (either through tax-related expenditures or the results of being a victim of a crime perpetrated by a substance abuser) is used in the calculations.

Process Data Analysis

Analysis of Drug Court Practices

Statistical frequencies were performed across all sixty-nine Drug Court programs on each of over 200 adult Drug Court practices to determine the number of programs that implemented each practice. The frequencies provided us with the amount of variation that existed across programs in implementing any particular practice. The practices were categorized by component for each of the Ten Key Components (based on earlier work by Carey, Finigan, & Pukstas, 2008).

Some Drug Court practices did not vary greatly across these sixty-nine Drug Courts. If all Drug Courts performed the same practice, it was not possible to determine whether courts that performed a given practice had better outcomes than courts that did not. If a practice was not included in the results as a practice related to positive outcomes, this does not necessarily mean that the practice is not important; alternatively, it might not have been measurable with these

data. Practices that were common in over 90% of the programs are reported on the NPC Research Web site.[3]

Analysis of Practice in Relation to Recidivism and Costs

The analyses presented in this paper include only evaluations that had recidivism and cost outcomes (a total of sixty-nine programs). The quantitative analysis assessed court-level characteristics (practices performed or services provided by the program) and court-level outcomes, specifically, average reduction in number of rearrests and average increase in cost savings for each Drug Court. Costs, in particular, can vary across jurisdictions based on many factors that are not related to the Drug Court program, including cost of living in the area and the availability of different resources. For this reason, the *percent difference* (effect size) between the Drug Court participant sample and the comparison sample was used as a method for equilibrating the results across sites.

This study defines *recidivism* as the average number of rearrests over two years from program entry. *Reduction in recidivism* is defined as the percent decrease in average number of rearrests for the Drug Court participants when compared with the comparison group.

Outcome costs are defined as costs incurred because of criminal recidivism for both the Drug Court participants and comparison group members in the two years after Drug Court entry (or an equivalent date for the comparison group). Recidivism-related costs include rearrests, new court cases, probation and parole time served, and incarceration in jail and prison. For this study, reductions in outcome costs (or increases in cost savings) were calculated as the percent difference in outcome costs between the Drug Court group and the comparison group. The higher the percentage, the bigger the cost savings for Drug Court participants over the comparison group.

For the analyses of Drug Court practices in relation to outcomes, we coded the vast majority of the data on program practices as *yes* or *no* questions, either *yes,* the program performed that practice, or *no,*

[3] See Appendix B at http://www.npcresearch.com/Files/Appendix_B_Practices_performed_in_90_percent_or_more_of_the_programs_in_this_analysis.pdf.

the program did not perform that practice. For example, the practice "a representative from treatment regularly attends Drug Court sessions" was coded as *yes* if the treatment representative regularly attended court or *no* if the treatment representative did not. In a few cases, we used continuous data (such as the number of days between arrest and program entry). We analyzed program recidivism and cost outcomes for those practices where the data revealed sufficient variation across sites.

To be considered a *best practice* for this article, data on a Drug Court practice had to be available in at least forty programs ($n \geq 40$), with at least ten programs in each yes or no category. That is, at least ten programs engaged in that practice *and* at least ten programs did not engage in that practice. However, in three cases where differences were substantial and significant, we included a practice where we had data for only thirty-five programs. In addition to best practices, we also included *promising practices*, where $n \geq 20$ and at least five programs represented each *yes/no* category.

We considered analyzing the practice and outcome data using a mixed model approach that used a nested design with *Drug Court program* as a grouping variable and outcome data at the client level (number of rearrests and two-year outcome costs per individual); however, we determined this would not best support the purpose of this analysis of best practices, which was to determine what program practices are related to program-level outcomes rather than individual outcomes (e.g., average reductions in recidivism, not whether or not a particular individual was rearrested or experienced a specific program practice). Therefore, these data could best be applied to program level analyses such as t-tests. The use of control variables was also considered (such as program population characteristics—ethnicity, gender, or drug of choice; rural vs. urban; program capacity; number of case managers or treatment providers; etc.). However, the sample size (n = 69) was not large enough to control for the numerous potential variables. Further, determining which variables to include as controls for each separate program practice on a theoretical basis when analyzing over 200 program practices was too complicated to be feasible and would not provide helpful or meaningful results.

We ran t-tests to compare the reduction in recidivism and the improvement in cost savings between courts that answered *yes* and courts that answered *no* for each practice. In cases where the data for a practice were continuous variables (such as number of treatment agencies that worked with the program), we used regression analyses to determine overall significance and examined the data for clear cut points. We then ran t-tests using these cut points. Results were considered statistically significant at $p < .05$ and considered "trends" up to $p < 0.15$.

Drug Court Population and Program Characteristics

Of the sixty-nine programs with recidivism data, 69% were post-plea only, 96% took offenders with felony charges, and 51% took offenders with either misdemeanor or felony charges.

The Drug Court programs included in this analysis ranged from a capacity of 20 active participants to over 400. The participant population for these programs varied in racial/ethnic composition within each Drug Court from 100% Latino to 99% White to 96% African–American. Participant gender ranged from 13% female in some Drug Courts to 55% female in others. Drugs of choice also varied widely, with some courts being made up entirely of methamphetamine users (100%), some consisting of mostly heroin users (80%), while others had a majority of marijuana users (78%). The average length of stay in these Drug Courts ranged from five months to twenty-nine months. The average graduation rate was 46%. A table that provides a description of the range in program and participant characteristics across the study sites can be found on the NPC Research Web site.[4]

Recidivism rates and costs also varied widely between sites based on factors that had little to do with the program itself, such as the availability of the police to make arrests (e.g., fewer police may result in fewer arrests) and the cost of living in the area. For this reason, we equilibrated the recidivism and cost outcomes across programs by

[4] See http://www.npcresearch.com/Files/Characteristics_of_program_and_participant_population_in_69_drug_courts.pdf.

creating a percent difference between the Drug Court group and its comparison group for each outcome to establish the effect size. The effect size for the recidivism rate consisted of the difference in the number of rearrests between the Drug Court participants and comparison group divided by the number of rearrests for the comparison group. The percent increase in cost savings was calculated by subtracting the recidivism-related costs for the Drug Court from the recidivism costs for the comparison group, then dividing by the comparison group recidivism costs.

The average reduction in recidivism across these sixty-nine programs was 32%, and the average increase in cost savings was 27%. Just over 9% of the sixty-nine Drug Court programs had significantly greater participant recidivism than their comparison group, and 3% had outcomes that cost significantly more money than the comparison group. An additional 10% showed no significant difference in recidivism between the Drug Court and comparison group, and 23% showed no significant difference in costs. Just over 81% of the programs had significant reductions in recidivism of 10% or greater (up to 100% reductions), and 74% had significant cost savings of 16% or higher (up to 95% savings in costs).

Limitations of the Analyses

One limitation of these analyses is that some Drug Courts may have comparatively high-risk populations, for example, populations that have higher rates of mental illness, more severe addictions, low educational levels, and few economic opportunities. Drug Courts with proportionately more participants in this situation are more likely to have fewer positive outcomes, despite the fact that such Drug Courts might be implementing best practices. The data on risk level of the participants in these Drug Courts were not available to determine how this factor might have impacted outcomes.

Secondly, and related to the first limitation, is that the analyses performed were univariate correlations and there was no experimental control over what services or policies were provided by the programs in this study. Therefore, we cannot confidently attribute causality. That is, we cannot say with certainty that a particular practice caused

a particular reduction in recidivism or increase in cost savings. The more effective programs might have differed on variables that had nothing to do with their outcomes.

These analyses of best practices did not control for program population characteristics or some context characteristics (such as rural vs. urban programs). However, because of the vast flexibility and variation in the Drug Court model, many types of programs and populations were represented in this sample and, therefore, these findings should hold for many Drug Court programs.

RESULTS

The findings from these analyses are extensive. We found over fifty practices with significant correlations with recidivism or cost or both and some practices which were of interest because they were not significantly related to outcomes. The presentation of the results is therefore broken down into sections. The first section provides the full list of practices that met the criteria for best practices. This section also includes lists of the top ten practices by effect size for reduced recidivism and the top ten practices related to cost savings. The second section describes the promising practices that were significantly related to reductions in recidivism or to cost savings. The third section describes practices that are interesting because they were not significantly related to either outcome. Finally, the last section provides a discussion of the overarching themes among these practices.

Best Practices

Table 1 lists the best practices along with the overall effect sizes and level of significance for reductions in recidivism and for cost savings. These effect sizes show how large the reductions in recidivism and the increases in cost savings are for Drug Courts that perform a specific practice compared with the Drug Courts that do not. For example, courts where law enforcement is a member of the Drug Court team had 87% greater reductions in recidivism than courts that did not have law enforcement on the team. The figure 87% is the effect size. Although the Drug Courts that do not include law enforcement on the

team still reduced recidivism, the Drug Courts that do include law enforcement reduced recidivism 87% more. Table 1 also has the practices organized within each of the Ten Key Components (NADCP, 1997) following the convention established by these authors in an earlier study (Carey, Finigan, & Pukstas, 2008).[5]

TABLE 1	DRUG COURT BEST PRACTICES RELATED TO REDUCED RECIDIVISM AND HIGHER COST SAVINGS (BY KEY COMPONENT)		
KC[1]	**Practice**	**Reduction in Recidivism**	**Increase in Cost Savings**
1	Law enforcement is a member of the Drug Court team	0.87*	0.44†
1	Judge, both attorneys, treatment, program coordinator, and probation attend staffings	0.50*	0.20
1	The defense attorney attends Drug Court team meetings (staffings)	0.21	0.93*
1	A representative from treatment attends Drug Court team meetings (staffings)	1.05†	0.00
1	Coordinator attends Drug Court team meetings (staffings)	0.58†	0.41
1	Law enforcement attends Drug Court team meetings (staffings)	0.67*	0.42~
1	Judge, attorneys, treatment, probation, and coordinator attend court sessions (status review hearings)	0.35†	0.36~
1	A representative from treatment attends court sessions (status review hearings)	1.00†	0.81†

[5] NPC Research provides a table of these best practices with greater detail including the specific recidivism reductions and relative cost savings in programs that did and did not perform each practice as well the sample size for each category. See Appendix C at http://www.npcresearch.com/Files/Appendix_C_Best_practices_comparing_yes_to_no_with_N_sizes.pdf.

TABLE 1	DRUG COURT BEST PRACTICES RELATED TO REDUCED RECIDIVISM AND HIGHER COST SAVINGS (BY KEY COMPONENT)		
KC[1]	Practice	Reduction in Recidivism	Increase in Cost Savings
1	Law enforcement attends court sessions (status review hearings)	0.83*	0.64*
1	Treatment communicates with court via e-mail	1.19*	0.39
2	Drug Court allows nondrug charges	0.95*	0.30
3	The Drug Court excludes offenders with serious mental health issues	0.16	–0.43*
3	The time between arrest and program entry is 50 days or less	0.63*	–0.19
3	Program caseload (number of individuals actually participating at any one time) is less than 125	5.67*	0.35
4	The Drug Court works with two or fewer treatment agencies	0.74*	0.19
4	The Drug Court has guidelines on the frequency of individual treatment sessions that a participant must receive	0.52*	–0.19
4	The Drug Court offers gender-specific services	0.20†	–0.10
4	The Drug Court offers mental health treatment	0.80†	0.12
4	The Drug Court offers parenting classes	0.65*	0.52˜
4	The Drug Court offers family/domestic relations counseling	0.65†	–0.12
4	The Drug Court offers anger management classes	0.48	0.43˜

TABLE 1	DRUG COURT BEST PRACTICES RELATED TO REDUCED RECIDIVISM AND HIGHER COST SAVINGS (BY KEY COMPONENT)		
KC[1]	Practice	Reduction in Recidivism	Increase in Cost Savings
4	The minimum length of the Drug Court program is 12 months or more	0.57*	0.39
5	Drug test results are back in two days or less	0.73*	0.68*
5	In the first phase of Drug Court, drug tests are collected at least two times per week	0.38	0.61˜
5	Participants are expected to have greater than 90 days clean (negative drug tests) before graduation	1.64˜	0.50†
6	Only the judge can give sanctions to participants	0.31˜	0.04
6	Sanctions are imposed immediately after noncompliant behavior (e.g., Drug Court will impose sanctions in advance of a participant's regularly scheduled court hearing)	0.32	1.00*
6	Team members are given a copy of the guidelines for sanctions	0.55†	0.72˜
6	In order to graduate participants must have a job or be in school	0.24	0.83*
6	In order to graduate participants must have a sober housing environment	0.14	0.48˜
6	To graduate participants must have paid all court-ordered fines and fees (e.g., fines, restitution)	0.48˜	0.30
7	Participants have status review sessions every two weeks in first phase	0.48†	–0.23

TABLE 1	DRUG COURT BEST PRACTICES RELATED TO REDUCED RECIDIVISM AND HIGHER COST SAVINGS (BY KEY COMPONENT)		
KC[1]	**Practice**	**Reduction in Recidivism**	**Increase in Cost Savings**
7	Judge spends an average of 3 minutes or greater per participant during status review hearings	1.53*	0.36
7	The judge was assigned to Drug Court on a voluntary basis	0.84˜	0.04
7	The judge's term is indefinite	0.35*	0.17
8	The results of program evaluations have led to modifications in Drug Court operations	0.85†	1.00*
8	Review of the data and/or regular reporting of program statistics has led to modifications in Drug Court operations	1.05*	1.31*
9	All new hires to the Drug Court complete a formal training or orientation	0.54†	0.07

NOTE: Practices that are significantly related to reductions in recidivism are not always significantly related to cost savings and vice versa. This finding is most likely because the two outcomes are indicators of different factors. The recidivism outcome essentially reflects the number of times participants engaged the criminal justice system (i.e., the number of rearrests). The cost outcome often reflects the seriousness of the crimes associated with those rearrests. More serious charges often result in more extensive sentences—more time incarcerated and on probation or parole—and a greater number of new court cases, all of which are related to higher costs.

[1]Key Component; ˜Trend ($p<.15$); †$p < 0.1$; *$p < .05$

Top Ten Practices for Reducing Recidivism

Following are the top ten practices related to reducing recidivism from Table 1 ranked by effect size, starting with the largest.

1. Drug Courts with a program caseload (number of active participants) of less than 125 had more than five times greater reductions in recidivism than programs with more participants.

Figure 1 demonstrates how the reductions in recidivism decrease as programs get larger. Likely, as the Drug Court gets larger, the caseloads per case manager and treatment provider also get larger. The larger programs may be tempted to decrease the level of supervision or otherwise "water down" the Drug Court intervention. In addition, the role of the judge has been demonstrated to be a key factor in participant success. All of the Drug Courts in this study were single-judge programs and therefore the larger programs had a single judge seeing up to 400 active participants. Judges report difficulty in getting to know participants to the extent that they need to when they see over 100 participants. Although the reason for this result is not clear from the available data, this finding had the largest effect size by far of any finding in this study. Part of the reason for this extremely large effect size is that programs with populations of greater than 125 participants had a very small reduction in recidivism (an average of 6%) compared with programs with 125 or fewer, which had an average of 40% reduction in recidivism. Clearly the smaller programs did substantially better. We do not believe that, based on this result, larger

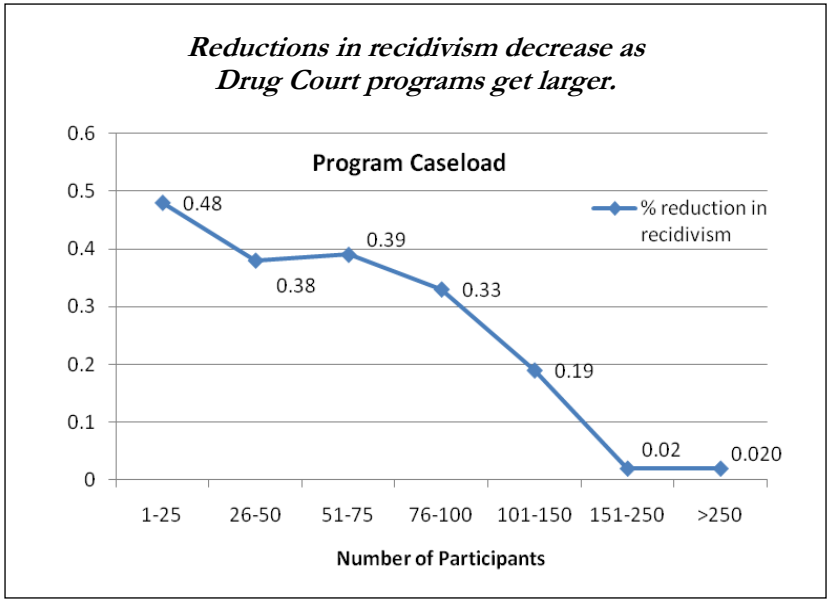


Figure 1. Participant Caseload Compared with Reductions in Recidivism

programs must become smaller. More research is needed to fully understand what is driving this result. In the meantime, larger programs should be examining their practices to ensure that they are maintaining fidelity to the Drug Court model and to best practices.

2. Drug Courts where participants were expected to have greater than 90 days clean (negative drug tests) before graduation had 164% greater reductions in recidivism compared with programs that expected less clean time.

Graduation requirements have been an important issue, and a contentious one, for some Drug Courts. This finding is consistent with the literature, which shows that the longer individuals remain abstinent from drugs and alcohol, the more likely they will continue to remain abstinent in the future (e.g., Kelly & White, 2011).

3. Drug Courts where the judge spent an average of three minutes or greater per participant during court hearings had 153% greater reductions in recidivism compared with programs where the judge spent less time.

Three minutes does not seem like much time. Yet one of the crucial aspects of the Drug Court model is the influence of the judge, which requires significant and meaningful interaction with the participant. Our data show a linear effect on positive outcomes when more judge time is spent with the participant (see Figure 2). Moving from under three minutes to just over three minutes effectively doubles the reduction in recidivism, while spending seven minutes or more effectively triples the positive outcome.

4. Drug Courts where treatment providers communicated with the court or team via e-mail had 119% greater reductions in recidivism.

Good communication is important for any successful team effort, and this is particularly true of Drug Court. For a Drug Court to provide immediate sanctions and rewards, communication about participant activities must be quick and accurate. Using e-mail as a primary communication method allows swift communication simultaneously with all team members, making this an effective format.

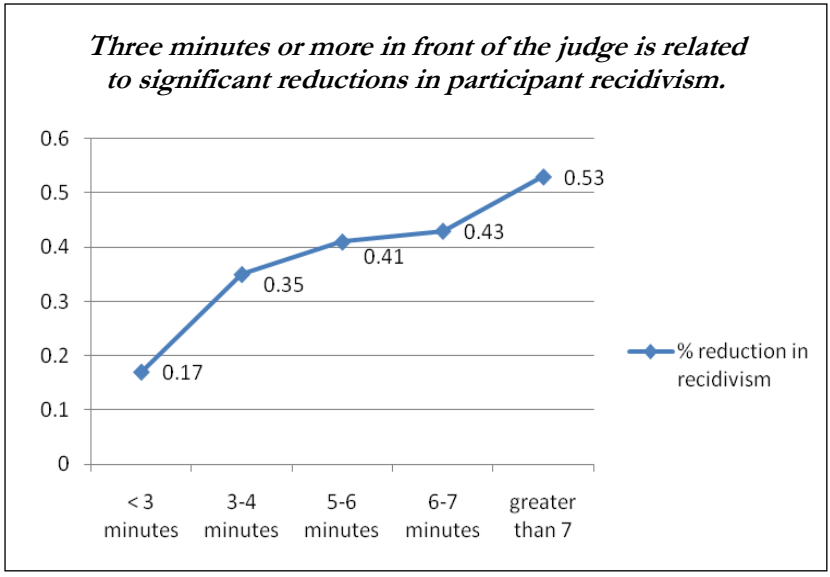


Figure 2. Number of Minutes before the Judge Compared with Reductions in Recidivism

5. Drug Courts where a representative from treatment attended Drug Court team meetings (staffings) had 105% greater reductions in recidivism.

Most of our sites (n = 50) required treatment providers to attend the case staffing because this is highly relevant to their role and is a crucial place for their feedback, but a large minority (11) did not. While they may have had feedback about participants delivered to the staffing, they did not send a representative to be part of the team. These data suggest that this is not as good a practice.

6. Drug Courts where internal review of the data and program statistics led to modifications in program operations had 105% greater reductions in recidivism.

Parallel to the practice of having independent evaluation of the Drug Court program (point ten on this top ten list) is the internal collecting, tracking, and use of data to improve program practice. The key elements to this best practice are twofold:

- The program uses an electronic data collection and management system that allows staff to provide the Drug Court with relevant statistics on program performance and operations, which the team can use to garner insights into its performance, guide improvements, and reveal areas where training is needed.
- The Drug Court *uses* the data as a basis for practical program change and continues to use it to monitor progress.

7. Drug Courts where a treatment representative attended court hearings had 100% greater reductions in recidivism than programs where treatment did not attend.

Most of the programs in this study required treatment providers to attend the case staffing because this is highly relevant to their role and is a crucial place for their feedback. However, the role of treatment seems less obvious when it comes to status hearings. Status hearings for Drug Court generally involve sanctions and rewards for activities related to treatment. Having treatment providers attend status hearings demonstrates to participants that the team works together to make decisions about their care and demonstrates in court that the program is intended to be therapeutic. This also makes it more difficult for participants to tell different stories to treatment and the Drug Court, thus "playing off" treatment providers and the rest of the team against each other.

8. Drug Courts that allowed nondrug charges (e.g., theft or forgery) had 95% greater reductions in recidivism than Drug Courts that accepted only drug charges.

This practice has been a source of controversy among Drug Courts. Early in the Drug Court movement, common belief held that the Drug Court was primarily geared to offenders with drug possession charges. This idea ignored the important role of drug addiction and abuse in many other crimes such as burglary or robbery. Increasingly, prosecutors and other referral sources to Drug Court began to feel that offenders with nondrug charges would also benefit from Drug Court. These data support that conclusion. This finding illustrates the greater impact Drug Court can have on public safety when participants with more serious offenses (including higher-risk participants) are given the benefit of intense supervision and treatment.

9. Drug Courts that had a law enforcement representative on the Drug Court team had 88% greater reductions in recidivism than programs that did not.

Programs that include a law enforcement representative on the team describe that role as crucial for two main reasons:

- Law enforcement often has more frequent contact than Drug Court personnel with Drug Court participants on the street and in home settings and therefore provides good insight into what is happening to participants in their lives outside of court and treatment.
- Including law enforcement creates a two-way process where law enforcement representatives not only contribute an important perspective to the Drug Court, but also return information to law enforcement organizations, which promotes a better understanding of the value of Drug Court.

10. Drug Courts that had evaluations conducted by independent evaluators and used them to make modifications in Drug Court operations had 85% greater reductions in recidivism than programs that did not use these results.

Evaluations by independent research teams are sometimes viewed by sites as an inconvenience required by a funder. Partly this perception may result from using evaluators who do not understand Drug Courts and do not address questions that might lead to program improvement. However, part of this perception may also reflect the discomfort or lack of familiarity of some Drug Court staff with the use of numbers or statistics. Whatever the reason, using evaluation feedback to modify program practices appears to be worth the effort.

The key elements to this best practice are twofold:

- The program has an evaluation by an independent research team that provides insights into its program performance, guidance on potential improvements, and training in ongoing data collection to monitor improvements.
- The Drug Court *uses* the independent evaluation as a basis for practical program change.

Top Ten Practices for Cost Savings

Many of the top ten practices for reducing recidivism are the same ones that also contribute to saving costs. Following are the top ten practices related to increased cost savings from Table 1 ranked by effect sizes, starting with the largest.

1. Drug Courts where internal review of the data and program statistics led to modifications in program operations had 131% higher cost savings.

Using data from program management information systems (MIS) to track progress and make program modifications correlates strongly with cost savings. Regularly monitoring data further provides feedback that the team can use to make necessary adjustments to meet goals in a timely and regular manner. This finding appears in both of the top ten practices lists.

2. Drug Courts that had evaluations conducted by independent evaluators and used them to make modifications in Drug Court operations had 100% greater cost savings.

Having a good, useful independent evaluation is important to this best practice. As with the preceding practice, this practice depends on the program's willingness to make changes based on data and to continue to use data to monitor progress. This finding appears in both of the top ten practices lists.

3. Drug Courts where sanctions were imposed immediately after noncompliant behavior had 100% greater cost savings.

The value of having sanctions imposed immediately after noncompliant behavior is a central tenet of behavior modification. It also appears to increase positive outcomes and cost savings in Drug Courts. *Immediately* is defined as bringing a participant in to the next available court hearing if they are not already scheduled for it, or administering the sanction before the next court hearing. Study results also showed that when programs wait until the scheduled court appearance for noncompliant participants instead of bringing them in earlier, participant outcomes do not improve. If teams wait too long (two weeks or more) before applying a sanction, the participants may

have other issues that are more relevant by then, or they may even have worked to improve their behavior by then, in which case they are receiving a sanction at the same time as they are doing well, providing them with a message that is unclear and may even be defeating.

4. Drug Courts where the defense attorney attended Drug Court team meetings (staffings) had 93% greater cost savings.

The value of having a defense attorney present at staffing is twofold: first, it helps protect the rights of the Drug Court participant, and second, it appears to increase positive outcomes and cost savings. The goal of problem-solving courts is to change behavior by leveraging compliance with treatment while protecting both participant rights and public safety. Drug Court participants are seen more frequently, supervised more closely, and monitored more stringently than other offenders. Thus, they often have violations of program rules and probation. Counsel must be there to rapidly address the legal issues, settle the violations, and move the case back into treatment and program case plans.

5. Drug Courts where participants must have a job or be in school in order to graduate had 83% greater cost savings.

Both having a job and being in school have a clear and logical connection to costs after the participant leaves the program. If the participant is engaged in positive activities that lead to higher (and legal) income, they are less likely to engage in drug use or other criminal activities.

6. Drug Courts where a treatment representative attended court sessions had 81% greater cost savings.

Having a treatment representative at Drug Court sessions related to significant cost savings, illustrating the importance of treatment providers as team members. This finding appears in both of the top ten practices lists.

7. Drug Courts where team members are given a copy of the guidelines for sanctions had 72% greater cost savings.

Interestingly, the results also showed that providing *participants* with written guidelines was not related to recidivism or cost outcomes. Therefore, it appears that guidelines may be more crucial for the *team* in determining its responses to participant behavior. Written guidelines can provide a range of potential team responses to participants' behaviors, including treatment responses, sanctions, and incentives rather than a one-to-one response for each behavior. This range of potential responses serves to remind team members of the variety of incentives and sanctions available while also providing some consistency across participants. Programs without written guidelines have a tendency to use a smaller number of sanctions and limit themselves to the incentives that they are most familiar with.

8. Drug Courts where drug test results were available in 48 hours or less had 68% greater cost savings.

Receiving drug test results quickly allows the team to respond more quickly with swift and certain sanctions and incentives. One method that works well for many programs is to use instant-results tests for the majority of drug tests, only sending to a lab for confirmation if the participant continues to deny use after a positive instant result. If the confirmation test comes back positive, the participant pays for that test as a sanction for providing false information in addition to any sanction or treatment response for the drug use itself. If the confirmation is negative, then the program pays the testing fee.

9. Drug Courts where drug tests were collected at least two times per week in the first phase had 68% greater cost savings.

Drug testing is the one truly objective means Drug Courts have of assessing whether their services are successfully changing participant behavior. It plays a crucial role in participant success. In focus groups, participants regularly reported that the only thing that kept them from using at the beginning of the program (before they were truly engaged in recovery) was knowing they would be tested and caught. Drug testing at least twice per week makes it more difficult for participants to use between tests, particularly if the tests occur on a random schedule. Testing less frequently makes prediction easier so that participants can find times to use without detection.

10. Drug Courts where a law enforcement representative attended court sessions had 64% greater cost savings than courts where law enforcement did not.

A law enforcement team member provides a unique perspective on participants and can contribute information that is invaluable to the team and the participants.

Promising Practices

Promising practices are those that significantly related to recidivism and costs, but did not meet the more stringent criteria outlined for best practices. The practices listed in Table 2 show promise for providing adult Drug Court programs with a strong infrastructure that contributes to program and participant success.[6]

Offer Services to Address Participant Needs

Drug Court programs that provide participant supports appear to have better outcomes. Many program services that address participant needs, including gender-specific services, mental health treatment, parenting classes, family counseling, and anger management classes, help participants avoid rearrest and save the program money in the long run (see Table 1). Three practices related to program services were encouraging enough to include under promising practices: residential treatment, health care, and dental care.

Residential Treatment—Offering residential treatment often completes a continuum of treatment services for those participants with the most severe substance abuse issues and may translate into a 106% improvement in recidivism outcomes.

Health and Dental Care—Most Drug Court participants had lifestyles that negatively impacted their physical health and many did not have consistent access to health or dental care. For example, use of

[6] The NPC Research Web site provides a table of promising practices with greater detail including the specific number of Drug Courts in each category and the specific recidivism reductions and relative cost savings. See Appendix D at http://www.npcresearch.com/Files/Appendix_D_Promising_practices_comparing_yes_to_no_with_N_sizes.pdf.

TABLE 2	DRUG COURT PROMISING PRACTICES		
KC[1]	Practice	Reduction in Recidivism	Increase in Cost Savings
4	The Drug Court offers residential treatment	1.06†	0.26
4	The Drug Court offers health care	0.50~	0.46
4	The Drug Court offers dental care	0.59†	0.38
6	Participants are required to pay court fees	0.18	2.08*
6	The Drug Court reports that the typical length of jail sanction is longer than two weeks	–0.59*	–0.45~

NOTE: For promising practices, $n \geq 20$ with at least 5 in each category.
[1]Key Component; ~Trend ($p<.15$); †$p < 0.1$; *$p < .05$

some substances (e.g., methamphetamines) creates serious physical health and dental problems. Programs that offered dental care had 59% greater reductions in recidivism than programs that did not and programs that offered health care had 50% greater reductions in recidivism.

Although not statistically significant, offering any one of these three services also produced improvements in cost of 23–26 percent.

Require Participants to Pay Court Fees

Court fees are one way that Drug Court programs create an institutionalized, sustainable source of program funding. These fees must be proportional to a participant's ability to pay and should not create a barrier to success or a disincentive to participate in the program. This fee strategy enhances participant engagement, promotes the belief that the program is valuable, and allows participants to invest in their own change process. Programs that required court fees had 208% higher cost savings than programs that did not. Note that these cost savings do not reflect the costs of running the program, but specifically refer only to outcome costs, costs that occurred outside of the program and are related to recidivism events such as rearrests and time in jail.

Therefore, the cost savings are not achieved because the program had collected larger participant fees.

Consider Participant Sanctions Carefully

Two of the promising practices involve the use of sanctions in Drug Court programs, specifically the use of jail as a sanction and terminating program participation owing to rearrest for drug possession. Some view these sanctions as tougher on crime, yet the results of this study indicate that programs have better outcomes when they address noncompliance issues through other strategies.

Use Jail As a Sanction Sparingly—This study assessed the impact of using briefer compared with longer jail sanctions. Drug Courts that levied longer-term jail sanctions had worse outcomes than those using shorter-term jail sanctions (see Figure 3).

Programs that used sanctions of less than six days had average reductions in recidivism of 46% compared with 19% for programs that used longer-term jail sanctions. In addition, jail is an extremely expensive resource. Programs relying on jail sanctions longer than two weeks saw 45% less cost savings after program participation.

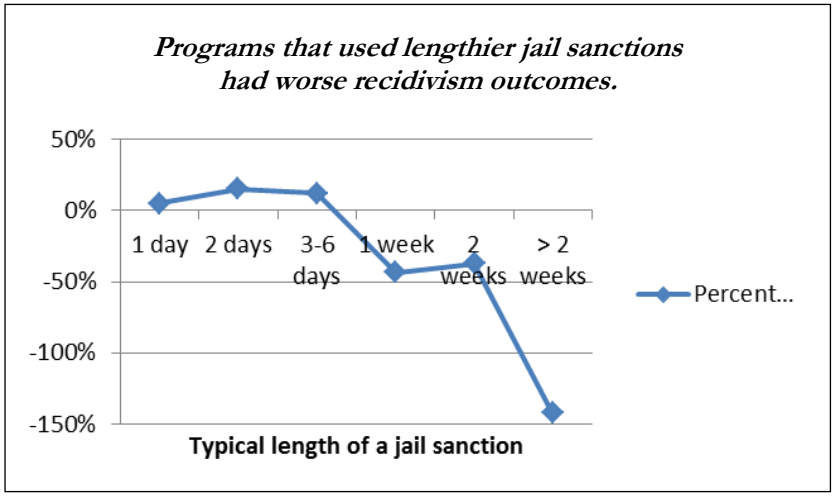


Figure 3. Duration of Jail Sanction Time Compared with Reduction in Recidivism

Retain Participants with New Possession Charges Rather Than Terminate Them—Although all programs must consider and establish policies and procedures for maintaining public safety and determining when participants are no longer appropriate for community-based interventions, a new arrest should not necessarily be grounds for automatic program termination. This study found that programs that terminated participants upon a new arrest for drug possession had lower recidivism reductions and lower cost savings than programs that did not terminate participants for a new drug charge. Programs that terminated participants for drug-possession arrests had 50% worse recidivism outcomes and 48% worse cost savings than programs that retained these participants in the program. These findings illustrate the importance of providing more services to this population of offenders, and that the continuity and persistence of Drug Court supervision and treatment pays off in the long run.

Train Staff in Preparation for Drug Court Program Implementation

Good management practices consistently demonstrate that employees need to understand their roles and tasks if they are to do their jobs effectively, and Drug Courts are no exception. As this article supports, Drug Court programs are collaborations with key elements that are important to implement to achieve desired outcomes. In this study, those programs that trained team members in preparation for program implementation averaged a 55% greater reduction in recidivism. Even more striking was the cost savings that resulted from training. Programs that invested in this practice had an average of 238% greater cost savings than programs that did not invest in training.

In sum, many of the promising practices described in this section involve activities or services that have resource implications programs might consider too expensive or time consuming, such as offering residential treatment or dental care or paying for staff training. However, this study provides evidence that these investments likely pay off in better long-term outcomes for both participants and the program as a whole. Smart use of system resources, such as limited

use of jail as a sanction and implementation of affordable participant fees, can also help make program investments feasible while at the same time improving outcomes.

Interesting Practices Not Significantly Related to Outcomes

Some practices are important by virtue of the fact that they were *not* significantly related to better or worse outcomes. Three main findings are particularly relevant to programs in determining their target population and their overall model. These findings relate to violence charges, mixing certain participant populations, and frequency of court appearances.

Drug Courts that allow participants with current violence charges or prior violence convictions had no difference in recidivism or cost outcomes.

This has been a highly political and controversial topic. Many prosecutors will not allow violent offenders in Drug Court because of public safety concerns. However, the data show that programs that allow violent offenders do equally well as programs that allow only nonviolent offenders. Other research also supports this finding (see Saum, Scarpitti, & Robbins, 2001; Saum & Hiller, 2008). In fact, research suggests allowing violent offenders into Drug Court programs can have a bigger positive effect on recidivism and cost outcomes than allowing only nonviolent offenders because greater savings are achieved when violent crimes are prevented rather than less serious (less costly) crimes.

In general, most violent offenders are not incarcerated for long and are subsequently back in the community under supervision that is much less intensive than the supervision provided by Drug Court. Because of proven reductions in recidivism for Drug Court programs compared with the traditional court system, Drug Courts actually do a better job of protecting public safety. However, choosing what kind of violence charges are allowed is important because the safety of the staff and other participants is paramount.

Drug Courts that mix pre- and postadjudication participants or allow participants with misdemeanors or felonies into the program had no difference in recidivism or cost outcomes.

The Drug Court model appears to work for offenders who have a substance use problem and are involved with the criminal justice system. Whether the program operated with a mix of pre- and postadjudication participants or operated either preadjudication or postadjudication exclusively had no relation to recidivism or cost in the current study. This finding is contrary to the findings by Shaffer (2006) and for the MADCE study (Rempel & Zweig, 2011) that mixing pre- and postadjudication offenders had worse outcomes compared with programs that served each of those populations exclusively. Further research needs to be performed to resolve this discrepancy.

Similarly, whether the charge that led to Drug Court participation was a misdemeanor or felony also had no relation to subsequent outcomes.

Drug Courts that see participants at court sessions weekly during the first phase had no better outcomes than courts that saw them every two weeks.

Although our best practice results show that seeing participants every two weeks in the first phase is related to significantly better outcomes (see Table 1) compared with programs that see participants monthly or less often, weekly court appearances do not appear to have significant additional benefit. Overall, what is important is assessing the risk and need level of participants and determining the appropriate level of court supervision needed at the time of entry (Marlowe et al., 2006). Perhaps for very high-risk and high-need participants, weekly court appearances might be appropriate, while participants that are more in the middle of the risk/need range might perform adequately with less frequent supervision.

Reiteration of Study Limitations

With over 200 practices being examined, determining a theoretical reason for using a particular covariate in the analysis for each in-

dividual practice was not feasible. Therefore, the analyses performed for the above results did not adjust for covariates (e.g., services available in the community or numbers of available case managers) or for the risk or need level of the participant populations.

SUMMARY AND CONCLUSIONS

Themes in Best Practices

Interestingly, when the best and promising practice results were examined for emerging themes among practices (see Tables 2 and 3), those themes led us back to the Ten Key Components. Following is a discussion of the main themes that emerged from a review of practices that significantly related to program outcomes.

Teams Sink or Swim Together—A holistic approach works. Having more people at the table collaborating pays off. Everyone brings value and the investment is worth the effort and cost. This result may be a function of communication. These data strongly make a case that all key players (e.g., judge, coordinator, treatment representative, prosecutor, defense attorney, law enforcement representative) should be members of the Drug Court team and be present both at status hearings and at staffing meetings.

Relationships Matter—Having teams that get together and work together, having fewer providers (which promotes more individual relationships and communication) and fewer participants (so that the team and judge know everyone), and ensuring participants get at least three minutes on average of the judge's attention at each review session all help create an effective program.

Wraparound and Habilitation Services Are Key—Drug Court programs that focus on providing participant supports have better outcomes. Programs with such wraparound services avert rearrests and save taxpayer money in the long run when they address participant needs such as relapse prevention, gender-specific services, mental health treatment, parenting classes, family counseling, anger management classes, health and dental services, and residential care.

Structure and Consistency Are Crucial—Practices that demonstrate this theme include having written guidelines for sanctions, guidelines on the number of individual treatment sessions, drug test results within forty-eight hours, drug testing at least twice per week, status reviews every other week, immediate sanctions (including those that occur outside of court and thus happen more swiftly), and a program designed to take at least twelve months. These factors ensure that participants are learning about structure, accountability, safety, and dependability.

Participants Must Be Set Up for Success—Participants should be stable before leaving the program. Best practices within this theme include requiring that participants have a job or be in school, have at least ninety days clean, have participated in the program at least twelve months, have sober housing, and have paid all fees before they can graduate. If these practices are in place, participants should be ready to set their own goals and succeed in their lives.

Continuous Program Improvement Leads to Positive Outcomes—Programs that collect and use data, seek out training, acquire the support and insights of experts (including evaluators), and use the data and expert feedback to make ongoing adjustments to enhance practices see improvements in outcomes. These results demonstrate that Drug Courts that develop practices that focus on understanding and improving program performance have better outcomes than those that do not.

The Drug Court Model Is Effective with Difficult Populations—Drug Courts work for a wide range of populations and for participants who are seen as difficult to change and serve. These findings show that an offender's criminal justice status (or mental health status) should not be a barrier. It does not matter whether a program's population is only preadjudication, only postadjudication, or a mix of both. Nor does it matter whether participants have violent histories or not, or whether they have misdemeanors or felonies. The focus is on treatment and consistent supervision. These results suggest that Drug Courts can successfully include a wide variety of offender populations.

Perhaps the most overarching theme is a picture of Drug Courts that are well organized. These programs have teams that are engaged in program activities and are collaborating, think through their program and clearly communicate expectations to staff and participants, and are dedicated to program improvement. These Drug Courts are the most effective in helping participants recover their futures, reducing participant recidivism, decreasing crime, and saving taxpayer money.

This manuscript is an original work by the three authors, Shannon Carey, Juliette Mackin, and Mike Finigan.

Funding for this project was provided by the National Drug Court Institute through Grant No. 2009-DC-BX-K006 awarded by the Bureau of Justice Assistance. The Bureau of Justice Assistance is a component of the Office of Justice Programs, which also includes the Bureau of Justice Statistics, the National Institute of Justice, the Office of Juvenile Justice and Delinquency Prevention, the SMART Office, and the Office for Victims for Crime. Points of view or opinions in this document are those of the authors and do not represent the official position or policies of the United States Department of Justice or the National Association of Drug Court Professionals, the National Drug Court Institute, or its sponsors, staff members, or officers.

References

The evaluation reports for the sixty-nine Drug Courts used for this study are available online at NPCresearch.com.

Belenko, S. (1998). Research on drug courts: A critical review. *National Drug Court Institute Review, 1*(1), 1–42.

Belenko, S. (2001). Research on drug courts: A critical review: 2001 update. *National Drug Court Institute Review, 4*, 1–60.

Carey, S.M., & Finigan, M.W. (2004). A detailed cost analysis in a mature drug court setting: A cost-benefit evaluation of the Multnomah County Drug Court. *Journal of Contemporary Criminal Justice*, *20*(3) 292–338.

Carey, S.M., Finigan, M.W., Crumpton, D., & Waller, M.S. (2006). California drug courts: Outcomes, costs and promising practices: An overview of phase II in a statewide study. *Journal of Psychoactive Drugs,* (SARC Suppl. 3), 345–356.

Carey, S.M., Finigan, M.W., & Pukstas, K. (2008). *Exploring the key components of Drug Courts: A comparative*

study of 18 adult drug courts on practices, outcomes, and costs. Portland, OR: NPC Research.

Carey, S.M., Pukstas, K., Waller, M.S., & Finigan, M.W. (2008). *Drug courts and state mandated drug treatment programs: outcomes, costs and consequences*. Portland, OR: NPC Research.

Carey, S.M., Sanders, M.B., Waller, M.S., Burrus, S.W.M., & Aborn, J.A. (2010a). *Marion County Fostering Attachment Treatment Court process, outcome and cost evaluation*. Portland, OR: NPC Research.

Carey, S.M., Sanders, M.B., Waller, M.S., Burrus, S.W.M., & Aborn, J.A. (2010b). *Jackson County Community Family Court process, outcome, and cost evaluation.* Portland, OR: NPC Research.

Carey, S.M., & Waller, M.S. (2011). *Oregon drug courts: Statewide costs and promising practices.* Portland, OR: NPC Research.

Carey, S.M., Waller, M.S., & Weller, J.M. (2010). *California drug court cost study: Phase III: Statewide costs and promising practices.* Portland, OR: NPC Research.

Crumpton, D., Brekhus, J., Weller, J.M., & Finigan, M.W. (2004). *Cost analysis of Baltimore City, Maryland, Drug Treatment Court*. Portland, OR: NPC Research.

Crumpton, D., Carey, S. M., & Finigan, M. W. (2004). *Enhancing cost analysis of drug courts: The transactional and institutional cost analysis approach.* Portland, OR: NPC Research.

Crumpton, D., Worcel, S.D., & Finigan, M.W. (2003). *Analysis of foster care costs from the Family Treatment drug court Retrospective Study*. Rockville, MD: Center for Substance Abuse Treatment.

Duvall, J., Staton-Tindall, M., Oser, C., & Leukefeld, C. (2008). Persistence in turning to faith as a predictor of drug use and criminality among drug court clients. *Journal of Drug Issues, 38*(3), 911–928.

Finigan, M.W. (1998). *An outcome program evaluation of the Multnomah County S.T.O.P. drug diversion program.* Portland, OR: NPC Research. Available at http:/www.npcresearch.com/Files/OPE.pdf.

Finigan, M.W., Carey, S.M., & Cox, A. (2007). *The impact of a mature drug court over 10 years of operation: Recidivism and costs*. Portland OR: NPC Research.

Fomby, T.B., & Rangaprasad, V. (2002). *Divert Court of Dallas County: Cost-benefit analysis*. Dallas, TX: Southern Methodist University, Department of Economics.

Gottfredson, D.C., Najaka, S.S. & Kearley, B. (2003). Effectiveness of drug treatment courts: Evidence from a randomized trial. *Criminology & Public Policy*, *2*(2):171–196.

Government Accountability Office. (2005). *Adult drug courts: Evidence indicates recidivism reductions and mixed results for other outcomes.* Washington, DC: Author.

Kelly, J.F., & White, W.L., eds. (2011) *Addiction Recovery Management: Theory, Research and Practice.* New York: Humana Press.

Longshore, D.L., Turner, S., Wenzel, S.L., Morral, A.R., Harrell, A., McBride, D., Deschenes, E., & Iguchi, M.Y. (2001). Drug courts: A conceptual framework. *Journal of Drug Issues, 31*(1), 7–26.

Lowenkamp, C.T., Holsinger, A.M., & Latessa, E.J. (2005). Are drug courts effective? A meta-analytic review.

Journal of Community Corrections, 15(1), 5–11.

Mackin, J.R., Carey, S.M., Finigan, M.W., Lucas, L.M., Lambarth, C.H., Waller, M.S., Herrera Allen, T., Weller, J.M., & Linhares, B. (2009). *Maryland problem-solving courts evaluation, phase III: Integration of results from process, outcome, and cost studies conducted 2007–2009*. Portland, OR: NPC Research.

Marchand, G., Waller, M.S., & Carey, S.M. (2006a). *Kalamazoo County (MI) Adult drug treatment court outcome and cost evaluation*. Portland, OR: NPC Research.

Marchand, G., Waller, M.S., & Carey, S.M. (2006b). *Barry County (MI) Adult Drug Court outcome and cost evaluation.* Portland, OR: NPC Research.

Marlowe, D.B., Festinger, D.S., Dugosh, K.L., Lee, P.A., & Benasutti, K.M. (2007). Adapting judicial supervision to the risk level of drug offenders: Discharge and 6-month outcomes from a prospective matching study. *Drug and Alcohol Dependence*, *88*(Suppl.1), S4–S13.

Marlowe, D.B., Festinger, D.S., Lee, P.A., Dugosh, K.L., & Benasutti, K.M. (2006). Matching judicial supervision to client risk status in drug court. *Crime and Delinquency*, *52*(1), 52–76.

McKean, J., & Warren-Gordon, K. (2011). Racial Differences in Graduation Rates from Adult Drug Treatment Courts. *Journal of Ethnicity in Criminal Justice*, *9*(1), 41–55.

National Association of Drug Court Professionals. (1997). *Defining drug courts: The key components* (NCJ Publication No. 165478). Washington, DC: U.S. Department of Justice, Bureau of Justice Assistance.

Rempel, M., & Zweig, R. (2011, July). *Findings and implications of NIJ's Multisite Adult Drug Court Evaluation (MADCE).* Presented at the National Association of Drug Court Professionals 17th Annual Training Conference, Washington, DC.

Saum, C.A. & Hiller, M.L. (2008). Should violent offenders be excluded from Drug Court participation: An examination of the recidivism of violent and nonviolent Drug Court participants. *Criminal Justice Review, 33*(3), 291–307.

Saum, C.A., Scarpitti, F.R., & Robbins, C.A. (2001). Violent Offenders in Drug Court. *Journal of Drug Issues, 31*(1), 107–128.

Shaffer, D.K. (2006). *Reconsidering Drug Court effectiveness: A meta-analytic review*. Las Vegas: University of Nevada, Department of Criminal Justice.

Shannon M Carey, *PhD, is executive vice president and senior research associate at NPC Research. Her research has focused on criminal justice and substance abuse, particularly Drug Courts and cost analyses. Dr. Carey has been involved in evaluations of over 150 adult, juvenile, DWI, reentry, and family treatment Drug Courts nationally. She has also led the efforts to create online tools that Drug Courts can use to determine their own costs and benefits.*

Juliette R. Mackin, *PhD, executive vice president and senior research associate at NPC Research, has worked in the areas of juvenile and adult Drug Courts, juvenile crime prevention, adolescent and adult substance use or abuse, strengths-based approaches to service delivery, child abuse and neglect prevention and treatment, early childhood behavioral health, and human services coordination. Dr. Mackin has helped develop, validate, and implement risk assessment tools in use statewide in Oregon and a strength-based assessment tool used in Alaska.*

Michael W. Finigan, *PhD, is president and founder of NPC Research, located in Portland, Oregon. NPC Research, founded in 1990, was created as a network of skilled professionals to produce research designed to aid public policy makers in making research-based decisions. The focus of Dr. Finigan's work is examining criminal justice issues along with substance abuse and mental health issues for both adolescents and adults.*

Direct correspondence to Shannon Carey at NPC Research, 5100 SW Macadam Avenue, Suite 575, Portland, OR 97239. carey@npcresearch.com

DRUG COURT POLICIES AND PRACTICES: HOW PROGRAM IMPLEMENTATION AFFECTS OFFENDER SUBSTANCE USE AND CRIMINAL BEHAVIOR OUTCOMES

Janine M. Zweig — Christine Lindquist
P. Mitchell Downey — John K. Roman — Shelli B. Rossman

[4] Adult Drug Court Rankings—*A sample of 23 adult Drug Courts were ranked by their ability to reduce substance use and criminal behavior.*

[5] Drug Court Practices and Criminal Behavior—*Drug Courts that prevented more criminal acts had high leverage over their participants, medium predictability of sanctions, positive judicial attributes, and admitted participants at the same point in the criminal justice process (i.e., all pre-plea or post-plea).*

[6] Drug Court Practices and Substance Use Outcomes—*Drug Courts that prevented more drug use had medium predictability of sanctions, participant populations that entered post-plea, and positive judicial attributes.*

[7] High-Performance Drug Courts—*The most effective Drug Courts created synergistic effects by implementing multiple best practices.*

THE JUSTICE POLICY CENTER at the Urban Institute, RTI International (RTI), and the Center for Court Innovation (CCI) conducted the Multisite Adult Drug Court Evaluation (MADCE)—a five-year study of adult Drug Courts funded by the National Institute of Justice. In addition to examining whether Drug Courts work to reduce drug use and crime, another goal of the MADCE was to explain *how* Drug Courts work by studying key program policies and practices that lead to more successful outcomes for participants. In this report, we identify variations in policies and practices across Drug Courts and determine whether these variations influenced program effectiveness.

In 1997, the Bureau of Justice Assistance (BJA) promulgated ten key components of Drug Courts. In part, these components recommend that Drug Courts monitor abstinence through frequent alcohol and drug testing, use coordinated strategies to respond to participants' compliance with sanctions and incentives, and provide ongoing judicial interaction with each Drug Court participant. Although the ten key components are consistently recommended as central to the Drug Court model, many have not been subjected to empirical investigation. When Drug Court programs have been evaluated, much of the previous literature focused on participant-level experiences rather than on court-level practices. However, the receipt and amount of Drug Court services correlates highly with individual outcomes. That is, Drug Courts routinely increase the amount of services they provide to participants in direct response to participants' infractions or other behaviors.

For this reason, this article focuses on the effectiveness of court-level practices. Few previous studies focused on court-level policies and many of those examined the effectiveness of specific Drug Court practices, primarily court appearances, treatment, and sanctions. In brief, although most Drug Courts require regular status hearings for program participants, requirements pertaining to the frequency of status hearings vary across courts. In a series of related studies, researchers were able to compare the impact of twice-monthly versus as-needed status hearings (Festinger et al., 2002; Marlowe et al., 2003; Marlowe, Festinger, & Lee, 2004; Marlowe et al., 2005). Overall, little support was found for the relationship between frequency of judicial status hearings and drug use or recidivism with the exception of two subgroups—those with a history of substance abuse treatment and those with antisocial personality disorder (ASPD)—who benefited from twice-monthly status hearings. Beyond the frequency of judicial status hearings, Finigan, Carey, and Cox (2007) examined whether judges differed in their success in reducing recidivism among Drug Court participants and whether they improved with experience. They found that all judges exhibited fewer rearrests for Drug Court participants than for comparison cases, and judges who had more than

one rotation on the bench achieved better outcomes during their second rotation.

The provision of substance abuse treatment is a major component of most Drug Courts and key to the program model (BJA, 1997). Harrell, Cavanagh, and Roman (2000) explored treatment as a court-level practice in an experimental study in which drug felony defendants were randomly assigned to one of three court dockets (sanctions, treatment, and standard[1]). After random assignment, defendants in the sanctions and treatment dockets who failed two drug tests while on pretrial release—and were therefore considered program eligible—were offered the intervention services available within their respective dockets. Outcomes were compared for program-eligible defendants in all three dockets, with some analyses restricted to the subset of defendants who agreed to participate in the intervention services available within the sanctions and treatment dockets.

Results indicated that program-eligible defendants within the treatment docket were more likely to test drug-free in the month prior to sentencing and had a smaller percentage of positive drug tests than program-eligible defendants in the standard docket. Reductions in drug use were even more significant among program participants in the treatment docket (i.e., those who agreed to receive the comprehensive treatment available). Being eligible for the treatment program had no impact on self-reported drug use or the likelihood of arrest in the year after sentencing, although program participants in the treatment docket did have fewer arrests for drug offenses.

Another key component of Drug Courts is using a coordinated strategy for governing participant compliance and noncompliance (BJA, 1997). Typically, Drug Courts respond to participant behavior with sanctions for noncompliance and incentives for compliance. Re-

[1] For the purposes of this study, the dockets were defined as follows: The sanctions docket had clearly defined penalties that were applied swiftly to participants for failing drug tests and encouraged entering treatment. The treatment docket offered comprehensive treatment programs designed to provide participants with skills, self-esteem, and community resources to help them leave the criminal life. While the sanctions and treatment dockets offered new intervention services, the standard docket handled drug cases in a routine manner (Harrell, Cavanagh, & Roman, 2000).

lated to this, results for the sanctions docket in the Harrell, Cavanagh, and Roman (1998) study included the following: program-eligible defendants in the sanctions docket who agreed to receive the intervention services were more likely to test drug-free in the month before sentencing (and had a lower percentage of positive drug tests) and were less likely to be arrested in the year after sentencing than program-eligible defendants in the standard docket.

Current Study

Although Drug Courts share several common elements, substantial variation has been documented in how policies and practices are implemented across Drug Courts (Carey, Finigan, & Pukstas, 2008; Rempel et al., 2003). The purpose of the current study is to identify how implementation of Drug Court policies and practices varies and which strategies are most effective in reducing and preventing criminal behavior and drug use. The study included a number of Drug Courts ($n = 23$) selected to reflect variations in key policies and practices. We chose ten specific policies and practices to explore that might relate to the ability to prevent future crime and substance use. Specifically, we examined the influence of leverage, predictability of sanctions, adherence to treatment best practices, drug testing, case management, judicial status hearings, point of entry into the program, multidisciplinary decision making among the Drug Court team, positive judicial attributes, and judicial interaction.

METHODS

Design

The MADCE was a longitudinal, quasi-experimental design consisting of twenty-three Drug Courts and six comparison sites. The study was designed to compare Drug Court participants to offenders with similar drug use, criminal histories, and psychosocial profiles in jurisdictions that do not offer Drug Courts. We conducted an extensive site-selection process to identify Drug Courts and comparison sites that reflected substantial variation in the implementation of various Drug Court polices, such as differences in sanction and supervi-

sion policies. To identify sites, we first administered the adult Drug Court survey as a Web-based instrument between February and June 2004 (see Zweig, Rossman, & Roman, 2011). A total of 380 Drug Courts completed the survey, representing a 64% response rate of the 593 Drug Courts identified across the U.S. that met the eligibility requirements of primarily serving adults and being in operation for at least one year at that time. Although national in scope, the sample was not nationally representative. Nonetheless, it provided an important foundation for understanding Drug Court programs throughout the country.

Using data from the survey, we chose twenty-three Drug Courts located in seven geographic clusters and then identified six comparison jurisdictions in similar locations.[2] The comparison sites included several alternative models for handling drug-involved offenders, representing the diverse activities employed in jurisdictions that had not implemented Drug Courts.[3] Notably, some comparison sites mandated offenders to community-based treatment, but without other components of the Drug Court model; other comparison sites involved standard probation.

Procedure

The data for the current analyses came from three sources. The first source of data was the Web-based adult Drug Court survey identified above. Drug Court staff completed the survey, answering general information questions about the Drug Court, program structure and operations, treatment and drug testing, and courtroom practices.

The second source of data was a process evaluation that included multiple contacts with Drug Courts ultimately included in the study.

[2] More detail about recruiting sites and selection criteria can be found in Rossman et al. (2011). Altogether, MADCE includes 29 sites in eight states (Florida, Georgia, Illinois, New York, North Carolina, Pennsylvania, South Carolina, and Washington).

[3] Comparison sites included: Pierce County, WA Breaking the Cycle program; Human Services Associates TASC in Florida; Stewart-Marchman-ACT Behavioral Health Care, Florida; Illinois TASC; and North Carolina probation (NC is divided into two judicial districts and, therefore, we divided the comparison participants similarly, representing two comparison sites).

In 2004, phone interviews about court operations were conducted with potential Drug Courts during site selection. The process evaluation assessed each Drug Court's adherence to best practices related to leverage, sanctioning, and treatment in order to secure a varied sample of Drug Courts. In 2006 after the impact study began, evaluation team members visited the twenty-three Drug Courts to interview stakeholders and conduct observations of staffing meetings and court hearings. Program structure and management, operations, treatment, drug testing, and courtroom practices were assessed through open-ended questions and observations.

The third source of data was in-person interviews with offenders across the twenty-nine Drug Court and comparison sites conducted at three intervals: (1) when participants enrolled in the Drug Courts or comparison sites to provide a baseline, (2) six months after the baseline interview, and (3) eighteen months after baseline. Baseline enrollment took place during a 16-month period from March 2005 through June 2006. During that time, Drug Courts and comparison sites identified people enrolling in or entering their systems. These individuals were recruited by trained field interviewers who conducted informed consent procedures. The interviews with study participants lasted 1.5–2 hours and covered topics such as background characteristics, attitudes and perceptions (e.g., perceived legal pressure, motivations, perceptions of court, and judicial fairness), in-program behavior (e.g., receipt of treatment and other services), and outcomes (criminal behavior, drug use, and other measures of personal functioning).

Offender Sample

We enrolled 72% of eligible study participants at baseline, for a total initial sample of 1,781 offenders. Subsequently, 86% of those individuals completed 6-month interviews, and 83% completed 18-month interviews. The majority of the sample was male (70%), and the average age of study participants was 33.7 years with the Drug Court group being significantly younger than the comparison group. More than half the sample was white (55%), one-third was black/African–American (33%), 6% was Hispanic/Latino, and 6% fell

into other categories including multiracial. Just over one-third (35%) of the sample reported having a high school diploma or GED equivalency diploma; one-quarter (25%) reported having some college-level education; and 41% of the sample had less than a high school education. Slightly more than one-third of sample members (36%) were working at the time of baseline. Sixty-two percent of the sample had never been married; 11% were married; and 27% were divorced, separated, or widowed at the time of the baseline interview. Half reported having children younger than 18 years of age.

Study members, on average, reported that they began using drugs at the age of 13.6 years and had been using drugs for an average of 20 years. In the six months before they entered the program, 81% of the sample used some form of illicit drug or alcohol, and 57% used drugs other than alcohol or marijuana (including amphetamines, cocaine, heroin, hallucinogens, and nonprescribed medications). The study grouped participants by their primary substance of abuse, because many were polysubstance users. The subgroups were alcohol; marijuana; amphetamines (including methamphetamine); cocaine (powder and crack cocaine); and a subgroup hereafter referred to as *other drugs* (heroin, hallucinogens, and nonprescribed medications).

More participants in the Drug Court group reported using drugs than in the comparison group. They also reported significantly more days of use. On average, participants in both groups used drugs or alcohol 12.9 days per month, or 7.4 days per month when alcohol and marijuana were excluded.

Significantly more individuals in the comparison group had prior arrests before the one that brought them into the study (92% of the comparison group versus 86% of the Drug Court group). Of those arrested, comparison participants reported having more prior arrests (about eleven) than the Drug Court group (about eight).[4]

[4] Although we employed strategies to recruit comparable offenders for both the treatment and comparison samples, some differences existed, and although we retained in the study the majority of offenders at 6 and 18 months, some differences existed between those who remained in the study and those who did not. We employed two statistical corrections to correct for baseline differences between the Drug Court

Analytic Strategy

We employed complementary approaches using quantitative and qualitative methodologies to evaluate the effectiveness of Drug Court policies and practices. First, we tested the effectiveness of particular practices using a traditional quantitative approach, hierarchical modeling. Generally, Drug Court participants are repeatedly exposed to the same judge; thus, it is easy to confuse the effect of the judge on outcomes with the effect of the court. Hierarchical models parse out individual effects on outcomes from court effects. This article presents findings for each policy and practice using hierarchical analysis of variance with follow-up Tukey tests of group comparisons.[5]

Second, we employed an innovative approach that ranked Drug Courts' levels of effectiveness at preventing drug use and crime. We created a score for each individual that was the difference between the person's expected outcome and his or her observed outcome in Drug Court. Thus, we predicted what participants' drug use and criminal activities would have been without Drug Court and subtracted the observed outcomes from the predicted outcomes.[6] For example, a Drug Court participant's actual observed outcome may have been two days of drug use per month. But, the same person's predicted outcome had they not been in Drug Court might have been ten days of drug use per month. Thus, this person's score on number of days of drug use prevented per month would be eight days.[7]

---

and comparison samples and between retained and attrited cases in the two follow-up interviews. More details can be found in Rempel and Farole (2011).

[5] Further details on why we chose this statistical analysis can be found in Zweig and colleagues (2011).

[6] We estimated drug use and criminal activity outcomes for the comparison group based on variables that predict such activities (e.g., criminal history at baseline, substance use history at baseline, etc.). Then, estimated coefficients from the comparison group were applied to Drug Court participants' characteristics (i.e., their values on variables that predict substance use and criminal activity) to determine the expected behaviors for each individual had they not been in the Drug Court program.

[7] Further details on how the study scored outcomes can be found in Zweig and colleagues (2011).

We then ranked Drug Courts based on the average performance of their participants. Overall, Drug Courts as a whole prevented 1.7 crimes per month on average, but this ranged widely ($SD = 16$, $r = -264–32$). Also, Drug Courts as a whole prevented 1.6 days of drug use per month on average, but this, too, ranged widely ($SD = 7$, $r = -33–37$). Positive average values for the Drug Courts indicated that participants did better as a result of being in Drug Court, whereas negative values indicated participants did worse than expected. Drug Courts were ranked based on two outcomes: days of drug use prevented and number of criminal activities prevented. Courts were ranked in general and then by particular subgroups of participants. [8]

Once the court rankings were created for the two outcomes, we assigned codes to each Drug Court that characterized the way they implemented particular policies and practices. From this, we identified patterns within effective Drug Courts and top–performing Drug Courts in how they implemented policies and practices and compared these with lower-performing Drug Courts.

RESULTS

Court Rankings

To determine whether the effect of Drug Court practices varied across participants, we created thirty-one subgroups based on participant attributes as self-described in the baseline interview. We chose these thirty-one measures for two reasons. First, the effectiveness of Drug Courts has been shown to vary based on some individual characteristics, such as participants' substance use and criminal histories. Second, we identified individual characteristics that seemed related to substance use and criminal behavior even if they had not been studied as part of a previous Drug Court evaluation. The thirty-one subgroups for which rankings were created reflect three broad categories:

- *Background Characteristics*—Age 30 and older or under age 30; male or female; in an intimate relationship or not; having features

[8] Further details on how rankings were developed can be found in Zweig and colleagues (2011).

of depression or not; and having antisocial personality disorder (ASPD) or not

- *Criminal History*—No prior arrests, one to four prior arrests, or more than four prior arrests; previous incarceration or no previous incarceration; and any relatives or friends with a conviction or no such relatives or friends
- *Substance Use Factors*—Age of first drug use 15 years or younger or over 15 years; any substance abuse treatment during the six months before baseline or no such treatment; any relatives or friends with drug problems or no such relatives or friends. Primary drug of choice: alcohol, marijuana, amphetamines, cocaine, or other drugs; drug use of any kind other than marijuana. Used aggression-inducing drugs (i.e., amphetamines, cocaine) at some point or never used aggression-inducing drugs

Court Rankings for Crimes Prevented

Table 1 describes the Drug Court rankings for crimes prevented. Throughout the rankings, each Drug Court is represented by a letter rather than court name to provide anonymity. Letters above the bold line in each column represent Drug Courts achieving participant outcomes better than the expected outcomes—that is, effective courts. Drug Courts below the bold line are those where participant outcomes were worse than the expected outcomes. In columns without a bold line, all courts achieved positive results.

In each column, bold letters represent the top three Drug Courts with the most participants meeting that subgroup criterion. To be eligible for such, a Drug Court had to have at least 50% of its population meeting that criterion. Columns with no bold letters indicate that no court in that subgroup met this criterion. In addition, a Drug Court had to provide five participants in the given subgroup to be included in that ranking. Therefore, some subgroups contain fewer courts because some courts did not meet this criterion. The general ranking indicates that eighteen of the twenty-three Drug Courts in our study effectively prevented crime for their participant populations. However, rankings varied substantially among the subgroups. On average, more Drug Courts performed positively for the following groups:

TABLE 1	COURT RANKINGS: SUBSTANCE USE PREVENTED AT 18 MONTHS										
	General Ranking	Age 30 and Over	Under Age 30	Male	Female	In Intimate Relationship	Not in Intimate Relationship	Features of Depression	No Features of Depression	Features of ASPD[1]	No Features of ASPD
1	W	**W**	Q	Q	W	**Q**	D	E	T	Q	W
2	Q	**S**	M	W	S	W	S	R	E	W	L
3	S	**G**	G	G	Q	G	W	A	//	G	S
4	G	Q	L	**L**	I	T	I	//	//	D	**G**
5	L	L	D	D	V	V	M	//	//	S	Q
6	D	V	V	B	M	M	**L**	//	//	M	V
7	M	D	T	M	T	S	V	//	//	V	D
8	V	B	S	S	U	N	K	//	//	L	M
9	T	R	U	V	G	L	G	//	//	T	N
10	N	N	K	K	O	D	B	//	//	R	**I**
11	I	I	I	R	R	O	**R**	//	//	I	B
12	R	M	N	N	C	R	N	//	//	N	K
13	B	T	O	T	K	**I**	T	//	//	O	T
14	K	K	R	E	E	B	E	//	//	B	E
15	O	O	E	I	B	E	J	//	//	K	U
16	E	J	B	O	**P**	K	O	//	//	J	O
17	F	E	J	**J**	A	A	C	//	//	E	R
18	J	A	**P**	F	//	J	P	//	//	C	P
19	C	C	C	C	//	**U**	U	//	//	A	**F**
20	U	U	**H**	A	//	H	F	//	//	P	J
21	P	F	A	U	//	C	A	//	//	U	C
22	A	H	//	**H**	//	P	**H**	//	//	H	A
23	H	//	//	//	//	//	//	//	//	//	H

TABLE 1	COURT RANKINGS: SUBSTANCE USE PREVENTED AT 18 MONTHS											
	General Ranking	No Prior Arrests	1–4 Prior Arrests	More Than 4 Prior Arrests	Previous Incarceration	No Previous Incarceration	Relatives/Friends with a Conviction	No Relatives/Friends with a Conviction	First Drug Use Age 15 or Younger	First Drug Use Over Age 15	Substance Abuse Treatment Before Baseline	No Treatment Before Baseline
1	W	R	L	W	I	Q	W	T	G	W	I	**Q**
2	Q	S	D	G	W	S	**Q**	V	S	**Q**	**W**	G
3	S	Q	**M**	S	O	D	**S**	K	W	**D**	S	T
4	G	P	N	**L**	S	M	G	M	Q	L	**L**	S
5	L	D	V	M	Q	V	D	O	V	S	M	**D**
6	D	O	Q	V	T	G	**L**	P	L	M	G	V
7	M	A	T	T	K	W	V	I	I	T	K	L
8	V	H	K	**J**	R	F	**M**	B	M	G	N	U
9	T	J	C	B	V	**L**	R	H	N	V	O	M
10	N	K	U	I	M	**N**	I	C	R	K	E	B
11	I	T	S	K	E	U	E	A	T	B	**R**	N
12	R	//	G	R	C	T	T	E	O	C	H	R
13	B	//	I	E	A	B	**N**	J	B	N	A	K
14	K	//	B	O	U	K	B	R	E	R	P	O
15	O	//	E	**F**	//	R	J	//	K	I	B	E
16	E	//	O	U	//	I	K	//	**F**	O	C	J
17	F	//	R	C	//	E	O	//	A	E	J	**F**
18	J	//	A	A	//	O	C	//	**P**	**J**	T	**C**
19	C	//	P	P	//	**J**	F	//	U	U	U	I
20	U	//	J	H	//	A	A	//	C	A	//	A
21	P	//	H	//	//	C	P	//	**H**	P	//	P
22	A	//	//	//	//	P	U	//	J	H	//	H
23	H	//	//	//	//	H	H	//	//	//	//	//

TABLE 1	COURT RANKINGS: SUBSTANCE USE PREVENTED AT 18 MONTHS										
				Primary Drug of Choice							
	General Ranking	Relatives/ Friends with Drug Problems	No Relatives/Friends with Drug Problems	Alcohol	Marijuana	Amphetamines	Cocaine	Other Drugs[2]	Other Than Marijuana	Tried Aggression Drugs[3]	Never Tried Aggression Drugs
1	W	Q	T	M	S	**V**	Q	M	Q	Q	A
2	Q	W	F	I	T	U	S	K	**M**	W	I
3	S	S	O	G	Q	W	M	T	G	S	O
4	G	D	P	L	G	S	W	E	W	G	K
5	L	G	C	**N**	B	T	K	R	V	**D**	**P**
6	D	**L**	I	C	K	D	R	O	**D**	L	E
7	M	**M**	K	J	V	R	L	S	S	M	C
8	V	V	H	A	O	//	E	P	I	**V**	J
9	T	E	R	T	M	//	J	//	L	N	//
10	N	I	A	K	R	//	I	//	**N**	T	//
11	I	**N**	E	//	I	//	V	//	E	E	//
12	R	T	J	//	**P**	//	B	//	R	I	//
13	B	R	//	//	E	//	T	//	T	K	//
14	K	K	//	//	C	//	O	//	K	B	//
15	O	B	//	//	A	//	A	//	J	**R**	//
16	E	J	//	//	J	//	C	//	B	O	//
17	F	O	//	//	U	//	H	//	O	J	//
18	J	C	//	//	//	//	U	//	P	P	//
19	C	A	//	//	//	//	//	//	C	C	//
20	U	U	//	//	//	//	//	//	U	F	//
21	P	P	//	//	//	//	//	//	A	U	//
22	A	H	//	//	//	//	//	//	F	A	//
23	H	//	//	//	//	//	//	//	H	H	//

NOTES: (A) Courts below the black lines were ones where we predicted that participants' expected outcomes would be better than their actual outcomes. (B) Courts were not included in the ranking if they had fewer than five people meeting the category criterion (indicated by //). (C) Bold letters represent the top three Drug Courts for percentage of population meeting that criterion. No bold letter indicates that no Drug Court had over 50% of their population meeting that criterion.

[1]Antisocial personality disorder; [2]Heroin, hallucinogenics, & prescription drugs; [3]Amphetaines, cocaine

- People age 30 years and older compared with younger than 30 years
- Males compared with females
- People with one to four prior arrests compared with those with no prior arrests or with more than four prior arrests
- People with no previous incarceration compared with those who had been incarcerated before
- People with relatives or friends with a conviction compared with those with no such relatives or friends
- People whose age of first drug use was older than 15 years compared with those age 15 or younger
- People with relatives or friends with drug problems compared with those with no such relatives or friends

We also examined court success for participant subgroups characterized by primary drug of choice. Drug Courts were more effective at preventing crime for participants whose primary drugs of choice included alcohol, amphetamines, cocaine, and other drugs.

All Drug Courts were effective at preventing crime within the other drug subgroup. All Drug Courts but one had positive outcomes within the alcohol and amphetamine subgroups. Drug Courts were less effective at preventing crime within the marijuana subgroup. Of the seventeen Drug Courts serving participants whose primary drug of choice was marijuana, only nine were effective.

When looking across the columns of Table 1, the top performing Drug Courts appear effective across a range of participant types, although the exact placement of the courts in the rankings varies somewhat across subgroups. For example, Court S ranked third in the general ranking, second for participants age 30 years and older, and eighth for participants under age 30. In addition, although rankings varied by subgroup, a set of high-performing Drug Courts emerged—with the top courts largely remaining the same across subgroups—as did a set of low-performing courts. The top five Drug Courts in the general ranking were G, L, Q, S, and W. Four of these Drug Courts appeared routinely in the top five courts across subgroups (G was in the top five courts 15 times; Q and S, 19 times; and W, 18 times). The other court that appeared in the top five courts across subgroups was

Court D, ranked sixth in the general ranking and ranked in the top five in twelve subgroups.

Court Rankings for Substance Use Prevented

Table 2 shows the Drug Court rankings for days of substance use prevented. According to the general ranking, twenty-two of the twenty-three Drug Courts in our study effectively prevented future substance use for their participant populations overall. Thus, more Drug Courts in the MADCE were effective at preventing substance use than criminal behavior.

Again, subgroups varied substantially. On average, more courts performed positively in preventing substance use for the following groups:

- People age 30 years and older compared with younger than 30 years
- Males compared with females
- People who had not been incarcerated before compared with those who had
- People with relatives or friends with a conviction compared with those with no such relatives or friends
- People whose age of first drug use was 15 years or younger rather than older
- People who had no substance abuse treatment within six months before baseline compared with those who had some
- People with relatives or friends with drug problems compared with those with no such relatives or friends

The pattern of Drug Court effectiveness for substance use prevented was similar to that found for crimes prevented. Court performance varied based on the participants' primary drug of choice. Drug Courts effectively prevented crime when the participants' primary drugs of choice included alcohol, amphetamines, cocaine, and other drugs but were less effective at preventing crime among participants whose primary drug of choice was marijuana. Therefore, although not all Drug Courts were effective for their participants in the marijuana subgroup, more of these Drug Courts prevented substance use more effectively than they prevented crime.

TABLE 2	COURT RANKINGS: SUBSTANCE USE PREVENTED AT 18 MONTHS										
	General Ranking	Age 30 and Over	Under Age 30	Male	Female	In Intimate Relationship	Not in Intimate Relationship	Features of Depression	No Features of Depression	Features of ASPD[1]	No Features of ASPD
1	G	M	G	G	M	G	D	E	E	G	L
2	M	B	U	Q	W	**U**	I	R	T	D	U
3	Q	I	Q	U	S	M	M	A	//	Q	M
4	U	Q	D	M	U	**Q**	U	//	//	M	Q
5	I	L	M	V	I	**I**	S	//	//	U	**I**
6	D	N	S	I	Q	T	V	//	//	S	N
7	S	U	V	K	T	W	**L**	//	//	I	**G**
8	L	C	I	T	**P**	S	N	//	//	V	V
9	F	**G**	K	**L**	G	V	C	//	//	C	**F**
10	V	**S**	L	F	V	B	O	//	//	T	T
11	C	**W**	T	C	O	K	G	//	//	K	C
12	T	T	**P**	S	R	D	K	//	//	W	W
13	W	V	C	B	C	P	W	//	//	L	B
14	K	O	**H**	D	E	L	T	//	//	O	S
15	N	R	O	E	B	C	J	//	//	P	E
16	B	J	A	W	A	E	B	//	//	R	K
17	P	E	N	O	K	N	**R**	//	//	H	P
18	O	D	E	N	//	R	P	//	//	B	O
19	E	K	R	R	//	A	E	//	//	A	D
20	R	A	J	**J**	//	H	F	//	//	N	R
21	J	F	B	A	//	O	A	//	//	J	J
22	A	H	//	**H**	//	J	**H**	//	//	E	A
23	H	//	//	//	//	//	//	//	//	//	H

TABLE 2	COURT RANKINGS: SUBSTANCE USE PREVENTED AT 18 MONTHS											
	General Ranking	No Prior Arrests	1–4 Prior Arrests	More Than 4 Prior Arrests	Previous Incarceration	No Previous Incarceration	Relatives/Friends with a Conviction	No Relatives/Friends with a Conviction	First Drug Use Age 15 or Younger	First Drug Use Over Age 15	Substance Abuse Treatment Before Baseline	No Treatment Before Baseline
1	G	S	Q	G	I	U	G	T	U	G	I	U
2	M	D	U	U	O	Q	**Q**	V	M	L	C	G
3	Q	P	**M**	M	W	M	I	O	Q	**Q**	**L**	M
4	U	R	V	I	Q	F	**M**	I	G	M	S	**Q**
5	I	Q	C	**L**	M	G	U	B	I	I	M	T
6	D	J	K	P	T	S	**S**	C	S	W	G	**D**
7	S	H	L	T	K	D	D	P	V	S	**W**	V
8	L	A	T	S	C	V	C	K	**F**	T	E	B
9	F	O	D	K	S	I	**L**	A	C	**D**	N	S
10	V	T	S	V	R	**L**	V	E	T	U	P	**F**
11	C	K	N	W	E	C	T	R	W	C	K	**C**
12	T	//	G	A	V	T	W	J	L	K	O	I
13	W	//	B	**J**	U	**N**	K	H	K	V	U	K
14	K	//	I	C	A	K	F	//	**P**	B	**R**	R
15	N	//	O	B	//	P	E	//	A	N	T	L
16	B	//	E	E	//	B	B	//	O	R	H	J
17	P	//	P	**F**	//	O	J	//	E	O	A	O
18	O	//	R	O	//	E	R	//	B	P	J	P
19	E	//	A	R	//	W	**N**	//	R	E	B	E
20	R	//	J	H	//	R	P	//	**H**	**J**	//	A
21	J	//	H	//	//	A	O	//	//	A	//	H
22	A	//	//	//	//	**J**	A	//	//	H	//	//
23	H	//	//	//	//	H	H	//	//	//	//	//

TABLE 2	COURT RANKINGS: SUBSTANCE USE PREVENTED AT 18 MONTHS										
				Primary Drug of Choice							
	General Ranking	Relatives/ Friends with Drug Problems	No Relatives/Friends with Drug Problems	Alcohol	Marijuana	Amphetamines	Cocaine	Other Drugs[2]	Other Than Marijuana	Tried Aggression Drugs[3]	Never Tried Aggression Drugs
1	G	I	F	I	Q	**V**	U	M	G	G	I
2	M	Q	C	M	V	U	S	K	U	M	A
3	Q	G	T	C	S	S	Q	T	M	U	K
4	U	**M**	P	G	I	T	M	S	Q	Q	O
5	I	U	O	**N**	M	D	J	E	I	D	P
6	D	D	I	L	K	W	R	P	D	I	C
7	S	S	R	T	B	R	T	O	S	S	E
8	L	V	E	J	G	//	W	R	C	L	J
9	F	**L**	K	A	C	//	E	//	T	C	//
10	V	K	A	K	**P**	//	I	//	V	V	//
11	C	T	H	//	U	//	C	//	J	T	//
12	T	E	J	//	T	//	L	//	L	W	//
13	W	W	//	//	A	//	O	//	O	F	//
14	K	C	//	//	O	//	V	//	E	E	//
15	N	J	//	//	E	//	B	//	B	K	//
16	B	N	//	//	J	//	K	//	R	B	//
17	P	B	//	//	R	//	A	//	F	P	//
18	O	O	//	//	//	//	H	//	N	N	//
19	E	R	//	//	//	//	//	//	K	O	//
20	R	P	//	//	//	//	//	//	W	R	//
21	J	A	//	//	//	//	//	//	P	J	//
22	A	H	//	//	//	//	//	//	A	A	//
23	H	//	//	//	//	//	//	//	H	H	//

NOTES: (A) Courts below the black lines were ones where we predicted that participants' expected outcomes would be better than their actual outcomes. (B) Courts were not included in the ranking if they had fewer than five people meeting the category criterion (indicated by //). (C) Bold letters represent the top three Drug Courts for percentage of population meeting that criterion. No bold letter indicates that no Drug Court had over 50% of their population meeting that criterion.

[1]Antisocial personality disorder; [2]Heroin, hallucinogenics, & prescription drugs; [3]Amphetaines, cocaine

Although rankings shift somewhat for the substance abuse outcome as they did with the criminal behavior outcome, a set of high-performing Drug Courts emerged—with the top courts largely remaining the same across subgroups—as did a set of low-performing courts. The top five Drug Courts in the general ranking were G, I, M, Q, and U. These five appeared in the top five performing Drug Courts across subgroups the most (G was in the top five courts 14 times; I, 17 times; M, 24 times; Q, 19 times; and U, 18 times). Thus, we concluded that the top-performing Drug Courts at preventing substance use were the same for both their overall population served and specific participant types. In addition, note that two Drug Courts (G and Q) appeared in the top five for both the crime and substance abuse outcomes.

Drug Court Policies and Practices

Below are the results of the analyses for each of the ten policies and practices examined. First, we present how the policy or practice was measured and operationalized in this study. Then, we present findings from both the qualitative and quantitative analyses. For each item, we describe the results for the criminal behavior outcome followed by the substance use outcome.

Leverage

Leverage measures the coercive power of the Drug Court (Longshore et al., 2001). The commonly held consensus is that the more leverage the court has over an individual, the more likely that individual will comply with the Drug Court requirements and therefore succeed in the program. Data for the leverage measure were collected from telephone interviews conducted before the impact study. We operationalized leverage based on five factors that we scored and summed for an overall leverage score:

- An employee of the Drug Court conducted case management (2 points).
- Drug Court participants regularly participated in court hearings (2 points).

- The Drug Court had explicit consequences for dropping out or failing out (2 points).
- The Drug Court told the participant about the explicit consequences (1 point).
- The participant signed a contract which specified the explicit consequences (1 point).

Each Drug Court's leverage was classified as high (7–8 points; 11 courts total), medium (5–6 points; 6 courts total), or low (0–4 points; 6 courts total). We overlaid these classifications on the rankings, coding each Drug Court based on its implementation, and examined resulting patterns.[9]

The qualitative analysis for leverage showed that nearly all of the high-leverage Drug Courts effectively prevented crime. Additionally, many high-leverage Drug Courts clustered toward the top of the ranks, indicating that the highest-performing courts had high leverage and lower-performing courts had either low or medium leverage, though no medium-leverage court was ineffective.

The quantitative analysis revealed that high-leverage Drug Courts prevented significantly more crimes than low-leverage courts ($F = 4.15$, $p < .05$). No statistically significant differences were found between medium- and high-leverage Drug Courts or between low- and medium-leverage Drug Courts for preventing crime. High-leverage courts prevented an average of 4.1 crimes per month compared with 1.4 crimes prevented by low-leverage courts. Medium-leverage courts prevented 2.0 crimes per month.

For substance use, again, most of the high-leverage Drug Courts were effective. However, the clustering of high-leverage Drug Courts toward the top of the ranks for the crime outcome was less pronounced than for the substance use outcome. Low- and medium-leverage courts were distributed throughout the ranks of effective courts, but no medium-leverage courts were ineffective.

In terms of preventing substance use, we found marginally significant differences among Drug Courts with varying leverage ($F = 2.38$,

[9] The full documentation of the qualitative analysis and tables for this finding and all later findings can be found in Zweig and colleagues (2011).

$p < .10$). High-leverage courts prevented an average of 2.6 days of substance use per month, medium-leverage courts prevented 3.1 days, and low-leverage courts prevented 1.8 days.

Predictability of Sanctions

Predictability of sanctions measures the extent to which the Drug Court communicated to participants how and when they would be sanctioned. A coordinated sanction policy (BJA, 1997; Goldkamp, White, & Robinson, 2001) and the extent to which participants are aware of the policy, aware of consequences for noncompliance, able to predict when a sanction will occur, and able to predict what the sanction will be (Longshore et al., 2001) are believed to influence a participant's compliance with program requirements and, thereby, program success. We measured this concept during process evaluation telephone interviews and operationalized predictability of sanctions based on three factors:

- The Drug Court maintained an official schedule of sanctions (2 points).
- The Drug Court provided the official schedule of sanctions to the participant (2 points).
- The Drug Court always or almost always adhered to the official schedule of sanctions (2 points).

We scored and summed responses to quantify the predictability of the sanction policies. Each Drug Court was classified as high predictability (6 points; 9 courts total), medium predictability (3–5 points; 4 courts total), or low predictability (0–2 points; 10 courts total).

The qualitative analysis showed all but one of the medium-predictability courts effective, and many of the low-predictability courts were more successful than anticipated. The high-predictability courts were dispersed throughout the ranks of effective Drug Courts and clustered below the bold line in Tables 1 and 2.

The quantitative analysis revealed that, for the overall model, statistically significant differences existed among Drug Courts with varied predictability of sanctions ($F = 3.31$, $p < .05$). However, the follow-up Tukey tests of differences among groups failed to identify

which groups were significantly different from one another. This was likely because Tukey tests of comparisons between groups are a conservative method for identifying group differences. However, the means for each group indicated that the medium-predictability Drug Courts were the most effective at preventing future crimes (4.3 per month), followed by the low-predictability courts (3.9 per month), whereas the high-predictability courts prevented 1.8 crimes per month. Nearly all medium-predictability courts were effective, while courts with a high predictability of sanctions were generally ineffective.

For the substance use outcome, our qualitative analysis showed a similar pattern to the crime outcome. However, all of the medium-predictability Drug Courts were effective and clustered toward the top of the rankings, and low-predictability Drug Courts were dispersed throughout the rankings. Medium-predictability courts prevented significantly more days of substance use than high-predictability courts ($F = 4.32$, $p < .05$), an average of 4.1 days as compared with 2.0 days per month. Low-predictability courts prevented 2.7 days of substance use per month.

Point of Entry into Drug Court Program

Goldkamp and colleagues and Longshore and colleagues (2001) both identify the point in the criminal justice process at which participants enter the Drug Court program—either pre- or post-plea—as important to the Drug Court model. The point in the criminal justice process at which participants enter the Drug Court program may influence how well they perform and their ability to succeed. We asked program representatives where in the criminal justice process participants entered into the Drug Court program, and operationalized the concept as pre-plea entry (diversion strategies) and post-plea entry (in which convictions stood or were lessened after completion of the program). Drug Courts were classified as pre-plea (all participants entered as part of a diversion strategy; 7 courts), combination (courts where some participants entered the program pre-plea and some, post-plea; 6 courts), or post-plea (10 courts).

The qualitative analysis for preventing criminal acts showed that pre-plea Drug Courts and post-plea Drug Courts clustered toward the upper rankings across subgroups. Combination Drug Courts dispersed throughout the rankings, and most of the ineffective Drug Courts were combination courts. Thus, Drug Courts with one point of entry into their program performed more effectively and prevented more crime than those that allowed multiple points.

The quantitative analysis supports this claim. Statistically significant differences ($F = 7.42$, $p < .05$) existed between Drug Courts in which all the participants entered the program through pre-plea courts versus through combination courts. Also, significant differences existed between post-plea courts and combined courts. The average number of crimes prevented per month for pre-plea courts was 4.6, for post-plea courts was 3.6, and for combined courts was 0.8.

In the qualitative analysis for the substance use outcome, a similar pattern holds as for the crime outcome. Drug Courts that had one point of entry into their program prevented more substance use. Drug Courts with participants who came in post-plea prevented significantly more days of drug use per month (3.0 days) than combined courts (1.7 days; $F = 3.88$, $p < .05$). Pre-plea courts prevented an average of 2.9 days of drug use per month.

Positive Judicial Attributes

Goldkamp and colleagues and Longshore and colleagues (2001) include courtroom dynamics and interactions with judges as important factors of the Drug Court experience for program participants. The idea was that participants developed a relationship with the judge, and the extent to which participants saw this relationship as constructive contributed to their program compliance and success. MADCE quantified this by measuring positive judicial attributes. The site-visit team observed, measured, and scored the judge's actions and demeanor toward the participants during Drug Court proceedings.

The team assigned the Drug Court judge a value of 1 to 5 for respectfulness, fairness, attentiveness, enthusiasm, consistency/predictability, caring, and knowledge. After summing the ratings for

each judge, the team created three approximately equal performance categories for the Drug Courts: high (30 points or more; 8 courts), medium (27–29 points; 7 courts), and low (0–26 points; 7 courts).

This qualitative coding showed that, across several subgroups, Drug Courts with high and medium scores for positive judicial attributes clustered in the upper rankings. Those with low scores clustered toward the bottom with a few exceptions. Drug Courts with high and medium scores on positive judicial attributes were more likely to be among top-performing courts than among ineffective courts.

The results of the quantitative analysis revealed statistically significant differences among Drug Courts depending on how they were coded for positive judicial attributes ($F = 5.81$, $p < .05$). Significant differences existed between Drug Courts with high scores on positive judicial attributes and courts with low scores. Also, significant differences existed between courts with medium scores and courts with low scores. Drug Courts with high scores for positive judicial attributes prevented 3.6 crimes per month, courts with medium scores prevented 4.2, and courts with low scores, 0.7 crimes per month.

A similar pattern holds for preventing substance use based on judicial attributes. In terms of the quantitative analysis, Drug Courts with high scores on positive judicial attributes prevented significantly more days of drug use per month (3.2 days) than courts with low scores (1.9 days; $F = 3.16$, $p < .05$). Courts with medium scores prevented 2.6 days of drug use.

Case Management

All Drug Courts in the MADCE sample had case managers to oversee participant progress and assist in accessing necessary services. We wanted to determine if the frequency of contact with case managers related to program success. A question on the Adult Drug Court Survey (Zweig, Rossman, & Roman, 2011) inquired about the frequency at which participants saw case managers during phase 1 (the first two months) of the program. Each Drug Court was classified as high frequency (more than one contact per week; 6 courts total),

medium frequency (one contact per week; 13 courts total), or low frequency (less than one contact per week or not at all; 4 courts total).

Drug Court rankings for preventing criminal acts based on frequency of case management during the first two months of the program showed no strong pattern, but some patterns emerged. Most of the high-frequency Drug Courts in which participants met with their case managers more than once per week were effective. Medium-frequency Drug Courts were dispersed throughout the ranks, both above and below the bold line in Tables 1 and 2, and ranked in the top two courts in several subgroups. All but a couple of courts classified as low frequency were ineffective or lower-performing.

Although no clear patterns were identified based on the qualitative coding, the results of the quantitative analyses showed evidence of some relationships between frequency of case management and court effectiveness. In terms of preventing criminal acts, the model was marginally significant ($F = 2.84$, $p < .10$). Drug Courts with case managers who met with participants more than once per week prevented more criminal acts per month (4.3 acts) than did low-frequency courts (1.2 acts). Medium-frequency courts prevented 3.0 criminal acts per month.

As with the crime outcome, no clear pattern emerged for the Drug Court rankings regarding preventing substance use. Many of the Drug Courts where case managers met with participants more than once per week proved effective, as did all of the courts where participants met with case managers less than once per week or not at all. Drug Courts that had case managers meet with participants once per week were dispersed throughout the rankings.

The quantitative analysis testing prevention of substance use showed marginally significant differences among Drug Courts based upon the frequency of case management meetings ($F = 2.50$, $p < .10$). Drug Courts where case management meetings occurred more than once per week prevented an average of 3.0 days of substance use per month; courts with case management meetings one time per week prevented an average of 2.1 days of substance use; and courts with less than one meeting per week or no meetings prevented 3.2 days of

use. Notably, Drug Courts that had infrequent case management meetings tended to rely on treatment providers to do this work. When treatment providers were the case managers, they were more likely than other providers to see participants more than once weekly (Zweig et al., 2011). This might explain why the Drug Courts with both high and low frequency of case management meetings prevented about the same numbers of days of drug use.

Other Court Policies and Practices

The remaining five Drug Court policies and practices did not relate to offender outcomes. However, because most of the Drug Courts included in MADCE followed a high standard with respect to these policies and practices, insufficient variation made empirically establishing their effectiveness difficult. Below are results summaries for these practices.

Adherence to Treatment Best Practices—The provision of treatment is considered a core aspect of the Drug Court model (BJA, 1997). To be included in the MADCE, the Drug Court had to provide some type of substance abuse treatment to their program participants. To understand the quality of the treatment, we asked a series of questions during the initial telephone interviews with potential sites. These questions did not cover a full set of best practices for treatment provision but did capture a picture of the treatment being provided. Thus, we operationalized adherence to treatment best practices based on the following five factors:

- The treatment provided by the Drug Court was structured, that is, the Drug Court followed a treatment program manual (2 points).
- A clinical assessment was conducted for treatment needs (1 point).
- Individualized treatment plans were developed for each participant (1 point).
- Individualized treatment plans were used to make referrals (1 point).
- Individualized treatment plans were updated periodically (1 point).

The responses were scored and summed for an overall score of adherence to best practices and each Drug Court was classified as high (6 points; 15 courts total), medium (4–5 points; 6 courts total), or low (0–3 points; 2 courts total).

After scoring Drug Courts for the above ratings, no clear patterns emerged for the crime or drug outcomes during the qualitative analysis. Similarly, we found no statistically significant differences between low-, medium-, and high-adherence courts for crimes prevented and substance use prevented during the quantitative analysis. Not enough variation existed among Drug Courts to fully examine this practice because most courts adhered to treatment best practices at either medium or high levels, based on very limited information rating the quality of the treatment provided.

Drug Testing—Routine drug testing to examine compliance with drug-use requirements is important to Drug Courts (BJA, 1997). During the Adult Drug Court Survey (Zweig, Rossman, & Roman, 2011), Drug Courts were asked about the frequency of drug testing during phase 1 (or first two months) of the program and classified as high frequency (more than once per week; 19 courts total), medium (once per week; 4 courts total), or low (less than once per week or not at all; 0 courts).

The results for frequency of drug testing during the first two months of the program mirror the results for adherence to treatment best practices. After coding court rankings for frequency of drug testing, most of which ranked as high frequency, neither qualitative nor quantitative analyses revealed any clear or statistically significant patterns for the crime or drug-use outcomes. Not enough variation exists between Drug Courts to fully examine this practice.

Judicial Status Hearings—Regular contact between Drug Court participants and the Drug Court judge is considered an essential aspect of the Drug Court model (BJA, 1997; Longshore et al., 2001), and the contact between participant and judge is thought to be an essential catalyst to program compliance and success. The practice was measured through questions asked during process evaluation site visits and operationalized as average frequency of judicial status hear-

ings each month. Each Drug Court was classified as high (four times per month; 16 courts total), medium (twice per month; 4 courts total), or low (once per month; 1 court). Two Drug Courts were missing data on this variable.

The results for frequency of judicial status hearings mirror the results for the two previous low-variability practices. Most Drug Courts had high frequency of status hearings; thus, neither the qualitative nor quantitative analyses show differences in outcomes among Drug Courts based on frequency of such hearings.

Multidisciplinary Team Decision Making—The foundation of the Drug Court model includes an interdisciplinary team of interested parties comprising court staff, treatment staff, prosecutors, defense attorneys, etc. (BJA, 1997). The MADCE hypothesized that the extent to which team members participated in a collaborative manner—that is, the extent to which members attend and interact in court staffings and decisions about specific participants—may affect program outcomes. Thus, during site visits, we observed team member interactions during court staffing meetings.

We operationalized multidisciplinary team decision making by scoring the attendance and level of participation of the following stakeholders at Drug Court staffings: judges, prosecutors, defense attorneys, program coordinators, case managers, probation officers, treatment liaison staff, and other stakeholders. Scores of 1 to 5 were assigned to each stakeholder (with zero points assigned if the stakeholder did not attend), and the scores were summed to reflect overall participation from the stakeholders. Each Drug Court was classified as high (23–25 points; 8 courts), medium (18–22 points; 6 courts), or low (15–17 points; 6 courts). Three Drug Courts were not scored because of missing data.

The results of the qualitative analysis showed no clear patterns for high-, medium-, and low-rated Drug Courts, and the quantitative analyses indicated no statistically significant differences among courts for either preventing crime or substance use. Thus, multidisciplinary team decision making was not directly related to outcomes for participants in this study.

Judicial Interaction—In addition to positive judicial attributes, the MADCE team created a second measure to capture interaction between Drug Court participants and judges. During process evaluation site visits, the team observed Drug Court hearings and noted the frequency with which the judge engaged in interactive behaviors during the court session. For each case reviewed by the judge during the session, the site visit team documented whether the judge made regular eye contact with the defendant for most of the appearance, talked directly to the defendant as opposed to through the defendant's attorney, asked nonprobing questions (e.g., questions eliciting only yes, no, or one-word answers), asked probing questions, imparted instructions or advice, explained the consequences of future compliance (e.g., phase advancements, graduation), explained consequences of future noncompliance (e.g., jail or other legal consequences), allowed the defendant to ask questions or make statements.

For each of these eight actions, we created a variable reflecting whether the judge engaged in that action for more than 50% of his or her cases. Then, we counted the total number of actions that the judge regularly displayed (i.e., actions displayed for more than 50% of observed cases). Based upon these scores, the Drug Courts were assigned a value of low, medium, or high with the cut points selected to create a relatively even spread of courts across categories. Six courts were classified as having high judicial interaction (6 or more actions); seven courts were classified as having medium judicial interaction (4–5 actions); and seven courts were classified as low (0–3 actions).

The results of the qualitative analysis showed no clear patterns for high-, medium-, and low-rated Drug Courts, and the quantitative analyses indicated no statistically significant differences among courts for either preventing crime or substance use. Thus, judicial interaction did not directly relate to participant outcomes in this study.

DISCUSSION

This analysis examined how the relationship between variation in implementation of ten Drug Court policies and practices affects participant outcomes. Among the Drug Court policies and practices ex-

amined, four predicted court effectiveness: leverage, predictability of sanctions, the point in the criminal justice process at which participants enter the program, and positive judicial attributes. We found all four of these policies and practices effective at preventing crime, and all but leverage to be effective in preventing substance use (although this finding was marginally significant). More specifically, Drug Courts that prevented higher numbers of criminal acts per month had high leverage, medium predictability of sanctions, participant populations that enter at the same time point in the criminal justice process, and medium or high scores on positive judicial attributes. Drug Courts that prevented more days of drug use per month had medium predictability of sanctions, participant populations that enter at post-plea, and high scores on positive judicial attributes.

In addition, when Drug Courts implemented the combined practices in the ways found to be effective, a synergistic effect may have occurred such that they were among the top-performing Drug Courts (that is, courts able to prevent the most crimes and the most days of drug use for many participant subgroups). Table 3 identifies the court policies and practices of the top-performing Drug Courts with respect to the four components that emerged in our analyses. Recall that

TABLE 3	COURT POLICIES AND PRACTICES FOR TOP-PERFORMING COURTS							
Court Policy/ Practice	**Top Performers: Crime & Drug Use Prevention**		**Remaining 3 Top Performers: Crime Prevention**			**Remaining 3 Top Performers: Drug Use Prevention**		
	G	**Q**	**L**	**S**	**W**	**I**	**M**	**U**
Leverage	High	High	Med	High	High	Low	High	Med
Sanctions predictability	High	Med	High	Low	High	Low	Low	Med
Program Point of Entry	post-plea	post-plea	post-plea	pre-plea	pre-plea	post-plea	post-plea	pre-plea
Positive Judicial Attributes	High	High	Med	Med	Med	High	High	Low

two courts were in the top-five-ranked courts for both crime and drug use prevention—Courts G and Q. As shown in Table 3, Court Q implemented all four policies in the ways we found to be effective, and Court G implemented three of the four policies in those ways. The remaining three courts in the top five for crime prevention (L, S, and W) and the remaining three courts in the top five for substance use prevention (I, M, and U) all implemented at least two or three of the four policies in the ways that appeared to produce positive outcomes.

These top-performing Drug Courts seemed purposeful in the ways they implemented policies and practices described here as most effective. The combination of these practices implied that these Drug Courts did not simply implement such components randomly; they fit the practices together. They apparently differentiated participants according to risk, need, or circumstance, rather than trying to fit one model of the Drug Court program to all participants. Additionally, these Drug Courts appeared to have judges who understood the value of building relationships with participants in which the individuals felt respected and supported, perhaps inclining them toward more success.

Several of the policies and practices we examined here have not been previously examined in the literature. Specifically, no previous studies of which we were aware examined the differential effectiveness of programs based on their participants' stage of criminal justice system processing when they enter the program. In addition, although leverage has been hypothesized to be a critical factor for Drug Court success (Longshore et al., 2001), ours was the first study to empirically document that Drug Courts classified as having high levels of leverage were the most effective at reducing criminal behavior among their participants.

Other findings generated from these analyses build on previous court-level research. For example, Harrell and colleagues (2000) demonstrated that graduated sanctions (as a court-level characteristic) were more effective than standard dockets in reducing arrest and the number of offenses committed among program participants. We built on these findings by examining the predictability of sanctions as a court-level characteristic. Interestingly, although highly predictable

sanctioning practices are considered a cornerstone for developing a coordinated strategy governing Drug Court responses to participants' compliance (and are listed as one of the Drug Court key components), we did not find empirical support for this practice. Drug Courts classified as having medium predictability of sanctions were the most effective, which suggests that flexibility in responding to participants' performances may be desirable.

In addition, we found strong evidence that positive judicial attributes positively influenced participant performance. Previous studies have identified substantial variation in participant success among various Drug Court judges (Finigan, Carey, & Cox 2007). We found that Drug Courts with a judge with more positive attributes were better able to prevent criminal behavior and substance use.

Conclusions and Implications

This study[10] contributes to our understanding of how Drug Courts should implement practices to increase their effectiveness in preventing crime and drug use. First, the results suggest that Drug Courts with high leverage, medium predictability of sanctions, single points of entry into the program, and high positive judicial attributes are better at preventing criminal activities and substance use. More specifically, Drug Courts with high leverage regularly monitor participants through Drug Court case managers and judicial hearings. They also have explicit known consequences for failure in the program that participants acknowledge in signed contracts. These practices might focus a participant's attention on the fact that the alternative to Drug Court is not desirable and that he or she is being monitored closely, making the consequence of noncompliance and the alternative for failure very real. These findings also imply that Drug Courts with low leverage (those courts which participants perceive as not having obvious consequences for failure or as not closely monitoring program compliance) are unable to succeed in preventing crime.

[10] Limitations to this analysis and how we addressed them can be found in Zweig et al., (2011).

Second, Drug Courts with medium predictability of sanctions have sanction schedules that participants may or may not know about and that may or may not always be followed. These courts have a coordinated sanctioning strategy, yet exercise some flexibility in its implementation in a way that apparently matters to participants. Perhaps participants perceive flexibility in implementation of sanctions as more fair than those Drug Courts that strictly follow a schedule that does not take into account particular individuals or circumstances. While it seems clear that participants need to know that sanctions are a consequence of noncompliance in the program, sanctions that are rigidly set or perceived as unfair may actually frustrate participants or weaken their resolve to comply with program requirements. In addition, if programs with rigid, highly predictable sanctioning practices had been shown to be the most effective in this analysis, that finding would run counter to our other finding on positive judicial attributes. Programs with judges who treated participants fairly and respectfully achieved better success than programs without such judges. Perhaps rigid sanctioning practices and some features of positive judicial attributes do not easily coexist in a single Drug Court.

Third, Drug Courts with single points of entry into their program have participant populations that either all entered the program before they entered a plea (a diversion program) or all entered the program after their plea. These courts do not have a mix of participants who represent different stages of the criminal justice system process. Perhaps Drug Courts that have a singular focus of participant population might be better at tailoring their practices to meet the needs of a preadjudication or a postadjudication population. When a mixed population is in the program, Drug Courts may be less organized in their approach or may be uniformly implementing practices when such practices might not be appropriate for their clientele.

Fourth, Drug Courts that have high scores on positive judicial attributes are those courts in which judges demonstrate to defendants respect, fairness, attentiveness, enthusiasm, consistency and predictability, caring, and knowledge about the person's case and situation. Our courtroom observations of judicial attributes indicate that how the judge builds a relationship with participants, treats participants,

and behaves in the courtroom matters for participant outcomes. This finding once again underlines the role of therapeutic jurisprudence in problem-solving courts.

Fifth, although the study results focused on the practices that were most effective for the most subgroups, policy makers and practitioners can see the results by subgroups in Tables 1 and 2 and use the information to determine which policies and practices are effective for the subgroups they serve. We find that while the top-performing Drug Courts tend to be effective across subgroups, the specific practices that are most effective vary for different groups. This analysis builds on the limited previous research indicating that not all practices are equally effective across the population subgroups served by Drug Courts.[11] Clearly, more detailed analyses of what works for specific subgroups could be conducted based on the findings presented in this paper.

Finally, findings from this study lend themselves to other future research endeavors. Specifically, we examined each Drug Court policy and practice by itself. Future analysis and research might include looking more closely at different combinations of policies and practices in order to identify critical combinations that appear to account for most of the variability in program effectiveness.

This project and report were supported through Grant Number 2003-DC-BX-1001 from the National Institute of Justice, Office of Justice Programs, U.S. Department of Justice. Points of view in this document are those of the authors and do not necessarily represent the official position or policies of the U.S. Department of Justice, Urban Institute, or its trustees.

[11] For examples see Marlowe et al., 2003; Marlowe et al., 2005; Marlowe, Festinger, & Lee, 2004; and Festinger et al., 2002.

REFERENCES

Bureau of Justice Assistance. (1997). *Defining drug courts: The key components*. Washington, DC: U.S. Department of Justice. NCJ 205621.

Carey, S.M., Finigan, M.W., & Pukstas, K. (2008). *Exploring the key components of drug courts: A comparative study of 18 adult drug courts on practices, outcomes and costs.* NPC Research: Portland, OR.

Festinger, D.S., Marlowe, D.B., Lee, P.A., Kirby, K.C., Bovasso, G., & McLellan, A.T. (2002). Status hearings in drug court: When more is less and less is more. *Drug and Alcohol Dependence, 68*(2): 151–157.

Finigan, M.W., Carey, S.M., & Cox, A. (2007). *Impact of a mature drug court over 10 years of operation: Recidivism and costs*. Portland, OR: NPC Research.

Goldkamp, J.S., White, M.D., & Robinson, J.B. (2001). Do drug courts work? Getting inside the drug court black box. *Journal of Drug Issues, 31*(1): 27–72.

Harrell, A.V., Cavanagh, S., & Roman, J.K. (1998). Findings from the evaluation of the DC Superior Court Drug intervention program. Submitted to the National Institute of Justice. Washington, DC: The Urban Institute.

Harrell, A.V., Cavanagh, S., & Roman, J.K. (2000, April). Findings from the evaluation of the DC Superior Court Drug intervention program. *National Institute of Justice Research in Brief*. Washington, DC: U.S. Department of Justice.

Harrell, A., Cavanagh, S., & Roman, J. (2000). Findings from the evaluation of the DC Superior Court Drug intervention program. Submitted to the National Institute of Justice. Washington, DC: The Urban Institute.

Longshore, D.L., Turner, S., Wenzel, S.L., Morral, A.R., Harrell, A., McBride, D., Deschenes, E., & Iguchi, M.Y. (2001). Drug courts: A conceptual framework. *Journal of Drug Issues 31*(1): 12.

Marlowe, D.B., Festinger, D.S., Dugosh, K.L., & Lee, P.A. (2005). Are judicial status hearings a "key component" of drug court? Six and twelve month outcomes. *Drug and Alcohol Dependence*, 79.

Marlowe, D.B., Festinger, D.S., & Lee, P.A. (2004). The judge is a key component of drug court. *Drug Court Review, 4*(2):.1–34.

Marlowe, D.B., Festinger, D.S., Lee, P.A., Schepise, M.M., Hazzard, J.E.R., Merrill, J.C., Mulvaney, F.D., & McLellan, A.T. (2003). Are judicial status hearings a key component of drug court? During-treatment data from a randomized trial. *Criminal Justice & Behavior, 30,* 141–162.

Rempel, M., & Farole, D.J. (2011). Impact methodology: Analytic strategy for producing unbiased estimates of drug court impact. In S.B Rossman, J.K. Roman, J.M. Zweig, M. Rempel, & Lindquist C., H. (Eds), *Volume 4: The Multisite Adult Drug Court Evaluation: The impact of drug courts.* Washington, DC: Urban Institute.

Rempel, M., Fox-Kralstein, D., Cissner, A., Cohen, R., Labriola, M., Farole, D., Bader, A., & Magnani, M, (2003). *The New York state adult drug court evaluation: Policies, participants and impacts*. Center for Court Innovation. New York: Center for Court Innovations.

Rossman, S.B., Roman, J.K., Zweig, J.M., Lindquist, C.H, & Rempel, M. (2011). *Volume 1. The Multisite Adult Drug Court Evaluation: Study Over-*

view and Design. Washington, DC: Urban Institute.

Zweig, J.M., Lindquist, C.H., Downey, P.M., Roman, J.K., & Rossman, S.B. (2011). Chapter 7: Impacts of court policies and practices. In S.B. Rossman, J.K. Roman, J.M. Zweig, M. Rempel, & C. Lindquist (eds.). *The Multisite Adult Drug Court Evaluation: The Impact of Drug Courts: Vol. 4.* (pp. 121–213). Washington, DC: Urban Institute.

Zweig, J.M., Rossman, S.B., & Roman, J.K. (2011). *The Multisite Adult Drug Court Evaluation: What's Happening with drug courts? A portrait of adult drug courts in 2004: Vol. 2.* Washington, DC: Urban Institute.

Janine M. Zweig, *PhD, is a senior fellow with the Urban Institute's Justice Policy Center. Her research interests focus on vulnerable populations, such as offenders (including those with substance use issues), victims of violent crime (including intimate partner violence and sexual violence), and adolescents (including issues related to teen dating violence, substance use, and other health risk behaviors). Her work includes quantitative and qualitative methodologies, longitudinal studies, and multisite evaluations.*

Christine Lindquist, *PhD, is a senior research sociologist at RTI International. Her research interests and areas of expertise include prisoner reentry, families and incarceration, criminal justice approaches to substance abuse treatment, and violence against women (including workplace approaches for addressing intimate partner violence and sexual assault among university women) with a particular focus on evaluating the effectiveness of interventions in these areas.*

P. Mitchell Downey, *MA, is a research associate with the Urban Institute's Justice Policy Center. He has served as a quantitative analyst on a variety of projects addressing crime policy questions, including the Multisite Adult Drug Court Evaluation.*

John K. Roman, *PhD, is a senior fellow in the Justice Policy Center at the Urban Institute. His research focuses on evaluations of innovative crime control policies and justice programs.*

Shelli B. Rossman*, MA, is a senior fellow in the Justice Policy Center at the Urban Institute. Her research interests encompass criminal justice including reentry, problem-solving courts, community-based and correctional supervision, case management and comprehensive service delivery for offender populations, delinquency prevention and intervention, and victimization; public health focusing on substance abuse, HIV/AIDS, and reproductive health; and community safety.*

Direct correspondence to Janine Zweig at 2100 M St. NW, Washington, DC 20037. jzweig@urban.org

IMPROVING DRUG COURT OPERATIONS: NIATX ORGANIZATIONAL IMPROVEMENT MODEL

Harry K. Wexler — Mark Zehner — Gerald Melnick

[8] Applying NIATx to Drug Courts—*The NIATx (Network for the Improvement of Addiction Treatment) performance improvement model was used to increase client access to and engagement in Drug Court services.*

[9] Improving Participant Flow in Drug Courts—*The NIATx performance improvement model reduced wait times, increased admissions rates, and reduced no-show rates in nine Drug Courts.*

[10] Achieving Best Practices in Drug Courts—*The NIATx performance improvement model shows promise for helping Drug Courts implement organizational changes to adopt best practices.*

BY UNITING JUSTICE with rehabilitation for substance-abusing offenders, Drug Courts introduced an important innovation to the court system. The expansion of the adjudication role and allowing judges to divert offenders from prison created a new paradigm. The use of criminal justice and social services in tandem (i.e., a carrot and stick approach) is widely accepted, and the Drug Court movement has achieved considerable recognition; however, to succeed, Drug Courts have had to respond to the challenge of integrating disparate criminal justice and treatment system components, each with individual concerns and philosophies regarding public safety missions, individual rights, and personal growth. While the Drug Court movement has consistently reported positive outcomes (Marlowe, 2010), offering substance abuse treatment as an alternative to incarceration requires substantial integration and management of organizational processes for each Drug Court—administrative practices that create barriers to treatment, duplication of efforts, and long wait times for treatment.

Each Drug Court's success corresponds with how well it addresses these operational challenges.

This article reports on a program in which NIATx (Network for the Improvement of Addiction Treatment) with assistance from the National Development & Research Institutes (NDRI) provided technical assistance for adult treatment Drug Courts that received grant awards from the Center for Substance Abuse Treatment (CSAT) in 2009. The program goal was to improve Drug Court operations that increase client access to and engagement in Drug Court services, thereby increasing recovery and reducing recidivism. The organizational improvement model that NIATx developed has been highly successful in improving the functioning of substance abuse treatment programs (McCarty et al., 2007; Hoffman et al., 2008). The present program applied these same techniques to improve access and engagement in Drug Courts.

ABOUT NIATX

Founded in 2003, NIATx works with behavioral health organizations to help them get more people into treatment and *keep* them in treatment long enough to experience the benefits of recovery. The NIATx model was developed in response to two national initiatives: Paths to Recovery, funded by the Robert Wood Johnson Foundation (RWJF), and Strengthening Treatment Access and Retention (STAR), funded by CSAT. The thirty-nine substance abuse treatment organizations that participated in the first initiatives used a simple process-improvement model to change the business practices and reduce administrative barriers to treatment that impeded their ability to deliver quality care (Cappocia et al., 2007).

NIATx Areas Of Application

The original NIATx projects generated a strong body of knowledge about how substance abuse treatment organizations could improve the quality of addiction treatment. NIATx has worked with nearly 3,000 behavioral health organizations around the country, most of whom are health care providers treating persons suffering from

substance use, mental health disorders, or both (McCarty et al., 2007; Hoffman et al., 2008). Within substance abuse treatment, the NIATx model has demonstrated success in all aspects of care, from screening and brief intervention to medically managed intensive residential treatment and therapeutic communities. NIATx has organized learning collaboratives (Kilo, 1998) for provider agencies working to improve outcomes for pregnant and postpartum women, adolescent substance abusers, those at risk for or suffering from HIV/AIDS, opioid abusers, cultural minorities (such as African–Americans and Latinos), and many other targeted treatment programs.

Calls for organizational and systems improvement to increase treatment access and quality within criminal justice settings have been growing (Heck & Thanner, 2006; McCarty & Chandler, 2009). Applications of the NIATx model have helped organizations to reduce their paperwork burden, increase recovery services for persons who have completed treatment, or adopt evidence-based practices such as medication-assisted treatment. Adopting a NIATx approach within Drug Courts offers an excellent opportunity to identify and remove process barriers in both the treatment and justice systems that impede the ability of substance abusers to achieve and maintain recovery.

The NIATx Model

As a starting place, the NIATx model of process improvement leads organizations or programs to focus upon four aims that address client access to and continuation in substance abuse treatment:

- Reduce wait time to treatment
- Reduce no-shows
- Increase admissions
- Increase continuation in treatment

To create improvement in these four aims, the NIATx model stresses five principles for successful organizational change (Gustafson & Hundt, 1995):

- Understand and involve the customer (the offender, or participant, in the case of Drug Courts)
- Fix key problems

- Pick a powerful change leader
- Get ideas from outside the organization or field
- Use rapid-cycle testing

In addition to these five principles, bringing management and staff together to work in an integrated manner is central to the NIATx model (McCarty et al., 2007). Support from a senior leader (the *executive sponsor*) is essential for a quality improvement project to succeed. The executive sponsor is usually the director or CEO of an organization or, in the case of Drug Courts, a judge. This person becomes responsible for authorizing the time and resources needed to complete the project successfully. The executive sponsor also designates a staff member as the *change leader* to manage the organizational improvement process that addresses one of the four aims. Together, the executive sponsor and the change leader agree to establish a *change project*—a process improvement initiative that sequentially targets *one* NIATx aim at *one* location with *one* population. The change leader, who is responsible for organizing and conducting the project, together with the executive sponsor, assembles a *change team*, which includes a short list of staff members from their Drug Court system. The change team measures baseline data, selects change ideas to test, implements and monitors the change, determines its impact, and reports the results.

The change team uses process improvement tools to identify and address organizational structural or system issues that interfere with or inhibit clients from accessing and continuing in treatment. Two fundamental tools are the walk-through and rapid-cycle testing using the plan-do-study-act (PDSA) cycle.

Walk-Through—This is the primary method of identifying potential targets for change. Staff members take on the role of a client needing treatment to experience the process as a participant would. Taking this view of Drug Court and treatment services—from arrest or first contact, through intake, screening, assessment, and admission, to final discharge or graduation—helps staff members to understand problems from the participant's perspective. Simultaneously, staff members involved with the process are asked to provide a candid description of their observations and experience. Input from participants

and from those who serve them helps the change team to prioritize areas that need work to achieve their change project goal.

Rapid Cycle Testing—After using the walk-through observations and feedback to identify areas for change, the change team (which should have an appointed data coordinator) relies on the PDSA cycle to turn a change idea into action. The PDSA cycle represents the sequential flow of information gathering, decision making, action, and assessment. Critical to change team success is doing a series of short rapid cycles, with each cycle—from planning through implementation—taking only two weeks. This allows the change team to assess quickly whether the new idea is leading them toward the intended improvement and to make decisions about what next steps should be. The team adopts the change as a new standard of operation only when it has been demonstrated to be an improvement through comparison of baseline and follow-up observations (for example, reducing time from first contact to assessment from eight days to two days).

The process of measuring change is very important and should speed the improvement process rather than delay it. By collecting just enough consistent data before, during, and after each change, teams measure progress with respect to the goals they set and provide information for evaluating a change's impact. Often in the PDSA change process, it is easier to rely on manual data collection for quick and rapid feedback on the success of the change. This means relying on small samples collected over short time periods to measure change progress.

Using this method of testing changes, the NIATx model (1) minimizes risks and expenditures of time and money because changes are not implemented systemwide until effectiveness is demonstrated; (2) reduces disruption to participants and staff in making changes; (3) lessens resistance to change by starting on a small scale; and (4) learns from the ideas that work as well as from those that do not. By starting with small changes to test ideas quickly and easily and by using simple, pragmatic measurements to monitor the effect of changes over time, the PDSA model can lead to larger improvements through successive quick cycles of change.

The NIATx Learning Collaborative

To foster the adoption and implementation of the process improvement model and expedite the sharing of innovations, NIATx organizes learning collaboratives that involve a variety of activities and services intended to facilitate the formation of a learning community for adult learning and provide practice in using the NIATx model, including the following:

- *Learning Sessions*—Change teams convene at single- or multiday workshops to learn from each other and outside experts.
- *Conference Calls*—Teleconference calls and webinars are held, generally monthly, during which change leaders discuss issues and share progress on their change projects.
- *Coaching*—An expert in process improvement works with a change team to help it make, sustain, and spread process improvement.
- *NIATx Web Site*—A storehouse of process improvement tools, promising practices, and success stories, this Web site (www.niatx.net) provides complete instructions on how to conduct a NIATx change project.

IMPLEMENTATION

CSAT funded grants to forty-four Drug Court treatment projects in 2009 (Substance Abuse & Mental Health Services Administration (SAMHSA), 2009). These grantees were invited to participate in the program to focus on access and engagement improvement efforts during 2010. Ten Drug Courts were chosen to participate in the NIATx Learning Collaborative for Adult Treatment Drug Courts to improve client access to and retention in Drug Courts. The ten courts represented diverse geography (East Coast, West Coast, Midwest, South,) urban and rural settings, ranges in size, different types of Drug Courts (tribal, family, prison diversion, etc.), and varying stages of maturation (less than two years of court existence to more than twenty years).

NIATx Technical Assistance

The approach with the ten Drug Courts followed the NIATx learning collaborative model described above. The first step toward participation in the NIATx learning collaborative for each Drug Court was to conduct a walk-through prior to any coaching or in-person training. Based on their walk-through findings and exploratory baseline measures, each Drug Court considered an aim, formed change teams, and delegated executive sponsor and change leader roles prior to attending the first of three learning sessions.

Two to three members of each Drug Court's change team attended the first learning session, a kickoff meeting that included training in the NIATx process improvement model and tools for change team success, establishing goals for their change project from the four NIATx aims, and creating a project charter. Subsequent learning sessions, held six months and one year after the kickoff, focused on peer networking and sharing lessons learned and success stories so that Drug Courts could learn from each other and from expert NIATx coaches in person.

Each site received additional assistance in the form of coaching via monthly technical-assistance telephone calls and a one-day site visit. Coaching support helped Drug Courts select personnel for change teams, utilize process improvement tools to identify change barriers (flow charts, fish-bone diagrams, etc.), select improvements to test (nominal group technique, etc.), monitor change data (spreadsheets, graphs, etc.), and communicate the results (storytelling, etc.). Each month, NIATx conducted a conference call or webinar for members of the ten change teams, which offered continued training and provided a forum for the teams to share their experiences in applying process improvement in Drug Court settings.

Over the course of one year, change teams implemented test changes through PDSA cycles progressively until they had achieved their target improvement, lost momentum on an aim, or identified a higher priority aim to address. At the third and final learning session,

nine of the ten original Drug Courts[1] came together to report their progress and exchange ideas on the success of their process improvement projects.

IMPROVEMENTS IN COURT OPERATIONS

Over the course of the 12-month collaborative, eight Drug Courts worked on reducing the wait time to treatment, two Drug Courts targeted reducing no-shows to appointments, and four Drug Courts targeted increasing admissions.

Each Drug Court self-reported its change project results to its collaborative peers at the final learning session in short presentations consisting of essential information that summarized the data they used to monitor and measure the effectiveness of their NIATx change efforts, what process they changed, and how.

Wait Time Reductions

The eight Drug Courts that focused on wait times conducted eleven change projects targeting the steps in the client flow. These courts achieved a median reduction of 57% in client wait time. The time it takes participants to traverse the steps from arrest to receiving addiction counseling is often influenced by inefficient business, bureaucratic, or administrative practices and policies. Wait time reduction improvements adopted by these Drug Courts fell into three general categories: scheduling modifications, paperwork revisions, and inclusive communications.

Scheduling Changes

Some Drug Courts improved wait times by modifying their scheduling practices. One court's change team concentrated on the treatment agency's process of scheduling admissions appointments. Traditionally participants had to contact the counselor, who would then offer an appointment slot according to his or her availability. Al-

[1] One of the original ten courts dropped out because of internal administrative issues but expressed interest in continuing with the NIATx process after the issues were resolved.

ternatively, the agency adopted an open-clinic scheduling method where participants needed only to contact the agency front-office staff for the next available appointment slot; counselors were assigned when the participants arrived for their appointment. This scheduling method produced an 84% reduction in wait time for participants between the orientation session and an admissions appointment, decreasing from an average of over twelve days to around two days.

A second Drug Court's change team addressed the elapsed time between screening for Drug Court and admission thereto. Their change team initially found that an unsatisfactory number of clients were being held over each week for a decision on admission. They PDSA-tested a different scheduling process wherein the daily docket for the court team began one-half hour before other Drug Court activity, thereby reducing distractions. This practice created a better environment for Drug Court staff to communicate about clients that resulted in thirty-seven and fifteen fewer days between screening and admission for preadjudication and postadjudication participants, respectively.

A third Drug Court reduced wait times by implementing a centralized electronic scheduling program coupled with the reassignment of participant scheduling responsibility away from counselors and onto the treatment facility administrative support staff. The Drug Court also changed the practice of having participants return for treatment the following Monday to having participants report for the next available session, sometimes resulting in same-day treatment, thereby considerably reducing wait times.

Paperwork Revisions

Drug Courts also improved wait times through paperwork reduction. One Drug Court's efforts reduced the time required for a Drug Court referral to be assessed for treatment from twenty-eight days to twelve days by developing an improved flow of referral paperwork between other criminal court divisions and the Drug Court team. They did this through the addition of an inbox in the courthouse specifically for Drug Court orders and by sharing new participant information among all Drug Court team members using a tracking spreadsheet.

However, while the improved wait times increased efficiency between referral and assessment, doing so created a new problem: it increased time between a participant's completed assessment and admission to treatment by 140%. The wait times between assessment and treatment grew from twenty-five days to as many as sixty, providing a lesson regarding the interdependence of many of the processes involved in getting participants into treatment. As part of the continuous improvement process, the change team then turned its attention to overcoming this new bottleneck.

Another Drug Court that implemented a paperwork change project improved wait times by changing the paperwork requirements, including the revision of a standard screening form to a simplified checklist that reduced the narrative obligation and included the date of referral. By including the date, the staffing team became more aware of the elapse of time to sentencing and allowed them to prioritize cases accordingly.

Inclusive Communication

Drug Courts also pursued reducing wait times by setting up more inclusive communication practices. One Drug Court did this by including a partner agency staff person in case management efforts. The court implemented a monthly clinical case staffing between treatment staff, Drug Court coordinators, and court staff to coordinate discharges, new admissions, and directly monitor capacity.

Another Drug Court, where participants waited on average sixty-two days for treatment assessment and placement, addressed this by increasing informal communications between the court staff and the health center. The Drug Court instituted a standard 30-day maximum wait. Communication between the court coordinator and treatment counselors increased, and they concentrated on efficiently assigning appointments, resulting in an average wait time of only ten days.

Admissions Increases

Four Drug Courts tested ways to improve their admission or referral totals. For three of these courts, monthly average admissions to

Drug Court treatment increased sharply to almost double (92%–100%) and the fourth court showed a fourfold increase in referrals owing to their very low baseline. Change team interventions that were effective for increasing admissions included staff placement and outreach.

Staff Placement

To boost their enrollment totals, the change teams of three courts placed a Drug Court coordinator on-site at the courthouse on the day of hearings to meet with new clients and their families to increase the rate of new admissions.

Outreach

Another court conducted substantial outreach and education about Drug Court with social workers at a partner referral agency to increase admissions to the court. The Drug Court ran successive change cycles that included developing a newsletter, conducting in-person meetings between court and referral agency personnel to build understanding and strengthen relationships, and rerouting referrals from the public defender's office to the jail social workers so that Drug Court staff received earlier notice.

Reductions in No-Show Rates

Reductions in no-show rates and related increases in program participation were accomplished by change team interventions including reminder calls, escorting participants, and reporting attendance to the Drug Court.

Reminder Calls

One Drug Court with a failure rate of 41% for participant appearances at scheduled orientation appointments was able to reduce that to 18% by making reminder phone calls to the participant the day prior to their appointment.

Escorting Participants and Reporting Attendance

Another Drug Court focused on participants' attendance at a 2-day pretreatment group with baseline attendance rates of 62 percent. After several PDSA cycles, they adopted changes that included escorting participants to the classroom and reporting attendance directly to the Drug Court. The rate of participant attendance improved to 76 percent.

Synergistic Improvement Effects

Drug Courts that achieved improvements on one aim realized improvements on other measures. For example, a Drug Court that produced a seven-day reduction in wait time by making intakes available on the same day the participant called for an appointment found a concomitant 35% increase in their intake completion.

DISCUSSION

The project described in this article represents a first step in applying the NIATx model to achieve organizational improvement best practices in the Drug Court environment. NIATx offers a method to pair systematic experimentation with innovation until it can be fully adopted in the court. Through participation in the learning collaborative and applying the NIATx process improvement model, the adult treatment Drug Courts improved organizational and administrative processes in their programs that reduced wait times and no-shows and increased admissions and participant engagement with treatment. These improvement projects provided courts of different models, sizes, populations, and geographies substantial gains in performance, experience, and training in the application of process improvement tools and organizational change for continued growth. At the final learning session, each of the Drug Courts reported that changes they had developed during this project had become standard procedure.

The Drug Court community appears especially interested in exploring and adopting best practices to improve their operations and outcomes. In a system focused on rehabilitation and accountability, strengthening offender adherence at each step, from monitoring ap-

pearances through treatment participation, imparts considerable value. During walk-through and change team discussions, a number of courts reported that delaying treatment hindered operations and interfered with the offender's recovery. The participating Drug Courts demonstrated the capacity of the NIATx model to facilitate organizational improvements such as timeliness of services in complex Drug Court environments. The NIATx approach has proved an effective practice in the participating Drug Courts and is a promising best practice for Drug Courts that face similar challenges.

Next Steps

Increasingly, Drug Courts and treatment programs serving criminal justice populations are requesting training and tools to implement process improvement. In addition to a wide array of free guides, tools, and other resources, NIATx regularly offers free webinars on current topics of interest as well as continuing education in NIATx implementation (available online at www.niatx.net). Several state and national Drug Court professional associations have hosted NIATx training workshops at annual meetings. NIATx continues to develop a pool of expert coaches, to maintain a roster of NIATx-experienced peer mentors within Drug Courts to support process improvement efforts in criminal justice, and to serve future collaborative efforts for the field.

New Directions

Research is needed to evaluate the longer-term impact of NIATx-facilitated changes and enhanced communication among Drug Court participants. The improved client flow within participating Drug Courts demonstrates the positive organizational effects of the NIATx-related changes, which may in turn improve participant recovery and recidivism. Considerable evidence supports the effectiveness of Drug Courts. A next step is to explore how organizational functioning influences outcomes. Proving the value of improved organizational effectiveness for participants would be especially beneficial.

The experiences of the Drug Courts that participated in the *NIATx* Learning Collaborative for Adult Treatment Drug Courts program of-

fer information and guidance to other court systems seeking operational changes to improve service coordination and delivery. Applying NIATx process improvement practices can help overcome resistance to organizational change and resolve operational issues that hinder the delivery of effective services. The lessons learned from this project confirm that the NIATx organizational change model offers a highly promising practice for improving the efficiency and success of Drug Court systems.

Points of view, opinions, and conclusions in this paper do not necessarily reflect those of the U.S. Department of Health & Human Services (DHHS), Substance Abuse and Mental Health Administration (SAMHSA), Center for Substance Abuse Services (CSAT), NIATx, or NDRI.

This report was supported in part by a purchase order (HHSP233200900406P) from the Substance Abuse and Mental Health Administration (SAMHSA), Center for Substance Abuse Services (CSAT), which was awarded to the Center for the Integration of Research & Practice (CIRP), National Development and Research Institutes, Inc. (NDRI) and by contract (HHSS283200700003I) from JBS, funded by the Substance Abuse and Mental Health Administration (SAMHSA), which was awarded to the University of Wisconsin–Madison.

REFERENCES

Cappocia, V.A., Cotter, F., Gustafson, D.H., Cassidy, E., Ford, J.H., Madden, L., Owens, B.H., Farnum, S.O., McCarty, D., & Molfenter, T. (2007). Making "stone soup": How process improvement is changing the addiction treatment field. *Joint Commission Journal on Quality and Patient Safety, 33*(2), 95–103.

Gustafson, D.H., & Hundt, A.S. (1995). Findings of innovation research applied to quality management principles for heath care. *Health Care Management Review, 20*(2), 16–33.

Heck, C. & Thanner, M.H. (2006). Drug court performance measurement: Suggestions from the National Research Advisory. *Drug Court Review, 5*(2), 33–50.

Hoffman, K.A., Ford, J.H., Choi, D., Gustafson, D.H., & McCarty, D. (2008). Replication and sustainability of improved access and retention within the Network for the Improvement of Addiction Treatment. *Drug and Alcohol Dependence*, *98(1–2)*, 63–69.

Kilo, C.M. (1998). A framework for collaborative improvement: lessons from the Institute for Healthcare Improvement's Breakthrough Series. *Quality Management in Health Care, 6*(4), 1–13.

Marlowe, D.B. (2010, December). Research update on juvenile drug treatment courts. *National Association of Drug Court Professionals: Need to Know.* Retrieved May 2, 2011, http://www.ndcrc.org/content/need-know-research-update-juvenile-drug-treatment-courts.

McCarty, D., Chandler, R.. (2009). Understanding the importance of organizational and system variables on addiction treatment services within criminal justice settings. *Drug and Alcohol Dependence, 103*(Suppl. 1), S91–S93.

McCarty, D., Gustafson, D.H., Wisdom, J.P., Ford, J., Choi, D., Molfenter, T., Capoccia, V., & Cotter, F. (2007). The Network for the Improvement of Addiction Treatment (NIATx): Enhancing access and retention. *Drug and Alcohol Dependence*, *88*(2–3), 138–145.

Substance Abuse & Mental Health Services Administration (SAMHSA). (2009). FY 2009 SAMHSA Grant Awards; Center for Substance Abuse Treatment [CSAT] TI09-003 adult treatment drug courts. Retrieved May 2, 2011, from http://www.samhsa.gov/Grants/2009/awards/ti0903.aspx.

Harry K. Wexler, *PhD, a senior principal investigator emeritus at National Development and Research Institutes (NDRI), has acquired a national reputation in the areas of substance abuse policy, treatment, and research during the last forty years. His current work focuses on the effect of open communication and consensus on treatment effectiveness and organizational change. He has written numerous articles and has served as editor of special issues of the Prison Journal.*

Mark Zehner *is an associate researcher with the Center for Health Enhancement Systems Studies (CHESS) and NIATx at the University of Wisconsin–Madison. He is currently the project lead at the NIATx National Program Office for several federally funded improvement collaboratives for treatment capacity and quality. Mr. Zehner is also a NIATx coach and a faculty presenter for the NIATx Change Leader and Coaching Academies.*

Gerald Melnick, *PhD, is a senior principal investigator at the Center for the Integration of Research & Practice (CIRP) at National Development and Research Institutes (NDRI). His research activities include the effect of organizational characteristics on the success of substance abuse treatment programs, the effect of stigma on recidivism in first-time nonviolent felons, and the preparedness of state criminal justice systems to treat co-occurring substance use and mental disorder.*

Direct correspondence to Harry K. Wexler, PhD, Center for the Integration of Research & Practice (CIRP), National Development & Research Institutes, Inc. (NDRI), 71 W 23 Street, 8th Floor, New York, NY 10010. (212) 845-4400. hkwexler@aol.com

PARTICIPATION OF DEFENSE ATTORNEYS IN DRUG COURTS

Michael Tobin

> ***[11] Responsibilities of Defense Attorneys in Drug Court—****A defense attorney's responsibilities to an individual client may differ from those of a member of a collaborative treatment court team.*
>
> ***[12] Decision to Enter Drug Court—****In representing a client potentially eligible for treatment court, a defense attorney should be knowledgeable about the court's procedures and explain the potential advantages and disadvantages of treatment court compared to traditional litigation.*
>
> ***[13] Defense Representation on a Drug Court Team—****Defense representatives must advocate for fair procedures in the Drug Court and educate the defense bar generally regarding Drug Court operations.*
>
> ***[14] Defense Attorneys Serving in Dual Roles—****Where the same defense attorney acts as adversary counsel for individual clients and a Drug Court team member, the attorney must take precautions to balance potential role conflicts.*

THE ROLE OF A DEFENSE ATTORNEY in a Drug Court is a complex one. General guidelines for defender programs (including assigned-counsel systems) and for individual defense attorneys can be useful, contributing to the effectiveness of Drug Courts. The recommended best practice for a defender organization is to recognize and implement the collaborative and nontraditional role of a defense representative on a Drug Court team. This representative does not serve as adversary counsel for individual Drug Court participants, but rather as an advocate for evidence-based practices that advance the court's

therapeutic goals.[1] Because Drug Courts' primary goals are to help participants overcome addiction and thereby to reduce recidivism, the defense representative helps the Drug Court's participants by advocating for effective court policies and practices.

General Purposes and Attributes of Treatment Courts

Drug Courts and other treatment courts "were created in response to the perception that the traditional, adversarial criminal justice system does not adequately address"[2] issues such as alcohol or drug abuse, which in turn are risk factors for future criminal involvement. These courts blend attributes of traditional court procedures with therapeutic procedures not generally associated with court hearings. The traditional attributes include mandatory court appearances and the potential for sanctions. The therapeutic procedures include the delivery of support services to participants and the use of incentives to encourage and recognize progress in treatment.

Drug Courts typically conduct frequent review hearings to oversee treatment for drug abuse, which may include abuse of alcohol as well as abuse of controlled substances. The Drug Courts offer participants the opportunity to obtain a lesser sentence or dismissal of charges upon successful completion of the treatment program. The Drug Court model "calls for collaboration among various components

---

[1] *EDITOR'S NOTE—The author's recommendation that "adversary counsel" and "defense representative" functions should ordinarily be performed by different attorneys is not universally agreed upon by defense experts and does not reflect an official position of NADCP or NDCI. Nevertheless, this article presents the considered wisdom of a highly experienced defense expert in addressing thorny ethical dilemmas commonly confronted in Drug Courts. Moreover, research does suggest outcomes may be improved by including separately designated defense representatives on the Drug Court team who have substantial training and experience with the Drug Court model, practices, and procedures.*

[2] *Critical Issues for Defense Attorneys in Drug Court,* p. 3 (National Drug Court Institute 2003). Although this article specifically references Drug Courts, many jurisdictions have implemented treatment courts to focus on other issues, such as alcohol abuse, mental illness, or issues unique to veterans. *See* W. Huddleston & D. Marlowe, *Painting the Current Picture: A National Report on Drug Courts and Other Problem-Solving Court Programs in the United States*, p. 1 and nn. 1–2 (Bureau of Justice Assistance 2011) (reporting a total of 3,648 problem-solving courts, including 2,459 Drug Courts).

of the criminal justice and substance abuse treatment systems to combine the coercive power of the court with effective and scientifically based treatment practices."[3] Studies of Drug Courts have confirmed that treatment is more successful than incarceration in preventing recidivism.[4]

The collaborative aspects of Drug Courts often include the participation of a public defender or other defense attorney on a Drug Court team.[5] As a team member, the defense attorney may have the opportunity to improve justice policy by expanding opportunities for defendants to have their social service needs addressed effectively and to have their cases dismissed or reduced. However, the nontraditional role of team member also raises ethical and practical questions regarding the boundaries of this collaborative role and the traditional adversarial role of defense counsel.[6]

---

[3] *Drug Courts: The Second Decade*, p. 17 (National Institute of Justice 2006).

[4] *See* W. Huddleston & D. Marlowe, *Painting the Current Picture: A National Report on Drug Courts and Other Problem-Solving Court Programs in the United States*, p. 9 (Bureau of Justice Assistance 2011) (citing numerous studies showing that Drug Courts reduce crime in comparison to other justice-system dispositions).

[5] *See, e.g.*, Defining Drug Courts: The Key Components, p. 8 (National Association of Drug Court Professionals (NADCP) 1997) (listing defender among important participants in the planning process for a Drug Court); *id.*, p. 11 (prosecutor and defense counsel, as members of drug-court team, must shed adversarial roles and focus on participant's "recovery and law-abiding behavior").

[6] See *America's Problem-Solving Courts: The Criminal Costs of Treatment and the Case for Reform,* pp. 30–41 (National Association of Criminal Defense Lawyers 2009). The defense attorney is not the only member of the typical Drug Court team who needs to adapt to a nontraditional role. The judge, although still the ultimate decision maker, receives input from all other team members and often seeks consensus from the team. The judge also talks directly to participants about many facets of their lives at the regular review hearings. The prosecutor and law enforcement (including the probation department) refrain from investigating or prosecuting violations of law that come to light as part of Drug Court.

The ability of team members to adapt to the nontraditional role of team member is critical to the success of the court; conversely, an inability to accept a collaborative role is counterproductive. The nontraditional role does not mean that the defense representative should always agree with other team members. The defense representative will generally best understand the barriers that make it difficult for participants to overcome addiction and to manage other life issues while engaged in an intensive treatment program. The defense representative may have the most compassion for and patience with Drug Court participants. Therefore, the defense representative may

Although research conclusively shows the effectiveness of Drug Courts, studies also show that effectiveness depends upon fidelity to specific components of such courts.[7] When key components are dropped or when the treatment programs are "watered down," lower graduation rates and higher recidivism have occurred.[8] Therefore, attorneys working in treatment courts need to be aware of (and to advocate for) the research-based approaches that lead to successful results for participants.

SUMMARY OF RECOMMENDATIONS

Defense attorneys should participate in all aspects of Drug Courts to ensure that these courts treat defendants fairly, following effective and therapeutic procedures. Each treatment court should include a defense representative on a team that oversees the court's policies and operations. Defendants participating in a Drug Court should also have access to adversary counsel, although as a practical matter, the therapeutic model of a Drug Court is inconsistent with traditional litigation procedures.[9]

Managers or staff attorneys of indigent-defense providers often serve on a Drug Court team to represent the interests of participants. This role is referred to as the "defense representative" in the balance of this article, and depending on the features of the jurisdiction, the

---

often need to remind and persuade other team members to refrain from unduly punitive actions and policies.

[7] W. Huddleston & D. Marlowe, *Painting the Current Picture: A National Report on Drug Courts and Other Problem-Solving Court Programs in the United States*, p. 14 (Bureau of Justice Assistance 2011).

[8] *Id.*, pp. 14–15.

[9] *See generally infra* nn. 56–60 and associated section. If the court is operating fairly and effectively, the participants view the Drug Court as collaborative, rather than as adversarial. Conversely, if participants frequently perceive unfairness in the court's procedures, the court is probably not fulfilling its therapeutic goals (because court participants are not necessarily defendants in pending cases while in Drug Court and are not necessarily formally represented by an attorney during Drug Court proceedings, the term "participants" is used in this article to refer generally to the individuals supervised in the treatment court program; the terms "clients" or "defendants" are used to emphasize either the attorney-client relationship or the pendency of criminal proceedings).

role may also be fulfilled by a private attorney or a representative of a bar association.[10] The defense representative should know the local justice system sufficiently to assess the benefits and risks of a proposed or existing Drug Court. The defense representative should also communicate regularly with the defense bar regarding the Drug Court's policies and practices.

The differences between the roles of defense representative and adversary counsel are discussed in detail below. Practical and ethical challenges often arise if the same person serves both as the defense representative on a Drug Court team and as adversary counsel for individual participants in the court. Thus, when possible, the defense representative should refrain from serving in these two roles simultaneously. The dual roles create at least the appearance of a conflict between the duty to assist the Drug Court (in fulfilling its broad, therapeutic mission) and the duty to advocate at each court session for individual clients.[11]

If the circumstances of a jurisdiction require an attorney to serve in these roles simultaneously,[12] he or she should clearly communicate

[10] Although indigent defendants and other defendants have common interests in a fair process, indigent defendants have the additional concern that Drug Courts do not impose financial requirements that render their participation impossible or impractical. Thus, the indigent-defense perspective is critical to ensure that any fees imposed on participants are waived or substantially reduced for indigent participants.

[11] For example, research suggests that direct interaction between the judge and participants furthers the court's therapeutic mission. *See, e.g.*, J. Miller and D. Johnson, *Problem Solving Courts: New Approaches to Criminal Justice,* p. 158 (Rowman & Littlefield 2009) (discussing how a judge in a reentry court promotes success of participants through "unique dialogues that address their individual strengths, needs, and challenges"). However, as adversary counsel, an attorney generally discourages a client from speaking in open court, especially if the judge is asking the client about possible rules violations.

[12] In a rural area, for example, there may be only one public defender in the county. The same attorney often serves both as a member of the Drug Court team and as the adversary attorney for individual participants. Serving in the dual roles may be the only practical way in such a county to operate a Drug Court with a defense attorney participating as a team member. If so, the defense attorney should educate other team members regarding the areas in which duties to individual clients take precedence over the role of a team member. However, when resources allow for separation of the team-member and adversary roles, this separation is the best practice both to avoid

with clients regarding the attorney's responsibilities as a member of the Drug Court team. The attorney should also advise other members of the team that when serving an individual client, the attorney may challenge the Drug Court's procedures and the specific actions of other team members.[13]

IMPORTANCE OF DEFENSE PARTICIPATION

Principle Eight of the American Bar Association (ABA) Ten Principles of a Public Defense Delivery System recommends that "[p]ublic defense should participate as an equal partner in improving the justice system." Although the attributes and policies of treatment courts vary widely, national studies show that when operated effectively, treatment courts can benefit individual defendants and the broader community by helping individuals overcome issues often linked to criminal behavior.[14]

A large percentage of defendants in the criminal justice system have a history of irresponsible use of drugs or alcohol.[15] Many others

---

ethical conflicts for the attorney and to promote fidelity to effective practices in the Drug Court.

[13] The attorney might, on behalf of a client, challenge a drug-testing procedure or the accuracy of a specific test result, even without any specific evidence that the test result was inaccurate. Depending on their frequency and the litigation methods used, these types of challenges may cause other team members to view the attorney as an adversary instead of a partner on the treatment court team.

In the role of team member, the defense representative should be interested in the accuracy of testing procedures and of specific test results (an interest that all team members should share). Thus, the defense representative should advocate for fair procedures to correct or confirm the results of less-reliable screening tests. The defense representative could also properly suggest ways to eliminate or reduce the ability of participants to use someone else's urine for testing. An adversary attorney, however, would arguably be unable to take steps that the attorney knew or suspected would lead to adverse legal consequences for a client.

[14] *See* R. Warren, *Evidence-Based Practices to Reduce Recidivism: Implications for State Judiciaries*, p. 15 & n. 86 (Crime and Justice Institute, National Institute of Corrections and National Center for State Courts 2007) (citing numerous "[r]igorous scientific studies and meta-analyses" showing "that Drug Courts significantly reduce recidivism among Drug Court participants in comparison to similar but nonparticipating offenders").

[15] *See, e.g., Drug Use and Dependence, State and Federal Prisoners,* 2004, p. 1 (U.S. Department of Justice, Office of Justice Programs, Bureau of Justice Statistics Spe-

suffer from mental disorders,[16] and some have multiple treatment needs.[17] Drug Courts and other treatment courts have shown the potential to reduce recidivism by combining regular court reviews with evidence-based treatment and case management.[18] These courts are also able to keep defendants in the community instead of serving substantial terms of incarceration.

Generally, these courts are operated by a team comprising representatives of several agencies. For example, a Drug Court team often includes a judge, prosecutor, probation agent, social worker, public defender, and law enforcement officer. "Active defender participation in all phases of the Drug Court, from design to operation, makes it more likely that the program will be client-oriented."[19]

A resolution of the National Association of Drug Court Professionals (NADCP) also supports the participation of a defense representative in the development and operation of Drug Courts. This resolution identifies eligibility criteria, selection of treatment provid-

---

cial Report, October 2006) (citing 2004 statistics that showed 53% of state inmates and 45% of federal inmates met the psychiatric community's criteria for drug dependence or abuse); *Alcohol and Crime*, p. 1 (U.S. Department of Justice, Office of Justice Programs, Bureau of Justice Statistics, April 1998) (citing 1996 statistics that showed 36% of the estimated 5.3 million persons supervised by corrections officials in the U.S. had been drinking when they committed the offense for which they were convicted).

[16] *See, e.g., Mental Health Problems of Prison and Jail Inmates*, p. 1 (U.S. Department of Justice, Office of Justice Programs, Bureau of Justice Statistics Special Report, September 2006) (citing 2005 statistics showing that slightly more than half of the inmates surveyed reported either a recent mental-health diagnosis or recent symptoms of a mental disorder).

[17] *See, e.g.*, *id.* (citing 2005 statistics showing that of state prison inmates reporting a recent mental-health diagnosis or recent symptoms of a mental disorder, 74% reported a history of substance abuse).

[18] *See, e.g.*, W. Huddleston & D. Marlowe, *Painting the Current Picture: A National Report on Drug Courts and Other Problem-Solving Court Programs in the United States*, p. 14 (Bureau of Justice Assistance 2011).

[19] Michael Judge, *Critical Issues for Defenders in the Design and Operation of a Drug Court*, p. 2 (NLADA Indigent Defense, November 1997). *See also* K. Weibrecht, *Evidence-Based Practices and Criminal Defense: Opportunities, Challenges, and Practical Considerations*, pp. 26–27 (National Institute of Corrections 2008) (discussing how when involved as a policy maker, defense attorney can educate others regarding the needs of defendants).

ers, confidentiality, and other court policies as proper topics for defender input.[20]

DEFENSE PARTICIPATION IN DEVELOPING A DRUG COURT

Defense representatives often participate in the planning for and development of a Drug Court.[21] This participation may result from membership in a criminal justice coordinating council or from formation of a local ad hoc work group interested in a treatment court. Some grant applications require that planning groups include a defense representative. Defense participation helps to ensure that the Drug Court has a therapeutic focus rather than a punitive focus.[22] To help ensure that the Drug Court provides effective services to participants, the defense representative should address such issues as eligibility criteria, application and admission process, access to treatment and other services, court expectations and procedures, incentives and sanctions, and confidentiality of information that court officials learn about participants in the Drug Court context.

The defense representative must work with representatives of other agencies in the planning and development of a Drug Court (the

---

[20] NADCP, Resolution regarding Indigent Defense in Drug Courts (April 19, 2002), *reprinted at* nlada.org/Defender/Defender_Library. *See also* K. Weibrecht, *Evidence-Based Practices and Criminal Defense: Opportunities, Challenges, and Practical Considerations*, pp. 26–28 (National Institute of Corrections 2008) (defense attorney should advocate for matching treatment to the needs of program participants, for use of treatment modalities that have a track record of effectiveness, and for evaluation procedures to ensure that practices remain evidence based).

[21] *See* G.F. Roper and J.E. Lessenger, Drug Court Organization and Operations, *reprinted in Drug Courts: A New Approach to Treatment and Rehabilitation,* p. 287 (Springer Science and Business Media 2007). *But see America's Problem-Solving Courts: The Criminal Costs of Treatment and the Case for Reform*, p. 8 (National Association of Criminal Defense Lawyers 2009) (noting that the criminal defense bar has not consistently had input in development of problem-solving courts throughout the country).

[22] *See* C.L. Asmus and D.E. Columbini, Juvenile Drug Courts, *reprinted in Drug Courts: A New Approach to Treatment and Rehabilitation,* p. 271 (Springer Science and Business Media 2007) (recognizing that the public defender advocates for rights of participants and "monitors sanctions imposed by the court to ensure that they are within the legal and philosophical parameters of the program").

court, prosecution, law enforcement, probation and parole, and social services are ordinarily represented on a Drug Court team). Thus, although the defense representative can influence the standards and procedures adopted for the Drug Court, the team must reach a consensus.

Ultimately, for the defense representative to recommend the Drug Court for consideration by the defense bar in individual cases, the court must present potential benefits to defendants when compared to other available means of resolving their cases (litigation or negotiation under preexisting procedures and penalty structures). If the Drug Court has this beneficial potential (for example, it provides both treatment services and the potential to earn dismissal or substantial reduction of charges), defense attorneys and their clients can assess the potential benefits on a case-by-case basis to determine whether to seek admission to the Drug Court. Conversely, if efforts to work in a collaborative manner are ultimately unsuccessful in developing a therapeutic court program with significant benefits for participants, the defense representative should consider withdrawing from further participation as a member of the Drug Court team.[23]

Written policies and other documents are important to provide consistency and fairness in the Drug Court's operations.[24] Written informational materials can assist the defense representative in educating other defense attorneys about the Drug Court. Standard forms

[23] Because the ability to influence court policies is generally greater for a member of the court team, a defense representative should not take this action lightly or without making every reasonable effort to improve the court's procedures. However, at some point, if the court is not providing effective services to participants, the continued participation of the defense representative sends the wrong message to the defense bar and to defendants. The label "treatment court" is misleading if the court does not follow effective practices.

[24] *See* G.F. Roper and J.E. Lessenger, Drug Court Organization and Operations, *reprinted in Drug Courts: A New Approach to Treatment and Rehabilitation,* p. 286 (Springer Science and Business Media 2007) (stating that benefits of a written manual include notice to participants of court's requirements and permanent record of the respective duties of court personnel).

should address waivers and authorizations that defendants are required to sign as a condition of participation.[25]

The success of Drug Courts depends on adherence to research-based practices. If either the court procedures or the treatment protocols are deficient, the Drug Court is unlikely to reduce recidivism. Therefore, the defense representative needs to learn the underlying principles behind a successful Drug Court and apply that knowledge to the specific criteria adopted or proposed in his or her jurisdiction.[26]

DEFENSE PARTICIPATION IN DRUG COURT OPERATIONS

Defense representatives often serve as members of a Drug Court team that oversees ongoing court operations.[27] If the planning phase

---

[25] *See id.*, p. 292 (recognizing need for waiver if defense attorneys do not appear at regular status hearings; need for waiver of confidentiality of medical information). If a Drug Court is complying with best practices, including participation of an effective defense representative on the court team, participants will rarely request the assistance or presence of an adversary attorney at the status hearings. Nonetheless, it is helpful for all defense attorneys to be familiar with the operations of a local Drug Court, and the court should welcome their attendance.

[26] Without a thorough knowledge of the type of treatment and supervision that is effective for the court's participants, the defense representative is unable to advocate for practices that will maximize the opportunities for participants to succeed. For example, the prevalent model for a Drug Court (including frequent judicial reviews) is most effective for high-risk participants. Michigan Supreme Court Administrative Office, *Best Practices for Standardized Risk Assessment*, p. 9 (2010); *see also* K. Weibrecht, *Evidence-Based Practices and Criminal Defense: Opportunities, Challenges, and Practical Considerations*, pp. 4, 8 (National Institute of Corrections 2008) (a higher level of treatment is appropriate for individuals who present a high risk of recidivism).

If the court's participants include persons properly classified as low risk, it may be counterproductive to require the same frequency of in-person court appearances. Michigan Supreme Court Administrative Office, *Best Practices for Standardized Risk Assessment*, p. 9 (2010). By keeping current with research findings regarding treatment courts, the defense representative is best able to advocate for effective practices and advise other defense attorneys about the strengths and weaknesses of the local Drug Court.

[27] *See* G.F. Roper and J.E. Lessenger, Drug Court Organization and Operations, *reprinted in Drug Courts: A New Approach to Treatment and Rehabilitation,* p. 288 (Springer Science and Business Media 2007).

has resulted in standards and procedures that benefit clients, the defense representative's main goal on the team may be to ensure that the Drug Court adheres to these standards and procedures (while continuously evaluating the court's benefits to clients and looking for areas for improvement). If the Drug Court's framework does not provide significant benefits to clients, however, the defense representative may need to insist upon substantial changes in the court's operations before he or she agrees to serve on the team.

If the same defense representative serves on the planning team and the operations team, the transition from one role to the other may be relatively seamless. The representative will generally understand the perspectives of the other team members and the reasons behind the written standards and procedures. Conversely, a defense representative without experience on the planning team may lack this base of knowledge and may need to learn enough information to evaluate the beneficial potential for clients.

Changes in Drug Court personnel, such as a new judge or prosecutor, can result in significant changes in court operations. Thus, the defense representative may have an opportunity to promote improvements in court procedures, but may also need to advocate against proposals that dilute the court's effectiveness.

The responsibilities of the Drug Court team may include the selection of treatment providers, admission of participants into the court, review of participants' progress, and regular staffing meetings before each court session. At the staffing meetings, the team generally reviews how each participant has done since his or her last court date and recommends to the Drug Court what action to take or what topics to address with each participant.[28]

For participants who are doing well, the Drug Court action will generally consist of a positive progress report, a brief conversation between the judge and the participant, and scheduling of the next

[28] *See id.*, pp. 294–96 regarding a typical day of Drug Court review hearings, including the team meeting before court.

court date.[29] The participant may be eligible for modest rewards for his or her positive report, such as a longer interval between court hearings (many Drug Courts have three specified phases for participants, each characterized by its own frequency of hearings and drug or alcohol tests[30]). A participant who has violated the Drug Court's rules may face a sanction, which could be community service work, a written assignment, extra drug or alcohol testing, ineligibility for an incentive, or brief confinement in jail.[31]

The defense representative, although not serving in the role of adversary counsel for each participant, can and should advocate generally for Drug Court practices that benefit participants. For example, the defense representative should advocate for a broad array of supportive services, including help with transportation, housing, and education, to assist indigent participants. Similarly, the defense representative should advocate for adherence to policies that protect participants and can seek to amend the Drug Court's policies and operations to serve participants better.[32]

The defense representative should advocate for policies of graduated sanctions and rewards that recognize the high incidence of relapse during treatment programs.[33] In the team meetings that often

---

[29] *See generally id.*, pp. 296–98, regarding the typical interaction between the Drug Court judge and participants at the court's review hearings.

[30] *See, e.g., id.*, p. 293 & Table 19.1.

[31] *See generally* D. Marlowe, Strategies for Administering Rewards and Sanctions, *reprinted in Drug Courts: A New Approach to Treatment and Rehabilitation,* pp. 317–333 (Springer Science and Business Media 2007) (describing strategies for use of rewards and sanctions in treatment courts in light of research regarding behavior modification).

[32] *See id.*, p. 325 (discussing "ratio burden" that can result from "multiple demands on clients that can be difficult to fulfill simultaneously"). The defense representative should assist participants in voicing practical considerations, such as work or school schedules, child-care duties, and transportation issues, that may limit their ability to attend all the recommended or required programming.

[33] *See, e.g.*, *id*., pp. 325–26 (distinguishing between "behaviors that clients are readily capable of engaging in," such as attending court and treatment sessions, and goals that may take longer to accomplish, such as prolonged abstinence from drugs). During the early phases of a client's treatment, rewards and sanctions of a relatively higher magnitude should be reserved for behaviors that the client can readily control. *Id.*, p. 326.

precede the court's review hearings, the defense representative should point out mitigating factors and may suggest potential sanctions other than incarceration.[34]

The defense representative should educate the local defense bar regarding treatment courts.[35] This education should include the Drug Court's potential advantages and disadvantages for clients represented by the local defense bar. Specific topics should include eligibility criteria and processes, legal consequences of successfully completing treatment (and of failure to complete treatment), and general policies and procedures of the Drug Court. The defense representative should encourage defense attorneys to contact him or her for specific information as needed. The defense representative should also encourage attorneys to observe at least one session of the Drug Court to understand the review sessions that their clients will attend if admitted to the program.

Drug Court participants are often not represented by adversary counsel at the court's review hearings. Participants frequently have questions and concerns that they may prefer to share with the defense representative rather than with the judge or with treatment providers. The defense representative should support participants by providing them with information about Drug Court procedures and by encouraging them in their efforts to complete the treatment court program. Where applicable, the defense representative must make clear that he or she is not serving as adversary counsel for program participants.[36]

---

[34] *See infra* nn. 71–74 and associated section regarding principles for effective sanctions in drug court.

[35] *See* NADCP, Resolution regarding Indigent Defense in Drug Courts (April 19, 2002), *reprinted at* nlada.org/Defender/Defender_Library ("Inclusion and training of private counsel appointed to represent indigent defendants in Drug Court is necessary, particularly in jurisdictions which do not have an institutional public defense entity"). *See also America's Problem-Solving Courts: The Criminal Costs of Treatment and the Case for Reform*, p. 40 (National Association of Criminal Defense Lawyers 2009).

[36] Although the defense representative protects the general interests of participants in fair and compassionate court procedures, his or her proper role is to work as a collaborative team member to promote the successful rehabilitation of participants. *See, e.g.*, J. Miller and D. Johnson, Problem Solving Courts: New Approaches to Criminal Justice, p. 166 (Rowman & Littlefield 2009) (acknowledging team approach as best

ADVERSARY COUNSEL: ADVICE TO CLIENTS REGARDING DRUG COURTS

All defense attorneys should be reasonably knowledgeable about Drug Courts operating in the jurisdiction where they practice.[37] This knowledge should include a general understanding of the criteria for eligibility, the requirements for successful completion of the treatment program, and the likely consequences for failure to complete the program.

Defense counsel should be familiar with a wide range of potential dispositions that may benefit his or her clients. Thus, knowledge about a local Drug Court is a specific example of an attorney's obligation to investigate potential ways of resolving cases to his or her clients' benefit.[38] The attorney need not have an encyclopedic knowledge of the specific details of the potential treatment programs offered or available through the court, but should have general knowledge and should be able to respond to reasonable questions from clients about the Drug Court. The attorney may wish to communicate with the defense representative on the Drug Court team regarding specific questions.

In advising a client about potential participation in a Drug Court, defense counsel should provide competent and zealous representation, which should include reasonable factual investigation, consideration of potential legal and factual defenses, consideration of other dispositional alternatives, and communication with the client about the potential advantages and disadvantages of the Drug Court.[39]

Participation in a treatment court often occurs as a result of a negotiated agreement to settle a pending case. The client must ultimate-

---

practice in a problem-solving court); J.L. Nolan, Jr., Reinventing Justice: The American Drug Court Movement, pp. 75–76 (Princeton, N.J. 2001) (successful Drug Courts rely upon a collaborative team approach).

[37] *See* ABA Model Rules of Professional Conduct 1.1 (lawyer shall provide competent representation, which includes necessary knowledge and preparation).

[38] *See id.*

[39] *See* ABA Model Rules of Professional Conduct 1.1 (competence), 1.4 (communication).

ly decide whether to seek admission to the Drug Court, to proceed to trial, or to pursue another disposition. Counsel's obligation is to prepare the client to make an informed choice. Counsel meets this obligation by preparing the case thoroughly, by negotiating effectively, and by communicating with the client regarding the range of possible ways to proceed.[40] In addition to describing the Drug Court, counsel may help the client make an informed choice by arranging for the client to attend a Drug Court session[41] and to meet with current or former participants of the Drug Court program.

As part of the adversary representation, counsel should advise the client about any waiver of rights in the Drug Court. In large part, the waiver of rights may be similar to any waiver of rights that accompanies a plea of guilty or no contest. However, there may be specific rights waived in connection with the Drug Court procedures, including the right to counsel at court hearings and the right to confidentiality of treatment records.[42]

---

[40] The timeline for applying to enter a Drug Court can be a concern for adversary counsel in advising a client (and for the defense representative, in the broader context of promoting fair procedures). A legitimate therapeutic purpose is served by encouraging a prompt commitment to treatment. *See, e.g.*, La Crosse County Drug Treatment Court Program, *Policies and Procedures Manual*, p. 5 (May 2009) ("Addicts are most vulnerable to successful intervention when they are in the crisis of initial arrest and incarceration, so intervention must be immediate and up-front"). Further, for a defendant with a serious addiction or a pattern of abusing drugs or alcohol, a delay in starting a treatment program may be detrimental. The defendant will be either in jail unable to post bail or at risk of arrest for additional offenses because of his or her drug or alcohol use.

However, an arbitrary deadline can interfere with counsel's ability to investigate the facts of the case, to investigate other possible dispositions, and to consult adequately with the client. *See generally America's Problem-Solving Courts: The Criminal Costs of Treatment and the Case for Reform*, p. 38 (National Association of Criminal Defense Lawyers 2009) (recommending that Drug Court should allow adequate time for case preparation, including litigation of motions). One possible approach is an opt-out period during which a client may enter Drug Court while adversary counsel continues to investigate the case, obtain and review discovery, and discuss with the client potential legal and factual defenses.

[41] *See id.*

[42] *See infra* n. 46 for sample language regarding a waiver of the right to counsel at review hearings in Drug Court. Regarding treatment records, the Drug Court will ordinarily require participants to sign an agreement that information may be released to specific individuals and agencies. Although the judge often will discuss aspects of a

Adversary counsel does not generally attend all Drug Court sessions.[43] Counsel should clearly communicate to his or her client, before the client seeks admission in the Drug Court, the extent to which counsel will be available to attend court hearings or to answer questions while the client is a participant.[44] If the client is required to request a new appointment of an adversary attorney for any issue that arises in the Drug Court, counsel should advise the client regarding the process for such a request.

Adversary counsel should also advise the client regarding the consequences of an unsuccessful termination from the Drug Court. The client needs to know the sentence or the range of potential sentences that he or she could face in a future sentencing hearing. Similarly the client needs to know the potential sentence that could follow future revocation of probation or parole. Counsel should also discuss with the client that if the client is unsuccessful in Drug Court, the client will have spent a period of time in a challenging and structured treatment program, after which the client may still face the applicable sentence. In sum, although the benefits of success may be substantial, the client also needs to understand that if he or she is unsuccessful, the overall consequences for the underlying charge may be more onerous than if the client has received a traditional sentence.

ADVERSARY REPRESENTATION IN DRUG COURT

The best practice for an indigent-defense program is to offer adversary representation whenever a Drug Court participant faces incarceration as a sanction.[45] If adversary representation is limited or

---

participant's treatment at the review hearings, in the presence of team members and the other participants, the records are not made available to the general public.

[43] *See infra* nn. 52–53 and accompanying text.

[44] *See* ABA Model Rules of Professional Conduct 1.4(b) (a lawyer shall explain an issue sufficiently that the client may make an informed decision). Access to the assistance of counsel could be a pertinent factor for a client to consider when deciding whether to participate in a Drug Court.

[45] *See* State of New Jersey Drug Court Program, Participation Agreement, ¶ 17 (participant has "right to an attorney during court proceedings"). *See generally* Rothgery

unavailable in Drug Court proceedings, prospective participants should be notified before entering the Drug Court. Participants may knowingly and voluntarily waive the right to counsel as part of an agreement to follow the rules of the Drug Court.[46] Despite this type of waiver, the attorney who served as adversary counsel on the underlying case should remain available to answer his or her client's questions during the time that the client is participating in the Drug Court.[47]

Ideally, Drug Court participants should have access to adversary counsel throughout the process. Regardless of the court's therapeutic purpose, the availability of adversary counsel is important, especially when a sanction will impact the client's liberty (for example, jail or an inpatient program). Participants may not need to consult frequently with counsel, especially when they are progressing well in their treatment programs or when they are satisfied with the court's measured response to infractions. However, their conduct in treatment and in the court hearings can affect the ultimate disposition of their under-

---

v. Gillespie County, 554 U.S. 191, 128 S. Ct. 2578, 2591 n.16 (2008) (constitutional right to counsel applies to critical stages of a criminal proceeding that amount to "trial-like confrontations") (citations omitted). When the court confronts a treatment court participant with information regarding a failed drug test or other alleged rules violations, the proceeding arguably meets the criteria for a "critical stage," thus implicating the constitutional right to counsel. As a practical matter, however, the court may have authority to modify bail (or the probation department may have authority to hold the participant in jail) pending an adversary hearing. Thus, if the participant is facing a sanction of one or two days in jail, he or she may agree to the sanction instead of requesting a formal hearing.

[46] Several Wisconsin counties include the following standard language in their participant contracts: "For purposes of regular drug court review hearings, I agree to waive my right to have my attorney of record present. I understand that my case may be discussed without my attorney or the prosecutor present." *See, e.g.*, *Dunn County Diversion Court Participant Contract*, ¶ 21; *Eau Claire County Drug Court Program Participant Contract*, ¶ 21; *Jackson County Drug Court Participant Contract*, ¶ 20; *Polk County Drug Court Participant Contract*, ¶ 20; *Trempeleau County Drug/OWI Court Participant Contract*, ¶ 20.

[47] *See generally supra* nn. 37–44 and associated section. The defense representative should be available to answer the questions of participants regarding the Drug Court. However, adversary counsel can best answer questions regarding the underlying case and the likely effect on its ultimate resolution if the client does or does not successfully complete the court program.

lying criminal cases and can affect their status in the Drug Court from week to week. Therefore, the ability to confer confidentially with adversary counsel can benefit participants while they participate in a Drug Court.

Because of differences among both the structures of defender programs and the procedures of treatment courts, local practices vary regarding the availability of appointed counsel throughout an individual defendant's participation in a Drug Court.[48] The defense representative should provide interested parties (including the local defense bar, prospective participants in the Drug Court, and other justice agencies) information regarding the scope of adversary representation that attorneys appointed for the indigent will provide in the Drug Court.[49] This communication should include providing access to materials such as policy manuals, participant contracts, and authorization forms for release of treatment information to specified parties.

In many Drug Courts, a defendant's participation in the court follows a negotiated agreement, such as a plea agreement or a diversion agreement.[50] If the defendant successfully completes the treatment

---

[48] Drug Courts follow one of three different models regarding the phase of the criminal proceeding at which the defendant is admitted to the court: pre-plea, between plea and adjudication, or postadjudication. *See* G.F. Roper, Roadblocks to Success, *reprinted in Drug Courts: A New Approach to Treatment and Rehabilitation,* p. 342 (Springer Science and Business Media 2007). The model of a particular court may affect whether the appointment of the attorney on the original charge continues throughout the time that the client is in the treatment court. For example, an appointment might continue for a case in which no adjudication of guilt has yet occurred, but not for a case in which the client has already been convicted and placed on probation.

[49] For staff public defenders, office policies may define the scope of representation that they are required or expected to provide. The high volume of cases assigned to public defenders make it difficult for them to appear regularly at review hearings for each client whom they represented before admission to treatment court. For appointed private attorneys, local rules regarding reimbursement and the attorneys' duties to other clients may influence whether or not attorneys ordinarily attend review hearings. However, the main reason for the rare attendance of adversary counsel may be the fairness of the procedures followed in many Drug Courts. *See infra* n. 53.

[50] *See* W. Huddleston & D. Marlowe, *Painting the Current Picture: A National Report on Drug Courts and Other Problem-Solving Court Programs in the United States*, pp. 24-25 (Bureau of Justice Assistance 2011) (noting that the participants in most adult Drug Courts have entered a plea of guilty as a condition of entering the court program). The agreement may call for dismissal of charges, reduction of charg-

program, the charge is often reduced or dismissed.[51] An indigent defendant is eligible for appointment of an attorney on the underlying charge. The attorney may negotiate on the client's behalf regarding participation in Drug Court. (Although the appointment is not for the specific purpose of seeking admission to Drug Court, the attorney advises the client of this option as part of representation on the pending charge.) However, in most Drug Courts, the attorney does not attend the court's regular review hearings, even when the defendant faces a sanction for noncompliance.[52] Nonetheless, Drug Courts should permit attendance and participation of adversary counsel.[53]

Defendants should be advised when a defense representative attends the Drug Court as a member of the court team, rather than as adversary counsel, for each individual defendant.[54] Although an attor-

---

es, and/or a lesser sentence upon successful completion of the treatment court program. Some Drug Courts accept individuals who are on supervision (parole or probation) and who seek to participate in Drug Court as an alternative to revocation of supervision.

[51] *See, e.g.*, Michael O'Hear, Rethinking Drug Courts: Restorative Justice as a Response to Racial Injustice, 20 *Stan. L. & Policy Rev*. 463, 479 (2009).

[52] *See, e.g., America's Problem-Solving Courts: The Criminal Costs of Treatment and the Case for Reform*, p. 34 (National Association of Criminal Defense Lawyers 2009) (describing some jurisdictions in which the custom for defense attorneys is not to appear in Drug Court). The absence of adversary counsel at these hearings is consistent with the collaborative approach characteristic of Drug Courts. *See Defining Drug Courts: The Key Components*, p. 11 (NADCP, Drug Court Standards Committee 1997) (recommending that the defense counsel and prosecutor "shed their traditional adversarial courtroom relationship and work together as a team").

[53] *See* G.F. Roper, Roadblocks to Success, *reprinted in Drug Courts: A New Approach to Treatment and Rehabilitation,* pp. 348–49 (Springer Science and Business Media 2007) (recommending that judge offer to adjourn hearing on imposition of sanctions until adversary counsel is available, but sharing experience that defendants and defense bar rarely contest sanctions when "satisfied that the judge will not impose sanctions heavy-handedly or without abundant, clear evidence of a violation"). Conversely, if participants are frequently contesting alleged violations or the severity of the sanctions, the court may lack that shared confidence in a fair process.

[54] *Cf. Defining Drug Courts: The Key Components*, p. 12 (NADCP, Drug Court Standards Committee 1997) (defense counsel should explain to the defendant the rules of the Drug Court and all rights that he or she is relinquishing as part of an agreement to enter the court program). Although *The Key Components* does not explicitly differentiate between a defense attorney serving in a representative capacity and serving as adversary counsel, many of the actions recommended for defense

ney who has served for a long time on a Drug Court team may understand his or her nontraditional role at the review hearings, the attorney should ensure that Drug Court participants also understand that the attorney's role is not to provide individual representation in Drug Court. If the Drug Court is not treating defendants fairly at the review hearings, the defense representative should seek improvements in the court process and should advise the defense bar of the concerns about the court's actions.[55]

A major distinction exists between an ordinary review hearing and an expulsion hearing, the latter generally occurring only after a participant has failed repeatedly to comply with treatment expectations or has been imprisoned for a new violation (and thus is unavailable for community-based treatment). Depending upon the original charges, a participant may face months or years of incarceration following expulsion rather than the day or two in jail he or she might receive as a Drug Court sanction. Thus, prompt access to adversary counsel is especially critical when a participant faces either an expulsion hearing or a sentencing hearing following expulsion.

ATTORNEY FULFILLING DUAL ROLES IN DRUG COURT

In some jurisdictions, the same attorney may simultaneously serve as adversary counsel and as the defense representative on the Drug Court team. For many Drug Court hearings (particularly for clients in compliance with the court's requirements), the client's wishes and the team's treatment goals for the client are identical. In this common situation, the dual roles do not present a challenge for the attorney. However, because many clients relapse or commit other infractions during the difficult treatment process, the potential exists for conflict between the two roles.

---

counsel are consistent with the role of defense representative described in this report. *See id.*, pp. 11–12.

[55] In addition to the efforts of the defense representative to improve court processes or to discourage further referrals to the court, adversary counsel may pursue litigation on behalf of clients aggrieved by actions of the Drug Court.

The attorney's adversarial role, ethically required for direct client representation, may be counterproductive for the therapeutic goals of the Drug Court.[56] Therefore, when the attorney is required as an advocate to argue against sanctions, he or she may be jeopardizing the collaborative approach that is widely accepted as integral to the effectiveness of Drug Courts.[57]

The different roles impact how the defense attorney perceives the direct conversations that regularly occur between the Drug Court judge and the individual participants. The success of Drug Courts stems in part from this interaction, which increases participants' belief that they are being treated fairly.[58] However, an attorney providing adversary representation does not ordinarily encourage a client to

---

[56] *See Defining Drug Courts: The Key Components*, p. 6 (NADCP 1997) (observing that the traditional role of defense counsel may contribute to alcohol or drug abuse by reinforcing the client's denial of the underlying problem). *See also Critical Issues for Defense Attorneys in Drug Court*, p. 3 (National Drug Court Institute 2003) ("desires of the treatment team are, at times, conflicting and seemingly put the defense attorney in a box"). For example, despite believing that a client needs long-term or intensive treatment to achieve and maintain sobriety, adversary counsel will ordinarily advocate for a lesser treatment dosage if consistent with the client's wishes. *See* K. Weibrecht, *Evidence-Based Practices and Criminal Defense: Opportunities, Challenges, and Practical Considerations*, p. 31 (National Institute of Corrections 2008) (interpreting ethical standards for defense counsel to presume that counsel should advocate for the dispositional result preferred by the client)

[57] *See, e.g.*, *Defining Drug Courts: The Key Components*, p. 3 (NADCP 1997) (after the participant is accepted into the Drug Court, the team's focus is "on the participant's recovery and law-abiding behavior"); J. Miller and D. Johnson, *Problem Solving Courts: New Approaches to Criminal Justice,* p. 158 (Rowman & Littlefield 2009) (stating that Drug Court team members must step outside their ordinary professional roles to work collaboratively).

[58] *See, e.g.*, D.C. Gottfredson, B.W. Kearley, S.S. Najaka, and C.M. Rocha, *How Drug Treatment Courts Work: An Analysis of Mediators*, p. 26, 44:1 Journal of Research in Crime and Delinquency (2007) (number of judicial hearings increases participants' perceptions of procedural fairness, which in turn reduces drug usage and criminal activity); *Defining Drug Courts: The Key Components*, p. 15 (NADCP 1997) (Key Component # 7 addresses ongoing judicial interaction with each participant to demonstrate that the judge cares about the participant and is keeping track of his or her progress).

communicate directly with the judge, particularly if the attorney does not know in advance the substance of the client's statements.[59]

Another challenge for a dual-role attorney is the simultaneous representation of all or most of the Drug Court participants. For example, if multiple participants face sanctions during the same review session, it may be difficult for the attorney to present a credible argument that each one has a unique mitigating circumstance.[60]

If a Drug Court consistently follows fair procedures and relies more heavily on incentives than on sanctions, many participants will become comfortable with direct and candid conversations with the presiding judge. Thus, the conflicts between the adversary role and the defense representative role may be relatively infrequent during the court's staffing meetings and review hearings. Nonetheless, when possible, an individual attorney should refrain from serving simultaneously in both roles.

MAJOR ISSUES FOR THE DEFENSE ATTORNEY IN DRUG COURT

Eligibility for Participation

A critical and difficult issue for a Drug Court is the eligibility criteria. A Drug Court that limits eligibility to defendants charged with minor offenses may not provide sufficient incentives for many defendants to complete a long period of intense treatment and supervi-

[59] *Cf.* ABA Standards for Criminal Justice, Defense Function, § 4–6.2 (Commentary) (3rd ed. 1993) (because statements made by the defendant during plea negotiations may be used against the defendant in future proceedings, "the accused should be cautioned by counsel against making any statements that have not been carefully explored in advance with counsel").

[60] ABA Model Rules of Professional Conduct 1.7(a)(2) prohibits representation of a client when a substantial risk exists that the representation will be materially limited by obligations to another client. For example, in the context of arguing against sanctions that the Drug Court generally imposes, an attorney might have to argue on behalf of one client that her brief time in the court is a mitigating factor (she is still under the powerful effects of addiction) and then to have to argue that another client's substantial time in the court without a violation is a mitigating factor. Arguably, both clients would be better served by separate attorneys who would not have to argue seemingly inconsistent positions before the same judge.

sion.[61] Conversely, a Drug Court that accepts defendants charged with serious offenses (and defendants with prior records) may achieve a higher rate of program completion because defendants are motivated to complete the program instead of serving a substantial term of imprisonment.[62] A defense representative, through familiarity with research regarding this risk–reward principle, may influence other members of the Drug Court team regarding eligibility criteria.

A defense representative is expected, as a member of the Drug Court team, to support agreed-upon eligibility criteria (particularly if he or she participated in establishing them). Therefore, a conflict of interest may arise if the defense representative (or a colleague in the same defender organization) acts as adversary counsel for clients seeking admission to the Drug Court.[63] The defense representative has an institutional interest in supporting the agreed-upon admission criteria, which support successful treatment outcomes and favorable dis-

---

[61] *See, e.g.*, Michael O'Hear, Rethinking Drug Courts: Restorative Justice as a Response to Racial Injustice, 20 *Stan. L. & Policy Rev.* 463, 480 (2009) (a Drug Court is "less a diversion from prison than a diversion from other alternatives" if it focuses on possession offenses and on defendants without serious prior records); G.F. Roper, Roadblocks to Success, *reprinted in Drug Courts: A New Approach to Treatment and Rehabilitation,* p. 348 (Springer Science and Business Media 2007) (some defense attorneys recommend a straight sentence of "weeks or months" to their clients instead of a longer period of participation in Drug Court).

Furthermore, the Drug Court should take into account the risk level and risk factors (needs) of participants to determine the appropriate level and type of treatment. *See* L. Gutierrez and G. Bourgon, *Drug Treatment Courts: A Quantitative Review of Study and Treatment Quality 2009-04*, p. 3 (Public Safety Canada 2009). Low-risk individuals do not need (and should not receive) the same treatment programming as high-risk individuals. *Id.*

[62] *See Drug Courts: The Second Decade*, p. 2 (National Institute of Justice 2006) (Drug Courts have moved from "low-level first-time offenders to focusing on those whose substance abuse and criminal activity may be more serious"). *See also* R. Warren, *Evidence-Based Practices to Reduce Recidivism: Implications for State Judiciaries*, pp. 21–22 (Crime and Justice Institute, National Institute of Corrections and National Center for State Courts 2007) ("Effective recidivism-reduction programs target moderate- and high-risk offenders"; participation of low-risk offenders in intensive treatment can actually increase their risk of reoffending).

[63] ABA Model Rules of Professional Conduct 1.7(a)(2) prohibits representation of a client when a substantial likelihood exists that the attorney's ability to represent the client will be materially limited by the attorney's other responsibilities. *See supra* n. 11 and accompanying text.

positions for participants. However, adversary counsel for an individual client has an obligation to advocate for admission to the Drug Court, if the client wishes to participate, even if the circumstances of the client's case do not appear to meet the admission criteria.[64]

Regardless of the specific eligibility criteria and screening procedures, the defense representative should communicate to other Drug Court personnel that defense attorneys are ethically required to seek admission for clients on a case-by-case basis. By learning about practices and outcomes in other jurisdictions, the defense representative may persuade the team to expand the eligibility criteria or to apply them more flexibly. If other members of the Drug Court team respect the defense representative's duty to individual clients, he or she may be effective in advocating for their admission to the Drug Court.

The defense representative may also seek to persuade policy makers to allocate additional resources to the Drug Court, which may expand its capacity to accept new applicants. The court's track record in reducing recidivism can be used to show whether that jurisdiction should support the Drug Court as a viable option to traditional prosecution and punishment.

Cultural Competency in Drug Court

Drug Courts should provide services that effectively meet the needs of all participants, regardless of race, gender, age, or ethnicity. By collecting demographic information of participants and by track-

---

[64] *See generally* ABA Model Rules of Professional Conduct 1.2(a) (lawyer shall generally abide by decisions of the client regarding the objectives of the representation, including whether to settle a case or proceed to trial). As an adversary attorney, an attorney may be ethically required to seek admission to Drug Court for a low-risk client, if the client prefers that disposition. Thus, if the same attorney also serves as the court's defense representative, he or she may be precluded from advocating for the best practice regarding the population served by the treatment court. *See supra* nn. 61–62 and accompanying text regarding the reasons for accepting moderate-risk and high-risk defendants as participants in Drug Court.

A jurisdiction with a Drug Court may also provide other diversion options for low-risk defendants. If so, adversary counsel may seek a favorable disposition that does not require the intensive treatment and the frequent court appearances characteristic of Drug Courts.

ing outcomes, a Drug Court team can assess whether it is providing services that lead to success for participants from all cultural backgrounds.

NADCP has recognized that Drug Court teams should continually review their programs for evidence of racial or ethnic disparity and, if necessary, take corrective action to address such disparity.[65] In recommending that Drug Courts focus on this issue, NADCP noted the disproportionate incarceration of racial and ethnic minorities nationwide.[66] NADCP also noted lower success rates reported for minority participants in some Drug Courts[67] and the importance of training Drug Court personnel "on how to identify and administer evidence-based, culturally sensitive and culturally competent interventions and assessment tools."[68]

Incentives and Sanctions for Drug Court Participants

Drug Courts generally use incentives and sanctions to shape participants' behavior, rewarding compliance and imposing negative consequences for noncompliance. The defense representative can help temper the tendency that other team members may have to recommend or impose unnecessarily harsh sanctions. Familiarity with research regarding incentives and sanctions can help in ensuring that the Drug Court does not overreact to the inevitable instances of noncompliance. This knowledge of the research can also help other team members to understand the importance of incentives to provide positive reinforcement.

Defense attorneys, whether serving as a defense representative on a Drug Court team or as adversary counsel, should be aware of the likely consequences for participants for conduct occurring after they enter the Drug Court. Negative consequences can occur either as sanctions (within the framework of the Drug Court) or as a sentence

---

[65] NADCP, *Resolution of Board of Directors on the Equivalent Treatment of Racial and Ethnic Minority Participants in Drug Courts*, p. 2 (June 2010).

[66] *Id.*, p. 1.

[67] *Id.*, p. 2.

[68] *Id.*, p. 3.

following expulsion from the Drug Court. Both types of consequences need to be considered in light of the dispositional alternatives other than Drug Court (for example, a participant might face short periods of incarceration as a sanction in Drug Court, but might face a prison sentence for the underlying offense if expelled).

Incentives

Not all justice professionals instinctively embrace the idea of a court providing tangible incentives such as gift cards or movie passes to a participant for having a clean urine test and appearing in court as scheduled. After all, millions of people obey the law every day without receiving these rewards. However, to counteract the power of chemical addiction and dependency, immediate and tangible rewards are important ways for a Drug Court to show some benefits of abstinence.[69]

Sanctions

Four general principles for effective sanctions within a treatment program are certainty, promptness, magnitude, and fairness.[70] Certainty and promptness of sanctions are the most important principles.[71] Therefore, the Drug Court's ability to identify and to respond

---

[69] M. Stitzer, Motivational Incentives in Drug Courts, *reprinted in Quality Improvement for Drug Court: Evidence-Based Practices,* p. 99 (National Drug Court Institute 2008). *See also* Strategies for Administering Rewards and Sanctions, *reprinted in Drug Courts: A New Approach to Treatment and Rehabilitation,* pp. 326–328 (Springer Science and Business Media 2007) (discussing the value of tangible rewards for Drug Court participants, particularly to help new participants before they begin to experience intrinsic rewards of sobriety and other prosocial behaviors).

[70] D. Marlowe, Strategies for Administering Rewards and Sanctions, *reprinted in Drug Courts: A New Approach to Treatment and Rehabilitation,* pp. 319–324 (Springer Science and Business Media 2007).

[71] *Id*., pp. 319–322. Frequent and random drug tests for participants create a high degree of certainty that the Drug Court will discover a participant's drug usage. Conversely, if testing is conducted infrequently or on a predictable schedule, the certainty of a sanction for drug usage is greatly reduced. The promptness principle reflects that the more quickly a sanction occurs, the greater likelihood that the participant recognizes that connection between the sanction and the underlying conduct. Conversely, when a criminal defendant is sentenced months or years after an offense, "the effects of sanctions should be expected to be minimal." *Id*., p. 321.

quickly to misconduct is more critical than the severity of the sanctions imposed.

The magnitude of the response, in a Drug Court environment, should take into account the strength of the participant's drug or alcohol dependency and the expectation that relapse is a common occurrence during treatment. During the early phase of treatment, "clients might receive verbal reprimands or writing assignments for providing drug-positive urine samples but might receive community service or brief jail detention for failing to show up for counseling sessions or failing to provide urine samples."[72] The fourth principle, fairness, calls for fair procedures and professional, respectful communication with participants when imposing sanctions.[73]

Indiscriminate use of incarceration as a sanction can result in substantial incarceration for participants in a Drug Court, even for those who successfully complete the treatment program.[74] In advising a client regarding potential participation in a Drug Court, defense counsel should be aware not only of the range of sanctions generally used, but also the likelihood that most participants will experience some setbacks during their time in the court-sponsored program.

Conversely, counsel should consider and discuss with the client the likely outcome if he or she receives a traditional sentence. This

---

[72] *Id.*, p. 326; *see also* T.J. Kelly, J.M. Gaither, and L.J. King, Relapse, *reprinted in Drug Courts: A New Approach to Treatment and Rehabilitation,* p. 386 (Springer Science and Business Media 2007) ("it is not necessary or desirable that a participant be incarcerated for every drug use episode"). The harsher sanctions during the early phase of treatment should be reserved for intentional violations of court procedures, such as skipping an appointment, rather than for succumbing to a powerful addiction of dependency.

[73] D. Marlowe, Strategies for Administering Rewards and Sanctions, *reprinted in Drug Courts: A New Approach to Treatment and Rehabilitation,* p. 324 (Springer Science and Business Media 2007). A Drug Court's failure to follow fair procedures, including the opportunity to respond to alleged violations, may adversely affect the commitment of participants to their treatment programs. *Id.* If participants perceive that they have been treated fairly and respectfully, they are likely to accept sanctions for misconduct. *Id.*

[74] *See, e.g.*, M. O'Hear, Rethinking Drug Courts: Restorative Justice as a Response to Racial Injustice, 20 *Stan. L. & Policy Rev.* 463, 481 (2009) (citing studies from Santa Clara and Baltimore that showed an average time in excess of 50 days' incarceration for sanctions).

consideration should encompass not only the length of the initial period of incarceration, but also whether the client is likely to comply with probation or parole requirements. Most clients eligible for a Drug Court have a history of court involvement that suggests, absent an intensive and successful course of treatment, the potential for future legal difficulties.

Confidentiality of Information Disclosed in Drug Court

Participants may have concerns not only about use of information within the justice system (e.g., in a future sentencing or revocation proceeding), but also about public access to information stemming from their participation in a Drug Court. Local law and procedures may differ regarding specific practices such as whether review hearings are transcribed, whether members of the public may attend the review hearings, whether records are accessible under local law on public records, and whether the judge orders attendees not to disclose information communicated in these hearings.

Although members of the Drug Court team need to receive information about participants, such as treatment records and results of drug tests, the defense representative should seek to protect confidentiality through adoption of procedures limiting access to information, disclosure of information, and use of information.

When a defendant agrees to participate in a Drug Court, he or she is required to sign release forms to allow members of the court team to review treatment records. Despite the legitimate purpose for requiring this consent to disclosure of records, the defense representative should ensure that disclosure is no broader than is necessary. A policy manual, written contract, or memorandum of understanding can be a valuable resource to document the limits on disclosure of treatment records.[75]

The frequency of treatment sessions, tests for alcohol and drug use, and review hearings results in members of the treatment court

[75] *See, e.g.*, *La Crosse County (Wisconsin) Drug Court Manual*, p. 10 (2009) ("Drug Court files are separate and distinct from Circuit Court files…All Drug Court files are confidential and are not open to the general public").

team learning when participants relapse. Members of the team thus commonly encounter evidence of positive drug tests and incriminating statements during the participant's gradual and uneven path to recovery. "Defenders will want to ensure that such evidence is used for the limited purpose of treatment and cannot be used against the client" in other contexts.[76]

Criteria and Procedures for Expulsion from Drug Court

The criteria for expulsion from Drug Court contribute to the completion rate for participants. The therapeutic model anticipates relapse and uses a range of sanctions and incentives to enhance the chances for successful completion of treatment. If a Drug Court is impatient with the uneven progress of participants and expels them after a specified number of violations, the court will likely have a lower completion rate. Because the length of time that a person participates in treatment is directly related to the likelihood of future success,[77] Drug Courts should use the motivational tools of incentives and sanctions to retain participants and to optimize their chances for success.

The success of an individual participant depends in large part upon his or her conduct while in the Drug Court. A participant who regularly adheres to the court's expectations will ordinarily complete the program; a participant who regularly skips court sessions, who is imprisoned for a new crime, or who is unable to benefit from treatment is much less likely to succeed. Nonetheless, the court's overall completion rate and its general policies regarding expulsion are pertinent information for defense attorneys in advising their clients regarding participation in a Drug Court.

Expulsion from Drug Court may result in substantial incarceration. Depending upon the stage of the criminal proceeding at which the participant entered Drug Court, he or she may face sentencing in an adjourned felony case or may face revocation of parole. Further-

[76] M. Judge, Critical Issues for Defenders in the Design and Operation of a Drug Court, *Indigent Defense,* p. 4 (National Legal Aid and Defender Association 1997).

[77] *See, e.g.,* W. Meyer, *Developing and Delivering Incentives and Sanctions*, p. 1 (National Drug Court Institute, April 2007).

more, the postexpulsion decision of the sentencing court or parole board may be influenced by the participant's failure to complete the treatment court program successfully. Therefore, the Drug Court should provide the participant with the right to appointment of adversary counsel in an expulsion hearing.[78]

Sentence Following Expulsion from Drug Court

Although Drug Courts have shown success at reducing recidivism,[79] not all participants successfully complete the court program. The unsuccessful participant typically faces a sentencing hearing on the original charge (or faces imprisonment in the revocation proceeding) that precipitated the referral to the treatment court. In some jurisdictions, an unsuccessful participant may face a greater penalty than if he or she had never participated in the Drug Court.[80] However, absent a new conviction, a participant's failure to complete the program should not be a basis for an increased sentence.[81] The defense repre-

---

[78] Some Drug Courts have adopted specific policies to notify participants of the right to counsel in this type of hearing. *See, e.g.*, *Brown County (Wisconsin) Drug Court Program Manual*, p. 13 (2009) (expulsion hearing, if requested, occurs on the record, "and the participant is entitled to legal representation"); *La Crosse County (Wisconsin) Drug Court Participant Handbook,* p. 10 (2009) (attorney may appear both for initial hearing before Drug Court team and, if the matter proceeds further, for judicial hearing on expulsion).

[79] *See supra* nn. 4, 14, and accompanying text.

[80] *See, e.g.*, M. O'Hear, Rethinking Drug Courts: Restorative Justice as a Response to Racial Injustice, 20 *Stan. L. & Policy Rev.* 463, 481& n. 100 (2009) (citing studies from New York that showed failing participants receiving longer sentences than nonparticipants receive).

[81] The defense representative may wish to consider whether unsuccessful participants should have the option of having their cases transferred from the Drug Court judge to another judge for sentencing. In some jurisdictions, cases may routinely be returned to another judge when the defendant (whether successful or unsuccessful) has ended his or her participation in Drug Court. If the defendant has the option of remaining before the Drug Court judge or having the case transferred, the decision is a tactical one to make in consultation with adversary counsel.

Another potential safeguard is to let the defendant know, before he or she enters Drug Court, what the sentence will be if the defendant does not complete the court program. This alternative depends on local sentencing law and practices, as well as the phase of the proceedings at which the participant enters the Drug Court (for example, if the participant enters Drug Court in lieu of revocation of parole, the potential in-

sentative (and the defense bar in general) should advise judges and prosecutors that increased sentences for noncompletion may deter many defendants from participation in Drug Court.

Defense Representative's Role in Decisions about Individual Participants

The defense representative on a Drug Court team should ordinarily refrain from voting to admit to the court clients represented by attorneys working in his or her office. Similarly, the defense representative should not vote on sanctions or expulsion of these clients. If the defense representative intends to vote (or otherwise advocate) regarding these decisions, the clients should be notified that the defense representative is acting as a representative of the Drug Court and will vote according to the court's applicable standards and policies. Present or former clients of the public defender agency should be given the same access and consideration as clients of the private bar.

In general, the interests of indigent defendants are better served if a defense representative participates in admission decisions. The defense representative may be more receptive than other team members to accepting defendants with serious charges or significant criminal records. Also, the defense representative may advocate for criteria and policies that provide access regardless of financial status (for example, procedures to waive or defer fees that might otherwise preclude participation by indigent persons). However, when the defense representative's colleagues are serving as adversary counsel for defendants seeking admission to the Drug Court, ethical and practical concerns make the defense representative's recusal preferable to voting on the admission decision.

If the defense representative opposes admission into the Drug Court of a colleague's client, ethical issues arise regarding conflict of interest and confidentiality. A conflict of interest arguably exists between the defense representative's responsibility as part of the Drug Court team (which may include adherence to specified admission cri-

---

carceration time may be predetermined by the sentence originally imposed and the local parole law.

teria) and his or her responsibility to take no action adverse to a colleague's client (this responsibility exists whenever attorneys work together in the same office).[82] The confidentiality issue arises because attorneys in the same office generally have access to information regarding all clients of the office,[83] and the defense representative may not ethically use client-related information adversely in the decision regarding admission to the Drug Court.[84]

The ethical issues are magnified if the defense representative supervises the attorney providing the adversary representation. The defense representative must not discourage adversary counsel from seeking admission to the Drug Court on behalf of his or her clients (even for clients who may appear not to meet the stated admission).

Practical considerations also support the recommendation that the defense representative has a policy of not voting on the admission of a colleague's client. If the representative invariably votes in favor of admission, he or she will lose credibility with other members of the Drug Court team. However, if the representative votes against admission (or abstains) only in some cases when the prospective participant is a client of a colleague, others on the Drug Court team may believe that the representative has confidential and negative information about the client derived from working in the same office with adver-

---

[82] ABA Model Rules of Professional Conduct 1.10(a) provides that for attorneys "associated in a firm," a conflict of interest precluding representation by one attorney is generally imputed to his or her colleagues. An exception exists, however, that allows other attorneys in the firm to represent the client if the conflict "is based on a personal interest of the prohibited lawyer and does not present a significant risk of materially limiting the representation of the client by the remaining members of the firm. *Id.* 1.10(a)(1). Thus, whether other public defenders may represent a client in Drug Court (or seeking admission to the court) despite a conflict affecting their colleague depends on the interpretation of this rule on imputed disqualification (some states have adopted the ABA Model Rules with changes, so attorneys should review local rules and opinions).

In analyzing this ethical issue and others, attorneys must be familiar with the specific rules and ethics opinions applicable in their respective jurisdictions.

[83] *Id.*, 1.6, Comment ("Lawyers in a firm may, in the course of the firm's practice, disclose to each other information relating to a client of the firm," unless the client has given contrary instructions).

[84] *Id.*, 1.6(a) (general rule of confidentiality, which broadly prohibits a lawyer from revealing "information relating to the representation of a client").

sary counsel. Furthermore, multiple clients of the office may be applying for a single place in the Drug Court.[85]

Participation in decisions on expulsion or sanctions can be similarly problematic. The defense representative can support the therapeutic goals of the Drug Court by reminding other team members that overcoming addiction or dependence is generally an uneven journey, interrupted by relapse.[86] However, voting on potential expulsion or sanction for each individual creates the same dilemma as with admission decisions. The defense representative may lose credibility by opposing all negative consequences for violations.[87] Conversely, if the

[85] Because of limited resources (e.g., staff, treatment providers, or funding), Drug Courts may have a maximum number of participants at a given time. Therefore, if the number of applicants exceeds the court's capacity, the team may need to make admission decisions from among a pool of applicants all of whom meet the eligibility requirements. Ethical issues related to admission decisions may be minimized if the court uses criteria such as a diagnosis of addiction and a risk determination (from a standardized assessment instrument) to select participants. Another possible approach to address these ethical issues is to screen the defense representative from confidential information about treatment court applicants represented by colleagues (other members of the Drug Court team should then be informed of this screening procedure, so that they do not draw any inferences from the statements or votes of the defense representative).

The defense representative may also work with other team members to seek additional resources to expand the Drug Court's capacity. If the court can document its success in reducing recidivism, policymakers may increase funding to allow the court to serve additional participants.

[86] *See* T.J. Kelly, J.M. Gaither, and L.J. King, Relapse, *reprinted in Drug Courts: A New Approach to Treatment and Rehabilitation,* p. 386 (Springer Science and Business Media 2007) (stating that Drug Court judge "should carefully consider the consequences of incarceration and not allow traditional notions of 'tough on crime' to interfere with the effective use of treatment."); *see also* K.R. Lay and L.J. King, Counseling Strategies, *reprinted in Drug Courts: A New Approach to Treatment and Rehabilitation,* p. 170 (Springer Science and Business Media 2007) ("Relapse is an expected part of recovery in Drug Courts and might or might not occur at any stage and require return to an earlier stage").

[87] For example, the defense representative might be called upon to vote on potential sanctions for misconduct that occurred during a treatment session or for failure to show up to provide a urine sample. Members of the Drug Court team may reasonably conclude that the failure to impose some sanctions for violations potentially undermines not only the court's ability to promote participant compliance, but also the court's relationship with the service provider (for example, an agency providing treatment or drug testing). *See* D.A. Reilly, Building Supportive Services in Drug

defense representative votes for such consequences in selected cases, other team members may infer that the representative has confidential and negative information about the client.

In a jurisdiction in which the local public defender staff represent a large percentage of defendants, this issue can be difficult. The defense representative should consider reasonable alternatives to preserve a defense voice in these decisions without creating the ethical and practical issues discussed above. The participation of a private defense attorney in admission decisions may be an option in some Drug Courts. Another option may be that the applicant's adversary counsel, after having reviewed the eligibility criteria, presents the application to other members of the team, with the defense representative refraining from any formal vote.

In sum, the defense representative can advocate generally for fair criteria in all aspects of Drug Court's operations without formally advocating for specific actions requested by a client (or colleague's client). If participants have been fully informed of and agreed to the Drug Court's procedures, the defense representative can ethically, collaboratively, and effectively support the court's evidence-based practices.

CONCLUSION

Drug Courts provide a potentially beneficial option to persons who would otherwise be at high risk of substantial incarceration and recidivism. By addressing underlying risk factors such as addiction or a mental disorder, Drug Courts can benefit both the individual participants and the public safety of the broader community. Public defenders (and other representatives of the defense bar) can and should play an important role in ensuring the fairness and effectiveness of Drug Courts.

> *Points of view, opinions, and conclusions in this paper do not necessarily reflect those of the NADCP, National Legal Aid and Defender Association (NLADA,) or the Office of the Wisconsin State Public Defender.*

Courts, *reprinted in Drug Courts: A New Approach to Treatment and Rehabilitation,* p. 212 (Springer Science and Business Media 2007).

Michael Tobin *is the deputy director of the Wisconsin State Public Defender and previously served this agency as a staff attorney, a supervising attorney, and a division director. He has taught law school courses at the University of Puget Sound and the University of Wisconsin. He coauthored the Wisconsin Criminal Defense Manual and Thomson West's treatise on Wisconsin Criminal Practice and Procedure. He earned his undergraduate degree at Swarthmore College and law degree at the University of Texas.*

Direct correspondence to Michael Tobin, Deputy Director, State Public Defender, 315 N. Henry Street, Madison, WI 53704. (608) 266-8259. tobinm@opd.wi.gov

THE PREVALENCE OF HIV RISK BEHAVIORS AMONG FELONY DRUG COURT PARTICIPANTS

David S. Festinger — Karen L. Dugosh
David S. Metzger — Douglas B. Marlowe

[15] HIV Risk Behaviors in Drug Court—*A small percentage of participants in a large metropolitan felony Drug Court engaged in high-risk injection drug use, but a large percentage engaged in high-risk sexual behaviors.*

[16] HIV Risk Factors in Drug Court—*HIV risk behaviors were associated with being male, African–American, and younger.*

[17] Geographic Risk for HIV—*A large proportion of Drug Court participants resided in areas of the city with a high prevalence of persons living with HIV/AIDS, thus heightening the probability of exposure to the virus.*

ACCORDING TO RECENT ESTIMATES from the Centers for Disease Control and Prevention (CDC; Hall et al., 2008), approximately 1.2 million adults and adolescents in the United States are HIV positive, representing approximately 0.4% of the total population. An estimated 56,300 adolescents and adults were newly infected with the HIV virus in 2006. Seventy-three percent of these new infections occurred among males, 45% among African–Americans, and 17% among Hispanics. Over half of the new infections occurred among males who have sex with males (MSM).

The relationship between drug use and HIV risk is well documented. According to CDC estimates, injection drug use (22%) was the third most common high-risk behavior among individuals living with HIV [after male-to-male sexual contact (45%) and high-risk heterosexual contact (27%)]. In addition to risks of direct and indirect transmission associated with injection drug use, noninjection substance users are also disproportionately at risk for contracting HIV through sexual transmission. Substance use has been frequently linked to sexual risk behaviors and viral

transmission among both heterosexuals and MSM. Clearly, drug and alcohol use can affect economic status, social network membership, and decision making with respect to partner selection and condom use. These factors often lead to unsafe sexual practices (e.g., Brewer et al., 2007; Celentano, Latimore, & Mehta, 2008; Cheng et al., 2010; Kwiatkowski & Booth, 2000; Molitor, Bautista, & Choi; Royce et al., 1997). Finally, research has demonstrated that the biological effects of drug abuse can affect a person's susceptibility to HIV infection and the progression of AIDS (e.g., Bagby et al., 2006; Samet et al., 2003, 2004).

The high rates of drug use put substance-abusing offenders at a high risk for contracting HIV infection and for transmitting the virus to others. It is estimated that approximately 80% of prison and jail inmates were under the influence of drugs or alcohol at the time of their arrest (Belenko & Peugh, 2005; James, 1988; Teplin, 1994). Of those in jail who are HIV positive, intravenous drug use is among the most predominant methods of transmission (Dean, Lansky, & Fleming, 2002; Hammett et al., 1994, as cited in Swartz, Lurigio, & Weiner, 2004). In fact, early estimates (Vlahov et al., 1989) indicated that 85% of these infections were linked to intravenous drug use. More recent estimates identify this rate to be closer to one-half (Dean et al., 2002). In addition, other factors are likely to contribute to the elevated HIV risk in incarcerated individuals including poverty, unemployment, lack of health care access (Hammet, Harmon, & Maruschak, 1999), and social networks that include high-risk associates (Friedman et al., 1999).

Individuals in the criminal justice system have been found to be at a particularly high risk for HIV/AIDS infection and transmission. The relatively high prevalence rate for HIV infection has been well established in incarcerated populations. Nationwide, an estimated 22,144 HIV positive inmates were in state and federal prisons at the end of December 2008, accounting for 1.5% of the total prison population (Maruschak, 2009), almost four times higher than in the total U.S. population. Among them were 5,113 confirmed AIDS cases accounting for 0.4% of the total prison population. Furthermore, it has been estimated that 17%–25% of HIV-infected individuals pass through the prison system annually (Braithwaite & Arriola, 2003; Spalding et al., 2009).

Although the primary focus of HIV prevention efforts for the criminal justice system has been on incarcerated populations (e.g., Braithwaite & Arriola, 2003; Hammet et al., 1999), the majority of offenders are actually not incarcerated but rather are under community supervision, with over five million offenders on probation or parole (Glaze & Bonczar, 2009). Rates of drug involvement are particularly high in this population, putting them at higher risk for HIV infection. At the end of 2008, 30% of probationers had been charged with drug offenses and another 17% had been charged with driving while impaired (DWI). Approximately 37% of parolees had served a sentence for a drug offense. Belenko et al. (2004) examined the prevalence of HIV and risk behaviors in a sample of offenders who were under community supervision. They reported HIV/AIDS prevalence rates that mirrored those observed in inmates, rates of injection drug use that were slightly higher, and a high prevalence of risky sex behaviors.

Little research has focused on the rates of engagement in HIV risk behaviors in other types of community corrections settings. For instance, Drug Courts are one of the most empirically supported approaches for successfully diverting drug using offenders from incarceration to drug treatment and case management in the community (e.g., Aos et al., 2001; Latimer, Morton-Bourgon, & Chretien, 2006; Lowenkamp, Holsinger, & Latessa, 2005; Marlowe, DeMatteo, & Festinger, 2003; Marlowe, Festinger, & Lee, 2004; Wilson, Mitchell, & MacKenzie; Schaffer, 2006). Drug Courts are special criminal court dockets that provide a judicially supervised regimen of substance abuse treatment and other needed services for nonviolent, substance-abusing offenders in lieu of criminal prosecution or incarceration (Marlowe et al., 2008). The first Drug Court was established in 1989, and there are now more than 2,500 Drug Courts in the United States and its territories (National Association of Drug Court Professionals, 2011). Given the rapid expansion of Drug Courts to serve the needs of drug-involved offenders and the high prevalence of HIV risk behaviors that have been identified among other substance-abusing criminal justice populations, it is important to understand the prevalence of HIV risk behaviors among this growing population.

The purpose of this descriptive paper is to examine the prevalence of HIV drug and sex risk behaviors in a sample of participants from one felony Drug Court located in Philadelphia, Pennsylvania. Nearly two-thirds of all people living with HIV/AIDS in the city of Philadelphia are African–American, 75% are males, and almost two-thirds are under the age of 40 (Philadelphia Department of Public Health, 2009). Given these demographic disparities in HIV/AIDS rates in the city of Philadelphia, we also examined the relationship between race, gender, and age and engagement in high-risk behaviors. Findings from the study may provide an important first step in establishing the need for evidence-based HIV risk reduction interventions as a standard part of the Drug Court curriculum.

METHOD

Participants

A total of 269 participants were recruited from a felony preadjudication Drug Court located in the urban City of Philadelphia. To be eligible for the Drug Court program, participants are required to (1) be at least 18 years of age; (2) be charged with a nonviolent felony offense; (3) have no more than two prior nonviolent convictions, juvenile adjudications, or diversionary opportunities; (4) be in need of treatment for drug abuse or dependence as assessed by a clinical case manager employed by the court; and (5) be willing to participate in the Drug Court program for at least twelve months. Consecutive admissions over a 22-month period were approached at entry about their willingness to participate in the study, and the consent rate was 75% (269 of 360).

The study participants were primarily male (80%) and most self-identified as African–American (61%), Caucasian (18%), or Hispanic (24%). Their mean age was 24.31 years (SD = 7.55) and their mean educational attainment was 11.25 years (SD = 1.57). Less than one-half (44%) were regularly employed full or part time. Virtually all of the participants were unmarried (98%) and many lived in the homes of family or friends (61%) or in a controlled environment such as recovery housing (8%). They reported an average annual legal income of $7,040 ($SD$ = $9,077) with a range of $0–$55,000. Approximately 73% reported

marijuana as their primary drug of abuse, and 13% had a history of prior substance abuse treatment.

Nearly all of the participants (97%) were currently charged with delivery of a controlled substance or possession with the intent to deliver a controlled substance. In addition, 28% were charged with conspiracy related to a drug offense, and small proportions were charged with forgery (1%), felony retail theft (1%), or prostitution (1%) (participants could have multiple charges). They had an average history of 1.15 ($SD = 0.71$) criminal arrests prior to their current charge. Most participants were represented by a public defender (84%).

To monitor potential selection bias, demographic data and criminal records were obtained for individuals who did not participate in the study. These data were received in aggregate batches from the Drug Court and were de-identified. Individuals who did not participate in the study were more likely to be male (91% vs. 80%), $X^2(1) = 7.76$, $p < .005$, African–American (75% vs. 61%), $X^2(1) = 6.78$, $p < .01$, and represented by private defense counsel (22% vs. 16%), $X^2(1) = 3.57$, $p = .06$.

Procedures

Study procedures were approved by the Institutional Review Boards of the Treatment Research Institute and the City of Philadelphia. After participants provided informed consent to participate in the study, a research assistant administered a battery of instruments to the participants in a private room. The battery included a health behavior survey that contained six items designed to evaluate the extent to which participants engaged in drug use and sexual behaviors in the past six months that increased their risk for HIV infection. Three items were related to intravenous drug use (i.e., number of times injected drugs, number of people shared needles with, frequency of needle cleaning rated on a five-point Likert-type scale), and three items were related to high-risk sexual behavior (i.e., number of sexual partners, number of same-gender partners, frequency of condom use rated on a five-point Likert-type scale). Importantly, these items were adapted from the well-validated Risk Assessment Battery (RAB) (Metzger, Navaline, & Woody, 2001) and were selected to measure rates of engagement in HIV risk behaviors that are

directly responsible for viral transmission. The 6-month time frame was selected to capture a representative sample of recent risk behavior and is standard for the RAB.

Data Analyses

Response frequencies were calculated for each item, and the results of these descriptive analyses are presented in the section that follows. In addition, chi-square analyses were used to examine differences in the rates of engagement in high-risk behaviors as a function of race (African–American vs. other) and gender. Correlation analyses were performed to examine the relationship between engagement in these behaviors and age among sexually active study participants. Finally, we used participant zip codes to map our study sample to the population-adjusted geographic concentration of HIV/AIDS in Philadelphia in order to identify their risk of coming into contact with the virus.

RESULTS

Drug-Use Risk Behaviors

Only two people in the sample (0.7%) reported injection drug use in the past six months. Both of these individuals indicated sharing needles with one person in the past six months and that they had cleaned their needles prior to use.

Sexual Risk Behaviors

Approximately 54% of participants reported having sex with multiple partners in the past six months, while 41% reported having only one partner and 6% reported not being sexually active during this time period. The average number of partners for those reporting multiple partners was 6.12 ($SD = 11.20$). Three percent of participants reported having sexual relations with same-gender partners.

Frequency of condom use among those who were sexually active ($N = 244$) is presented in Figure 1 following. Almost two-thirds (62%) reported engaging in unprotected sex at least once in the past six months, and 26% reported never using a condom during sexual activity. Among

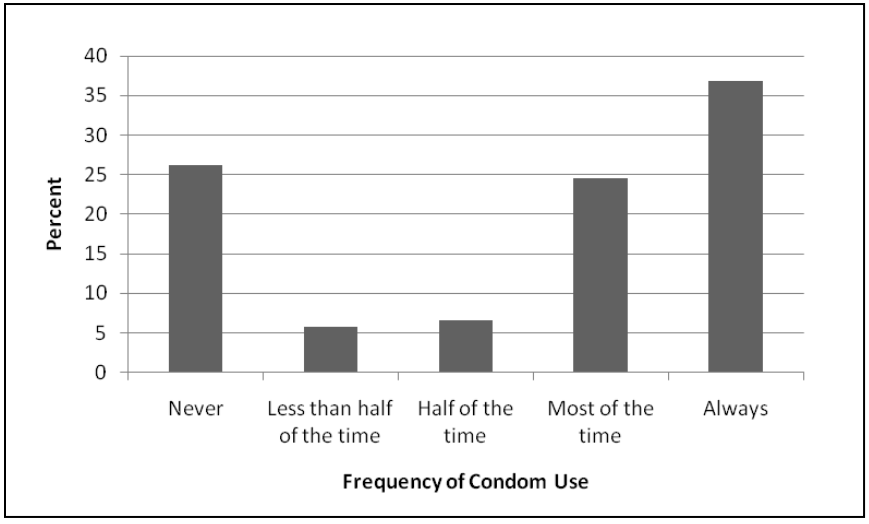


Figure 1. Frequency of Condom Use in Sexually Active Sample (*N* = 244)

those who had multiple partners ($N = 139$), 52% reported engaging in unprotected sex at least once in the past six months. Within the small sample of participants with same-gender partners ($N = 9$), 56% reported never using a condom and 44% reported always using a condom.

Gender Differences in Sexual Risk Behaviors

Within the sexually active sample, males were significantly more likely to report having multiple sexual partners in the past six months (63% vs. 30%, $X^2(1) = 16.28$, $p < .0001$). On average, men reported 4.51 ($SD = 9.69$) sexual partners and females reported 1.37 ($SD = 0.61$). There was a trend for males to be more likely to report having sex without a condom than females (74% vs. 61%, $p < .10$). While the overall rate was low, females were more likely than males to report having same-gender sexual partners (17% vs. 1%, $p < .0001$, Fisher's exact test).

Racial Differences in Sexual Risk Behaviors

Within the sexually active sample, African–Americans were significantly more likely to report having multiple sexual partners than members of other racial groups (63% vs. 47%, $X^2(1) = 5.92$, $p < .05$. There

were no significant differences in the reporting of sexual activity without a condom (60% vs. 67%, $p = .19$) or having same-gender sexual partners (4% vs. 3%, $p = 1.0$, Fisher's exact test).

Age Differences in Sexual Risk Behaviors

Within the sexually active sample, age was significantly related to reporting multiple sexual partners ($r = -.15$, $p < .05$). The likelihood of reporting multiple sexual partners decreased as a function of age. There was a nonsignificant trend for condom use to decrease as a function of age ($r = .11$, $p < .10$). Age was not related to having same-gender sexual partners ($p = .21$).

Zip Code Mapping

As displayed in Figure 2, over one-third of the Drug Court participants in this study resided in Philadelphia zip code areas with the highest prevalence (1%–4%) of the adult population currently living with AIDS.

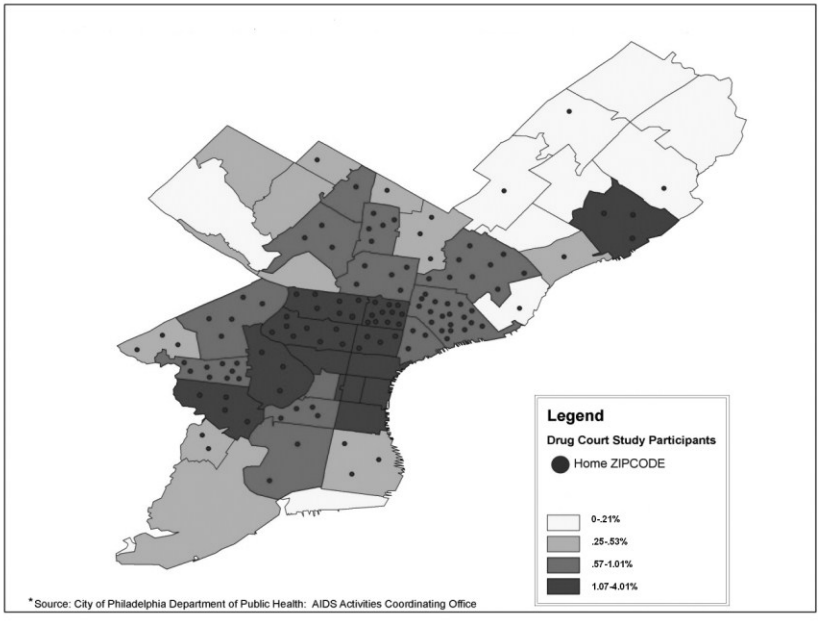


Figure 2. Prevalence of Persons Living with AIDS in Philadelphia by Participant Zip Code

Fully 80% were from zip code areas with over 0.5% prevalence of adults living with AIDS.

DISCUSSION

The current study is among the first to provide estimates of the prevalence of HIV risk behaviors in a Drug Court population. Understanding the extent to which Drug Court participants engage in behaviors that put them at risk for contracting HIV infection is important for a number of reasons. First, research has demonstrated that individuals who are involved in the criminal justice system are at high risk of contracting HIV. In addition, criminally involved offenders who are under supervision in the community have more opportunities to engage in risky behaviors than persons in prison, which may increase their risk of contracting HIV infection. Finally, Drug Courts are becoming an increasingly popular diversion strategy for criminally involved substance abusers. The size of this population is expected to increase exponentially as more and more Drug Courts are established. Understanding the prevalence of HIV risk behaviors among Drug Court participants will help us to determine the extent of the need for HIV risk reduction interventions in Drug Court programs.

Rates of HIV drug risk behaviors were low in the current sample. The rate of injection drug use was 0.7%, only slightly higher than the rate reported for probationers and parolees (0.15%) (Belenko et al., 2004) and in the general population (0.17% in the past year) (Substance Abuse and Mental Health Services Administration, 2009). Importantly, the rate of injection drug use in the Drug Court sample is significantly lower than the rates reported among prisoners (e.g., Abiona et al., 2009; Swartz, Lurigio, & Weiner, 2004; Fox et al., 2005). Of the two people who reported any injection drug use in the past six months, both indicated that they cleaned their needles prior to use. Of course, we cannot verify the effectiveness of their cleaning methods or needle sharing behaviors. While one may have expected higher rates of IV drug use in this felony Drug Court, this rate is not surprising given the fact that almost three-fourths of the sample reported marijuana as their primary drug of abuse.

Conversely, Drug Court participants engaged in a number of sexual behaviors that may increase their risk of contracting HIV. Over half of the sample indicated they had sex with multiple partners in the past six month, and two-thirds of the sexually active sample reported having sex without a condom at least once during the past six months. About half of participants who reported having multiple partners indicated that they had sex without a condom at least once during the past six months. These rates are slightly higher than those reported in a sample of probationers and parolees (Belenko et al., 2004). Among probationers and parolees, about half (48%) of individuals reported having vaginal sex with casual partners in the past six months. Of those with casual partners, a little more than a third (38%) reported having sex without a condom at least once in the past six months. Among the general population, estimates of the percentage of people who have had sex with multiple partners during the past year range from 9% to 13% (Holtzman, Bland, Lansky, & Mack, 2001; Leigh, Temple, & Trocki, 1993).

Consistent with the disparities in the rate of HIV transmission in the U.S. (CDC, 2008) and in line with data specific to the City of Philadelphia (Philadelphia Department of Public Health, 2009), significantly higher rates of engagement in risky behaviors were associated with being African–American and male. Results related to age were mixed. While younger people were significantly more likely to have multiple partners, there was a nonsignificant trend for them to be more likely to use condoms every time they had sex. The results related to age are consistent with those observed in other studies (e.g., Binson et al., 1993; Dolcini et al., 1993; Leigh, Temple, & Trocki, 1993; Reece et al.; Sanders et al., 2010).

Perhaps the most striking finding comes from the results of the zip code mapping analysis. Over a third of Drug Court participants resided in areas of Philadelphia with the highest density of persons living with AIDS (i.e., 1%–4%). According to the World Health Organization, an epidemic is considered generalized when greater than 1% of the population is infected. This designation not only provides a measure of prevalence but also indicates the increased potential for individuals to come in contact with the virus. In high-prevalence settings, most unprotected sex

can be considered high risk. In the current sample, the great majority of participants come from high prevalence neighborhoods, and all have a history of substance use, which is associated with sexual risk and infection among heterosexuals and MSM (Metzger, Woody, & O'Brien, 2010).

This study has several limitations. First, the study relies on self-reported data that were collected during a face-to-face interview. Participants may have felt embarrassed or uncomfortable answering questions of such a personal nature and, for this reason, may have under-reported their engagement in drug and sexual risk behaviors. Second, the risk instrument had a limited number of items and was intended to be a survey rather than a risk scale. For this reason, we could not calculate composite risk scores. Future studies should evaluate HIV risk using validated risk measures that provide composite scores and that can be self-administered to help reduce self-presentation concerns (e.g., Audio Computer Assisted Self Interview RAB) (Metzger et al., 2000). Third, 25% of those approached refused to participate in the study. Because participants who refused were more likely to be male and African–American, the prevalence rates of high-risk behaviors cited in the present study may be an underestimate of rates in the Drug Court population as a whole. Finally, the study examines the prevalence of HIV risk behaviors in a single felony Drug Court in Philadelphia. Future research should be conducted in other settings in order to evaluate the generalizability of the current findings.

Despite their proven efficacy in addressing substance abuse and criminal recidivism, Drug Courts have yet to be evaluated with respect to HIV and sexually transmitted infection (STI) risk reduction. Given the prevalence of high-risk behaviors (e.g., Belenko at al., 2004) and the alarming rates of HIV infection and STIs among criminal offenders (14%–26%) (Hammet, Harmon, & Rhodes, 2002; Spaulding et al., 2009) along with the rates of high-risk behaviors found in the current study, Drug Courts may represent an important yet unexplored opportunity to deliver risk reduction interventions, HIV testing, and referral to HIV care. Research should be expanded to further document the prevalence of high-risk behaviors among Drug Court participants and to identify useful strategies for reducing risk.

This research was supported by grant #R01-DA-14566 from the National Institute on Drug Abuse (NIDA). This research has been approved by the Institutional Review Boards of the Treatment Research Institute and the City of Philadelphia. The views expressed are those of the authors and do not necessarily reflect the views of NIDA.

The authors gratefully acknowledge the continuous collaboration of the staff and clients of the Philadelphia Treatment Court as well as the Office of the District Attorney of Philadelphia, Defender Association of Philadelphia, Philadelphia Coordinating Office of Drug and Alcohol Abuse Programs, and Philadelphia Health Management Corporation. We also thank Patricia Arabia, Jason Croft, Gloria Fox, Matthew Haines, and Jason Matejkowski for their assistance with this project.

REFERENCES

Abiona, T., Balogun, J., Adefuye, A., & Sloan, P. (2009). Pre-incarceration HIV risk behaviours of male and female inmates. *International Journal of Prisoner Health, 5*(2), 59–70.

Aos, S., Phipps, P., Barnoski, R., & Lieb, R. (2001). The comparative costs and benefits of programs to reduce crime. *Costs and Benefits of Preventing Crime,* 3–19.

Bagby, G.J., Zhang, P., Purcell, J.E., Didier, P.J., & Nelson, S. (2006). Chronic binge ethanol consumption accelerates progression of simian immunodeficiency virus disease. *Alcoholism: Clinical and Experimental Research, 30*(10), 1781–1790.

Belenko, S., Langley, S., Crimmins, S., & Chaple, M. (2004). HIV risk behaviors, knowledge, and prevention education among offenders under community supervision: A hidden risk group. *AIDS Education and Prevention, 16*(4), 367–385.

Belenko, S., & Peugh, J. (2005). Estimating drug treatment needs among state prison inmates. *Drug and Alcohol Dependence, 77*(3), 269–281.

Binson, D., Dolcini, M.M., Pollack, L.M. & Catania, J.A. (1993). Multiple sexual partners among young adults in high-risk cities. *Family Planning Perspectives, 25*(6), 268–272.

Braithwaite, R., & Arriola, K. (2003). Braithwaite and Arriola respond. *American Journal of Public Health, 93*(10), 1617.

Brewer, T.H., Zhao, W., Metsch, L.R., Coltes, A., & Zenilman, J. (2007). High-risk behaviors in women who use crack: Knowledge of HIV serostatus and risk behavior. *Annals of Epidemiology, 17*(7), 533–539.

Celentano, D.D., Latimore, A.D., & Mehta, S.H. (2008). Variations in sexual risks in drug users: Emerging themes in a behavioral context. Current *HIV/AIDS Reports, 5*(4), 212–218.

Center for Disease Control and Prevention. (2008). Subpopulation estimates from the HIV Incidence Surveillance System—United States, 2006. *Morbidity*

and Mortality Weekly Report, 57(36), 985–989.

Cheng, W.S., Garfein, R.S., Semple, S.J., Strathdee, S.A., Zians, J.K., & Patterson, T.L. (2010). Binge use and sex and drug use behaviors among HIV(-), heterosexual methamphetamine users in San Diego. *Substance Use & Misuse, 45*(1–2), 116–133.

Dean, H.D., Lansky, A., & Fleming, P.L. (2002). HIV surveillance methods for the incarcerated population. *AIDS Education and Prevention, 14*(5 Supplement), 65–74.

Dolcini, M.M., Catania, J.A., Coates, T.J., Stall, R., Hudes, E.S., Gagnon, J.H. & Pollack, L.M. (1993). Demographic characteristics of heterosexuals with multiple partners: The National AIDS Behavioral Surveys. *Family Planning Perspectives, 25*(5), 208–214.

Fox, R.K., Currie, S.L., Evans, J., Wright, T.L., Tobler, L., Phelps, B., & Page-Shafer, K.A. (2005). Hepatitis C virus infection among prisoners in the California state correctional system. *Clinical Infectious Diseases, 41*(2), 177–186.

Friedman, S.R., Curtis, R., Neaigus, A., Jose, B., & Des Jarlais, D.C. (1999). *Social networks, drug injectors' lives, and HIV/AIDS*. New York: Kluwer Academic.

Glaze, L.E., & Bonczar, T.P. (2009). *Probation and parole in the United States, 2008* (NCJ 228230). Retrieved from U.S. Department of Justice, Office of Justice Programs, Bureau of Justice Statistics website: http://bjs.ojp.usdoj.gov/index.cfm?ty=pbdetail&iid=1764.

Hall, H.I., Song, R., Rhodes, P., Prejean, J., An, Q., Lee, L.M., et al. (2008). Estimation of HIV incidence in the United States. *JAMA: Journal of the American Medical Association, 300*(5), 520–529.

Hammett, T., Harmon, P., & Maruschak, L. (1999). 1997 update: HIV/AIDS, STDs, and TB in correctional facilities. *Issues and practices in criminal justice.* Washington, DC: National Institute of Justice, U.S. Department of Justice.

Hammett, T.M., Harmon, M.P., & Rhodes, W. (2002). The burden of infectious disease among inmates of and releasees from U.S. correctional facilities, 1997. *American Journal of Public Health, 92*(11), 1789–1794.

Hammett, T.M., Harold, L., Gross, M., & Epstein, J. (1994). *HIV AIDS in correctional facilities: Issues and options.* Washington, DC: National Institute of Justice.

Holtzman, D., Bland, S.D., Lansky, A., & Mack, K.A. (2001). HIV-related behaviors and perceptions among adults in 25 states: 1997 Behavioral Risk Factor Surveillance System. *American Journal of Public Health, 91*(11), 1882–1888.

James, D. (1988). Prison, mental illness, and identity. *Lancet, 2*(8624), 1371.

Kwiatkowski, C.F., & Booth, R.E. (2000). Differences in HIV risk behaviors among women who exchange sex for drugs, money, or both drugs and money. *AIDS and Behavior, 4*(3), 233–240.

Latimer, J., Morton-Bourgon, K., & Chretien, J. (2006). *A meta-analytic examination of drug treatment courts: Do they reduce recidivism?* Retrieved from Department of Justice Canada, Research and Statistics Division website: http://www.justice.gc.ca/eng/pi/rs/rep-rap/2006/rr06_7/rr06_7.pdf.

Leigh, B.C., Temple, M.T., & Trocki, K.F. (1993). The sexual behavior of U.S. adults: Results from a national survey. *American Journal of Public Health, 83*(10), 1400–1408.

Lowenkamp, C.T., Holsinger, A.M., & Latessa, E.J. (2005). Are drug courts ef-

fective: A meta-analytic review. *Journal of Community Corrections, Fall,* 5–28.

Marlowe, D.B., DeMatteo, D.S., & Festinger, D.S. (2003). A sober assessment of drug courts. *Federal Sentencing Reporter. 16,* 153–157.

Marlowe, D.B., Festinger, D.S., Dugosh, K.L., Arabia, P.L., & Kirby, K.C. (2008). An effectiveness trial of contingency management in a felony preadjudication drug court. *Journal of Applied Behavior Analysis, 41*(4), 565–577.

Marlowe, D.B., Festinger, D.S., & Lee, P.A. (2004). The judge is a key component of drug court. *Drug Court Review, 4*(2), 1–34.

Maruschak, L.M., & Beavers, R. (2009). *HIV in prisons,* 2007–08 (NCJ 228307). Retrieved from U.S. Department of Justice, Office of Justice Programs, Bureau of Justice Statistics website: http://bjs.ojp.usdoj.gov/index.cfm?ty=pbdetail&iid=1747.

Metzger, D.S., Koblin, B., Turner, C., Navaline, H., Valenti, F., Holte, S., et al. (2000). Randomized controlled trial of audio computer-assisted self-interviewing: utility and acceptability in longitudinal studies. American *Journal of Epidemiology, 152*(2), 99–106.

Metzger, D.S., Navaline, H.A., & Woody, G.E. (2001). Assessment of substance abuse: HIV risk assessment battery (RAB). In R. Carson-DeWitt (Eds.), *Encyclopedia of drugs, alcohol, and addictive behavior, 2nd Ed.* Macmillan-Thompson/Gale.

Metzger, D.S., Woody, G.E., & O'Brien, C.P. (2010). Drug treatment as HIV prevention: A research update. *Journal of Acquired Immune Deficiency Syndromes, 55*(Suppl. 1)*,* S32–S36.

Molitor, T.W., Bautista, E.M.. & Choi, C.S. (1997). Immunity to PRRSV: double-edged sword. *Veterinary Microbiology 55,* 265–276.

National Association of Drug Court Professionals. (2011). *The facts on drugs and crime in America.* Washington, DC: Office of Justice Programs, U.S. Department of Justice.

Philadelphia Department of Public Health. (2009). *Philadelphia AIDS demographics, 2002–2008.* Retrieved from Philadelphia Department of Public Health Web site: http://www.phila.gov/health/AACO/AACODataResearch.html.

Reece, M., Herbenick, D., Schick, V., Sanders, S.A., Dodge, B., & Fortenberry, J.D. (2010). Condom use rates in a national probability sample of males and females ages 14 to 94 in the United States. *Journal of Sexual Medicine, 7*(Suppl. 5), 266–276.

Royce, R.A., Sena, A., Cates Jr., W., & Cohen, M.S. (1997). Sexual transmission of HIV. *New England Journal of Medicine, 336*(15), 1072–1078.

Samet, J.H., Horton, N.J., Meli, S., Freedberg, K.A., & Palepu, A. (2004). Alcohol consumption and antiretroviral adherence among HIV-infected persons with alcohol problems. *Alcoholism: Clinical and Experimental Research, 28*(4), 572–577.

Samet, J.H., Horton, N.J., Traphagen, E.T., Lyon, S.M., & Freedberg, K.A. (2003). Alcohol consumption and HIV disease progression: Are they related? *Alcoholism: Clinical and Experimental Research, 27*(5), 862–867.

Sanders, S.A., Reece, M., Herbenick, D., Schick, V., Dodge, B., & Fortenberry, J.D. (2010). Condom use during most recent vaginal intercourse event among a probability sample of adults in the United States. *Journal of Sexual Medicine, 7*(Suppl. 5), 362–373.

Shaffer, D.K. (2006). *Reconsidering drug court effectiveness: A meta-analytic review*. Las Vegas, NV: Dept. of Criminal Justice, University of Nevada.

Spaulding, A.C., Seals, R.M., Page, M.J., Brzozowski, A.K., Rhodes, W., & Hammet, T.M. (2009). HIV/AIDS among inmates of and releasees from U.S. correctional facilities, 2006: Declining share of epidemic but persistent public health opportunity. *PLoS One, 4*(11).

Substance Abuse and Mental Health Services Administration, Office of Applied Studies. (October 29, 2009). *The NSDUH Report: Injection drug use and related risk behaviors.* Rockville, MD.

Swartz, J.A., Lurigio, A.J., & Weiner, D.A. (2004). Correlates of HIV-risk behaviors among prison inmates: Implications for tailored AIDS prevention programming. *The Prison Journal, 84*(4), 486.

Teplin, L.A. (1994). Psychiatric and substance abuse disorders among male urban jail detainees. *American Journal of Public Health, 84*(2), 290–293.

Vlahov D., Brewer, T.F., Munoz A., Taylor E., Hall D., & Polk B.F. (1989). Temporal trends of (HIV-1) infection among inmates entering a statewide prison system, 1985–1987. *Journal of Acquired Immune Deficiency Syndrome, 1,* 283–290.

Wilson, D.B., Mitchell, O., & MacKenzie, D.L. (2006). A systematic review of drug court effects on recidivism. *Journal of Experimental Criminology, 2*(4), 459–487.

David S. Festinger, *PhD, is a senior scientist and director of TRI's Section on Law and Ethics Research, as well as a faculty member in the Department of Psychiatry at the University of Pennsylvania School of Medicine. His research focuses primarily on empirically isolating the active mechanisms of Drug Courts, developing empirically based dispositional procedures for substance-abusing offenders, and bringing experimental research methods to bear on major ethical questions involving human subjects in substance abuse research.*

Karen L. Dugosh, *PhD, is a research scientist in TRI's Section on Law and Ethics. She has been involved in Drug Court research for almost a decade and has recently begun to examine ethical issues surrounding research participation and informed consent in vulnerable populations. Her current research focuses on the development of an assessment to measure coercive pressures to participate in research that is tailored to the doubly vulnerable population of substance-abusing offenders.*

David S. Metzger, PhD, *is director of the Behavioral and Social Science Core at the Center for AIDS Research, Director of the HIV Prevention Research Division in the University of Pennsylvania's Department of Psychiatry, and the scientific liaison for TRI and the University of Pennsylvania's Department of Psychiatry. Currently, his work involves testing the safety and efficacy of behavioral and biomedical prevention interventions including HIV vaccines, social network interventions, and agonist drug treatments.*

Douglas B. Marlowe, *JD., PhD, is chief of Science, Law and Policy at the National Association of Drug Court Professionals and senior scientist in TRI's Section on Law and Ethics. He is a lawyer and research psychologist with expertise in evaluating substance abuse interventions for criminal offenders. Dr. Marlowe has published over 150 scientific papers related to Drug Courts and other interventions for drug abusers and criminal offenders.*

Direct correspondence to David S. Festinger, PhD, Treatment Research Institute, University of Pennsylvania, 600 Public Ledger Bldg., 150 S. Independence Mall West, Philadelphia, PA 19106. (215) 399-0980 x126. dfestinger@tresearch.org

HEADNOTES INDEX

The Headnote Index provides access to an article's major points or concepts using a cumulative indexing system. Each headnote can be located by volume, issue, and headnote (e.g., VIII1[1] is the first headnote in this issue).

BALLOT INITIATIVES

IV2[13] State Ballot Initiatives Threaten Drug Court
IV2[14] Specific Initiatives Addressed

CAMPUS DRUG COURTS

IV1[1] Crime & Campus Drug Courts
IV1[2] "Hard Core" Drinkers on Campus
IV1[3] Increase in Serious Student Offenses at CSU
IV1[4] Drug Court at CSU
IV1[5] CSU Campus Drug Court Pilot
IV1[6] Process & Design
IV1[7] Campus Drug Court Team (CDCT)
IV1[8] Campus Departments Involved
IV1[9] Evaluation
IV1[10] Future

COERCION

III1[1] Coercion Necessary
III1[2] Drug Courts Successful
III1[3] National Results
III1[4] Drug Court Retention
III1[5] Social Contracting
III1[6] Contingency Management
III1[7] Participant Motivation
III1[8] Drug Courts Provide Lesson

COMMUNITY REINTEGRATION & DRUG COURTS

III2[1] Importance of Reintegration
III2[2] What is Reintegration?
III2[3] The Court's Role
III2[4] The Court's Authority
III2[5] Courts & Communities
III2[6] Risks Involved
III2[7] Judicial Ethics
III2[8] Courts & Treatment

COST ASSESSMENTS

II2[9] Evaluating Multnomah County STOP Program
II2[10] Costs in Calculating Taxpayer Savings
II2[11] Multnomah County Justice System Savings
II2[12] Cost Savings to the Oregon Citizen
II2[13] Estimated Savings of Expanding Program

COUNTYWIDE APPROACHES

III1[9] Countywide Standards
III1[10] County Comparisons
III1[11] Program Comparisons
III1[12] Stakeholder Cooperation
III1[13] LA's MIS
III1[14] Orange County's MIS
III1[15] Countywide MIS
III1[16] Countywide Success

CREATININE-NORMALIZED CANNABINOID RESULTS

IV1[19] Non-Normalized Method for Detecting Drug Use
IV1[20] Considerations in Creatinine-Normalized Cannabinoid Drug Tests
IV1[21] Creatinine-Normalized Calculations
IV1[22] Interpreting Creatinine-Normalized Ratios
V1[5] Framing the Question
V1[6] Variables
V1[7] Research Review
V1[8] Perpetuating the 30-Plus Day Assumption
V1[9] Establishing the Cannabinoid Detection Window
V1[10] Client Detoxification
V1[11] Abstinence Baseline
V1[12] Cannabinoid Testing Following Positive Results
V1[13] Court Expectations & Client Boundaries

DEFENSE ATTORNEYS
VIII1[11] Responsibilities
VIII1[12] Decision to Enter Drug Court
VIII1[13] Representation on a Drug Court Team
VIII1[14] Serving Dual Roles

DRUG COURT CRITICAL REVIEW
II2[1] Consistent Findings
II2[2] Client Characteristics
II2[3] Drug Use
II2[4] Retention & Graduation Rates
II2[5] Recidivism Rates
II2[6] Postprogram Recidivism
II2[7] Cost Savings
II2[8] Improving Drug Court Evaluation
VIII1[1] Best Practices in Drug Court
VIII1[2] Characteristics of Effective Drug Courts
VIII1[3] Characteristics of Cost-Effective Drug Courts
VIII1[4] Adult Drug Court Ranking
VIII1[5] Practices & Criminal Behavior
VIII1[6] Practices & Substance Use Outcomes
VIII1[7] High-Performance Drug Courts

DRUG COURT SYSTEM
I1[23] Limited Enrolment, Limited Impact
I1[24] Serious & Disinterested Offenders Passed over
I1[25] Probation & Communities
I1[26] Drug Courts Offer More Effective Supervision
I1[27] Offender Inclusiveness & Communities Needs
I1[28] Denver

EVALUATION
I1[1] Consistent Findings
I1[2] Retention Rates
I1[3] Population Demographics
I1[4] Supervision
I1[5] Cost Saving
I1[6] Drug Usage
I1[7] Recidivism During Program
I1[8] Recidivism
I1[9] Design Weakness

EXPUNGEMENT
V1[1] Benefits
V1[2] Methods
V1[3] Results
V1[4] Discussion

FAMILY DRUG TREATMENT COURTS (FDTC)
III1[17] Development
III1[18] Jackson County
III1[19] Criminal/Civil Cases
III1[20] Immediate Involvement
III1[21] Appropriate Treatment
III1[22] Sanctions & Incentives
III1[23] Effectiveness
III1[24] Challenges
VI1 [9] Best Practices
VI1[10] Necessary Partners & Roles
VI1[11] Defining the Mission
VI1[12] Court Calendaring Practices
VI1[13] Phase Structure & Management of Client Behavior
VI1[14] Structure
VI1[15] Case Management
VI1[16] Questions to Be Answered

HIV
VIII1[15] Risk Behaviors in Drug Court
VIII1[16] Risk Factors in Drug Court
VIII1[17] Geographic Risk

IMPACT EVALUATIONS
IV2[9] Methodologically Sound Impact Evaluations
IV2[10] Comparison Group
IV2[11] Data Collection & Analysis
IV2[12] Evaluator Involvement Critical

JAIL-BASED TREATMENT
II1[19] Jail-Based Treatment Gap
II1[20] Jail-Based Treatment & Drug Courts
II1[21] A "Working Model"
II1[22] Communication With Drug Courts
II1[23] Jail Staff Support
II1[24] Program Space
II1[25] Staff Assignment
II1[26] Follow-Up & Re-Entry Courts

JUDGE
I1[10] Role

I1[11] Role Codified
I1[12] "Judge Effect"
I1[13] Self-Assessment
I1[14] Countertransference
I1[15] Participant Attitude
I1[16] Participant Psychology
I1[17] Court Environment & Process
I1[18] Shaping the Court Environment

JUDGE AS KEY COMPONENT
IV2[1] Role
IV2[2] Research Design
IV2[3] Study Measures
IV2[4] Study Sites
IV2[5] Original Study Findings
IV2[6] Study Replication: Misdemeanor Population
IV2[7] Study Replication: Felony Population
IV2[8] Judge is Key

JUVENILE DRUG COURTS
I1[19] Santa Clara: Cost Savings,
I1[20] Santa Clara: Retention
I1[21] Wilmington: Recidivism
I1[22] Wilmington: Postprogram Recidivism
VII1[1] Effects
VII1[2] Interventions
VII1[3] Suggestions for Practice
VII1[4] Policy Implications
VII1[1] Juvenile Treatment Courts
VII1[2] Training Needs
VII1[3] Response to Training Teams

MULTISYSTEMIC THERAPY (MST)
III2[25] Treating Adolescent Substance Use Effectively
III2[26] NIDA's Thirteen Principles
III2[27] What is MST?
III2[28] Evaluating the Effectiveness of MST
III2[29] MST & the Thirteen Principles
III2[30] MST & Juvenile Drug Court
III2[31] Evaluating MST in Juvenile Drug Court

NIATX IMPROVEMENT MODEL
VIII1[8] Applying NIATx to Drug Courts
VIII1[9] Improving Participant Flow
VIII1[10] Achieving Best Practices

PARTICIPANTS' SATISFACTION
IV1[11] Other Studies
IV1[12] CDAS/NIDA Drug Court Participant Study
IV1[13] CDAS Study Format
IV1[14] Basic Client Information
IV1[15] Motivation for Drug Court
IV1[16] Clients' Thoughts on Treatment
IV1[17] Clients' Opinions on the Court
IV1[18] Conclusions on Client Perceptions

PERCEPTIONS OF DRUG COURT
II1[15] Evaluating the FTDO Program in Maricopa
II1[16] 12-Month/36-Month Outcomes
II1[17] Difficulty of Compliance
II1[18] Helpfulness, Strengths, & Weaknesses

PERFORMANCE MEASUREMENT
V2[5] What Is Performance Measurement?
V2[6] Measuring Drug Court Performance
V2[7] Conclusion

PROCESS EVALUATION
V2[8] What Are Process Evaluations?
V2[9] Who Should Conduct Evaluations?
V2[10] What Are the Critical Elements?
V2[11] What Data Are Needed?
V2[12] Methodological Rigorousness
V2[13] Experimental Design & Comparison Groups

RECIDIVISM
V2[14] What We Know Now
V2[15] Recidivism Defined
V2[16] Choosing Drug Court Participants for Analysis
V2[17] Appropriate Comparison Groups
V2[18] Ensuring Drug Court & Comparison Samples Are Comparable

RESEARCH
II1[27] Recidivism & the Utah Juvenile Court
II1[28] Delaware Drug Court Evaluation
II1[29] Florida's First Judicial Circuit Drug Court Evaluation
II1[30] Monterey County First-Year Evaluation
II1[31] Riverside County Evaluation
II2[21] Monterey County First-Year Evaluation
II2[22] Butler County CDAT Evaluation
II2[23] King County Evaluation
II2[24] Suffolk County
II2[25] Volusia County Process & Output Evaluation
II2[26] Jefferson County Impact Evaluation
II2[27] Madison County Final Evaluation
II2[28] Santa Barbara County Year Three
III1[25] Cleveland
III1[26] Allen County
III1[27] Delaware Juvenile Diversion Program
III1[28] Orange County
III1[29] Creek County
III1[30] Project Exodus (Maine)
III1[31] Denver
III2[32] Dallas County DIVERT Court
III2[33] Maine's Statewide Adult Drug Court Program
III2[34] Maine's Statewide Juvenile Drug Court Program
IV1[23] Dallas County DIVERT Court
IV1[24] North Carolina
IV2[15] New York State Evaluation
IV2[16] Saint Louis Cost-Benefit Analysis
V1[14] Four Drug Court Site Evaluation
V1[15] Alaska's Therapeutic Court Evaluation
V1[16] Maine's Adult Drug Court Program
VI1[5] Findings from Ohio
VII1[1] Youth in Juvenile Drug Courts Compared with Outpatient Treatment
VII1[1] Team Meetings & Status Hearings in Juvenile Drug Court

RESEARCH AGENDA
V2[1] Past the First Generation of Research
V2[2] National Research Advisory Committee
V2[3] National Research Agenda
V2[4] Conclusion

RETENTION
II1[8] Early Predictors
II1[9] Treatment Outcomes
II1[10] Graduate/Nongraduate Similarities
II1[11] Predictors of Program Completion
II1[12] Arrest During Follow-Up
II1[13] Predictors of Rearrest
II1[14] Using Predictors

SANCTIONS
II1[1] Increased Performance
II1[2] Sanctions Need Not Be Painful
II1[3] In the Eyes of the Behavior
II1[4] Regularity of Sanctions
II1[5] Clarification of Expected Behaviors
II1[6] Effective Punishment
II1[7] Research Potential
VI1[1] Behavior Modification
VI1[2] Methods
VI1[3] Results in Sanctioning
VI1[4] Discussions

THERAPEUTIC APPROACH
III2[9] Common Factors in Treatment
III2[10] Client Factors
III2[11] Therapeutic Relationship Factors
III2[12] Importance of Perceived Empathy
III2[13] Client Acceptance
III2[14] Role of Warmth/Self-Expression
III2[15] Hope & Expectancy
III2[16] Conveying Hope

III2[17] Hope is Future-Focused
III2[18] Empowering the Client
III2[19] Model & Technique
III2[20] The Strengths Approach
III2[21] Strength-Based Implications for Practice 1
III2[22] Strength-Based Implications for Practice 2
III2[23] Strength-Based Implications for Practice 3
III2[24] Strength-Based Implications for Practice 4

TREATMENT, PARTICIPANTS
II2[14] Successful Treatment Programs
II2[15] Therapeutic Setting
II2[16] Treatment Completion
II2[17] Cognitive Behavioral Tx: What Works
II2[18] Effective Treatment Components
II2[19] Treatment Matching
II2[20] Sanctions & Incentives

VETERANS TREATMENT COURTS
VII1[1] Development
VII1[1] Local & Legislative Initiatives

ADULT DRUG COURT BEST PRACTICE STANDARDS

VOLUME I

NATIONAL ASSOCIATION OF DRUG COURT PROFESSIONALS
ALEXANDRIA, VIRGINIA

ADULT DRUG COURT BEST PRACTICE STANDARDS

VOLUME I

NATIONAL ASSOCIATION OF DRUG COURT PROFESSIONALS
ALEXANDRIA, VIRGINIA

Printed in the United States of America.

Drug Courts perform their duties without manifestation, by word or conduct, of bias or prejudice, including, but not limited to, bias or prejudice based upon race, gender, national origin, disability, age, sexual orientation, language, or socioeconomic status.

ADULT DRUG COURT BEST PRACTICE STANDARDS COMMITTEE

COMMITTEE CO-CHAIRS

Douglas B. Marlowe, JD, PhD
Chief of Science, Law, and Policy
National Association of Drug Court Professionals
Alexandria, Virginia

Carson L. Fox, Jr., JD
Chief Operating Officer
National Association of Drug Court Professionals
Alexandria, Virginia

COMMITTEE MEMBERS

P. Karen Blackburn, MA
Program Administrator
Administrative Office of Pennsylvania Courts
Pennsylvania Supreme Court
Philadelphia, Pennsylvania

Peter Bochert,
Statewide Drug Court Coordinator
New Mexico Administrative Office of the Courts
Santa Fe, New Mexico

Shannon Carey, PhD
Executive Vice President
Sr. Research Associate
NPC Research
Portland, Oregon

Paul L. Cary, MS
Scientific Director
Toxicology Laboratory
University of Missouri Health Care
Columbia, Missouri

Fred L. Cheesman II, PhD
Principal Court Research Consultant
National Center for State Courts
Williamsburg, Virginia

Michael Finigan, PhD
President
NPC Research
Portland, Oregon

Karen Freeman-Wilson
Mayor
City of Gary, Indiana

Carolyn Hardin, MPA
Executive Director
National Drug Court Institute
Alexandria, Virginia

Mary Kay Hudson, LSW
Director of Court Services
Indiana Judicial Center
Indianapolis, Indiana

Deborah Koetzle, PhD
Associate Professor & Executive Officer
Doctoral Program in Criminal Justice
John Jay College of Criminal Justice/CUNY
New York, NY

Mike Loeffler, JD
Fellow, NDCI
Sr. Assistant District Attorney
Bristow, Oklahoma

Austine M. Long, JD
Drug Court Coordinator
Montgomery County Circuit Court
Rockville, Maryland

John N. Marr, MS
Executive Minister
Boones Creek Christian Church
Johnson City, Tennessee

William G. Meyer, JD
Managing Arbiter
Judicial Arbiter Group, Inc.
Denver, Colorado

Valerie Raine, JD
Director, Drug Court Projects
Center for Court Innovation
New York, New York

Robert G. Rancourt
Minnesota District Court Judge
Minnesota Judicial Branch
Center City, Minnesota

Aaron Roussell, PhD
Assistant Professor
Department of Criminology and Criminal Justice
Washington State University
Pullman, Washington

Richard H. Schwermer, JD
Assistant State Court Administrator
Utah Administrative Office of the Courts
Salt Lake City, Utah

Jacqueline van Wormer, PhD
Assistant Professor
Department of Criminal Justice & Criminology
Washington State University
Spokane, Washington

Carol A. Venditto, MPA
Statewide Drug Court Manager
Administrative Office of the Courts
Trenton, New Jersey

Terrence D. Walton, MSW, CSAC
Director of Treatment
Pretrial Services Agency for the District of Columbia
Washington, DC

NADCP Board of Directors Research & Standards Committee

Jeffrey S. Bagley
Chief Superior Court Judge
Cumming, Georgia

Scott W. Henggeler, PhD (Committee Chair)
Medical University of South Carolina
Charleston, South Carolina

Jamey H. Hueston
District Court Judge
Baltimore City, Maryland

Connie Payne
Executive Officer, Statewide Services
Kentucky Administrative Office of the Courts
Frankfort, Kentucky

Observers

Ruby Qazilbash, MPA
Associate Deputy Director
Bureau of Justice Assistance
Washington, DC

Holly K. Rogers, MA
Public Health Advisor
Substance Abuse & Mental Health Services Administration
Rockville, Maryland

Peer Reviewers

Kenneth Arnold
Karen Barnes
Erica Bartlett
Gray Barton
Chet Bell
Kim Bingham
Michelle Cern
David S. Festinger
Karen Gennette
Socorro Gonzalez
Dana Graham
Jennifer Grandal
Helen Harberts
Paula Hendrix
Cary Heck
Ronald Ibarra
Anne Dannerbeck Janku
Michael Jewell
Melissa Knopp
Jeff Kushner
Wendy Lindley
Jaki Livingston
Christopher Lowenkamp
Melanie G. May
Gerald Melnick
Pamela Miller
Jessica Parks
Roger Peters
Chris Pleasanton
Noreen Plumage
Angela Plunkett
Vanessa Price
Michael Rempel
Charles Robinson
Ken Robinson
Michael Roosevelt
Shelli Rossman
Robert Russell
Ron Thrasher
Robert Ward
Henry Weber
Kristin Wood
Yolanda M. Woodhouse
Carrie Zoller

Editorial

Jennifer L. Carson
Production Editor
Editcetera
Berkeley, CA

NATIONAL ASSOCIATION OF DRUG COURT PROFESSIONALS
BOARD OF DIRECTORS

CHAIR

Robert G. Rancourt
Minnesota District Court Judge
Minnesota Judicial Branch
Center City, Minnesota

NADCP BOARD OF DIRECTORS

Hon. Jeff Bagley
Cumming, Georgia

Hon. Michael J. Barrasse
Scranton, Pennsylvania

Hon. Rogelio Flores
Santa Maria, California

Hon. Evert N. Fowle
Newport, Massachusetts

Hon. Richard Gebelein
Wilmington, Delaware

Hon. Pamela Gray
Washington, DC

Hon. Bob Helfrich
Hattiesburg, Mississippi

Scott Henggeler, PhD
Charleston, South Carolina

Domingo Herraiz
Washington, DC

Mary Kay Hudson
Indianapolis, Indiana

Hon. Jamey H. Hueston
Baltimore, Maryland

Hon. Russell B. Laine
Algonquin, Illinois

Hon. Leonia J. Lloyd
Detroit, Michigan

Hon. Stephen Manley
San Jose, California

General Barry R. McCaffrey
(USA Ret.)
Alexandria, Virginia

Connie Payne
Frankfort, Kentucky

Hon. Robert G. Rancourt
Center City, Minnesota

Hon. Ruben Reyes
Lubbock, Texas

Hon. Charles Simmons
Greenville, South Carolina

Hon. Keith Starrett
Hattiesburg, Mississippi

Hon. Korey Wahwassuck
Cass Lake, Minnesota

Rev. Dr. James G. White
Milwaukee, Wisconsin

EMERITUS BOARD MEMBERS

Hon. Melanie May
West Palm Beach, Florida

Hon. Louis Presenza (Ret.)
Philadelphia, Pennsylvania

Hon. Robert Russell
Buffalo, New York

Hon. John Schwartz
Rochester, New York

Hon. Jeffrey Tauber
Albany, California

NATIONAL ASSOCIATION OF DRUG COURT PROFESSIONALS

C. West Huddleston, III
Chief Executive Officer
1029 N. Royal Street, Suite 201
Alexandria, Virginia 22314
Tel. (703) 575-9400, Fax (703) 575-9402
www.allrise.org

THE NATIONAL ASSOCIATION OF DRUG COURT PROFESSIONALS

It takes innovation, teamwork, and strong judicial leadership to achieve success when addressing drug-using offenders in a community. That's why since 1994 the National Association of Drug Court Professionals (NADCP) has worked tirelessly at the national, state, and local levels to create and enhance Drug Courts, which use a combination of accountability and treatment to support and compel drug-using offenders to change their lives.

Now an international movement, Drug Courts are the shining example of what works in the justice system. Today, there are over 2,700 Drug Courts operating in the U.S., and another thirteen countries have implemented the model. Drug Courts are widely applied to adult criminal cases, juvenile delinquency and truancy cases, and family court cases involving parents at risk of losing custody of their children due to substance abuse.

Drug Court improves communities by successfully getting offenders clean and sober and stopping drug-related crime, reuniting broken families, intervening with juveniles before they embark on a debilitating life of addiction and crime, and reducing impaired driving.

In the 24 years since the first Drug Court was founded in Miami/Dade County, Florida, more research has been published on the effects of Drug Court than on virtually all other criminal justice programs combined. The scientific community has put Drug Courts under a microscope and concluded that Drug Courts significantly reduce drug abuse and crime and do so at far less expense than any other justice strategy.

Such success has empowered NADCP to champion new generations of the Drug Court model. These include Veterans Treatment Courts, Reentry Courts, and Mental Health Courts, among others. Veterans Treatment Courts, for example, link critical services and provide the structure needed for veterans who are involved in the justice system due to substance or mental illness to resume life after combat. Reentry Courts assist individuals leaving our nation's jails and prisons to succeed on probation or parole and avoid a recurrence of drug abuse and crime. And Mental Health Courts monitor those with mental illness who find their way into the justice system, many times only because of their illness.

Today, the award-winning NADCP is the premier national membership, training, and advocacy organization for the Drug Court model, representing over 27,000 multidisciplinary justice professionals and community leaders. NADCP hosts the largest annual training conference on drugs and crime in the nation and provides 130 training and technical assistance events each year through its professional service branches, the National Drug Court Institute, the National Center for DWI Courts, and Justice for Vets: The National Veterans Treatment Court Clearinghouse. NADCP publishes numerous scholastic and practitioner publications critical to the growth and fidelity of the Drug Court model and works tirelessly in the media, on Capitol Hill, and in state legislatures to improve the response of the American justice system to substance-abusing and mentally ill offenders through policy, legislation, and appropriations.

ACKNOWLEDGEMENTS

The ***Adult Drug Court Best Practice Standards*** has been a tremendous undertaking, which would have been impossible but for the dedication and contributions of so many. This project has been continuing for more than two years, and the five standards included in Volume I are the result of countless hours of effort.

First, I thank the committee of volunteer practitioners, researchers, and subject-matter experts who gave of their time and expertise to develop the topics and materials contained in these standards. Second, I thank the peer reviewers who provided valuable feedback on each of the standards. Finally, I thank the NADCP Board of Directors for their leadership and vision in supporting this tremendous endeavor. I reserve special thanks to Dr. Douglas Marlowe, whose unwavering passion and diligence went into each word, line, and sentence of this document.

As we approach a quarter century of Drug Courts, my firm belief is these standards will move our field to an even higher level of professionalism and success. I know this document will be utilized for years to come and improve the life-saving work done every day by Drug Court practitioners across the nation.

C. West Huddleston,
Chief Executive Officer
National Association of Drug Court Professionals

ADULT DRUG COURT
BEST PRACTICE STANDARDS

INTRODUCTION 1

I TARGET POPULATION 5

Eligibility and exclusion criteria for the Drug Court are predicated on empirical evidence indicating which types of offenders can be treated safely and effectively in Drug Courts. Candidates are evaluated for admission to the Drug Court using evidence-based assessment tools and procedures.

II. HISTORICALLY DISADVANTAGED GROUPS 11

Citizens who have historically experienced sustained discrimination or reduced social opportunities because of their race, ethnicity, gender, sexual orientation, sexual identity, physical or mental disability, religion, or socioeconomic status receive the same opportunities as other citizens to participate and succeed in the Drug Court.

III. ROLES AND RESPONSIBILITIES OF THE JUDGE 20

The Drug Court judge stays abreast of current law and research on best practices in Drug Courts, participates regularly in team meetings, interacts frequently and respectfully with participants, and gives due consideration to the input of other team members.

IV. INCENTIVES, SANCTIONS, AND THERAPEUTIC ADJUSTMENTS 26

Consequences for participants' behavior are predictable, fair, consistent, and administered in accordance with evidence-based principles of effective behavior modification.

V. SUBSTANCE ABUSE TREATMENT 38

Participants receive substance abuse treatment based on a standardized assessment of their treatment needs. Substance abuse treatment is not provided to reward desired behaviors, punish infractions, or serve other nonclinically indicated goals. Treatment providers are trained and supervised to deliver a continuum of evidence-based interventions that are documented in treatment manuals.

APPENDIX A. VALIDATED RISK AND NEED ASSESSMENT TOOLS 55

APPENDIX B. ON-LINE WEBINARS ON BEST PRACTICES IN DRUG COURTS 56

ADULT DRUG COURT
BEST PRACTICE STANDARDS

INTRODUCTION

This expansion of drug courts throughout the country makes it critical to ensure that the standards for drug court implementation and operations are effectively disseminated to the field. With funding and technical assistance provided through [NADCP's] National Drug Court Institute, the Administration supports the dissemination of these standards and related training for new and existing drug courts…

—White House, Office of National Drug Control Policy (2012; p. 20)

In 1996, a small group of Drug Court professionals convened to describe the key ingredients of the Drug Court model. Published early the following year, *Defining Drug Courts: The Key Components* (NADCP, 1997) [hereafter the *Ten Key Components*] became the core framework not only for Drug Courts but for most types of problem-solving court programs.

At the time, these farsighted practitioners had little more to go on than their instincts, personal observations, and professional experiences. The research literature was still equivocal about whether Drug Courts worked and was virtually silent on the questions of how they worked, for whom, and why. Now more than fifteen years since the *Ten Key Components* was published, science has caught up with professional wisdom. Research confirms that how well Drug Courts accomplish their goals depends largely on how faithfully they adhere to the *Ten Key Components*. Drug Courts that watered down or dropped core ingredients of the model paid dearly for their actions in terms of lower graduation rates, higher criminal recidivism, and lower cost savings. Failing to apply the *Ten Key Components* has been shown to reduce the effectiveness and cost-effectiveness of Drug Courts by as much as one half (Carey et al., 2012; Downey & Roman, 2010; Gutierrez & Bourgon, 2012; Shaffer, 2010; Zweig et al., 2012).

From Principles to Standards

Science has accomplished considerably more than simply validating the *Ten Key Components*. It is putting meat on the bones of these broad principles, in effect transforming them into practice standards (Marlowe, 2010). Armed with specific guidance about how to operationalize the *Ten Key Components*, Drug Courts can be more confident in the quality of their operations, researchers can measure program quality in their evaluations, and trainers can identify areas needing further improvement and technical assistance.

Until Drug Courts define appropriate standards of practice, they will be held accountable, fairly or unfairly, for the worst practices in the field. Scientists will continue to analyze the effects of weak Drug Courts alongside those of exceptional Drug Courts, thus diluting the benefits of Drug Courts. Critics will continue to tarnish the reputation of Drug Courts by attributing to them the most noxious practices of the feeblest programs. Only by defining the bounds of acceptable and exceptional practices will Drug Courts be in a position to disown poor-quality or harmful programs and set effective benchmarks for new and existing programs to achieve.

Procedures

A little more than two years ago, the NADCP embarked on an ambitious project to develop these *Adult Drug Court Best Practice Standards*. The standards were drafted by a diverse and multidisciplinary committee comprising Drug Court practitioners, subject matter experts, researchers, and state and federal policymakers. Each draft standard was peer reviewed subsequently by between thirty and forty practitioners and researchers with expertise in the relevant subject matter. The peer reviewers rated the standards anonymously along the dimensions of clarity (what specific practices were required), justification (why those practices were required), and feasibility (how difficult it would be for Drug Courts to accomplish the practices). All of the standards received ratings from good to excellent and were viewed as being achievable by most Drug Courts within a reasonable period of time.

None of the requirements contained in these standards should come as a surprise to Drug Court professionals who have attended a training workshop or conference within the past five years. The research supporting the standards has been disseminated widely to the Drug Court field via conference presentations, webinars, practitioner fact sheets, and NDCI's scholarly journal, the *Drug Court Review* (Marlowe, 2012). This document is simply the first to compile and distill that research into concrete and measurable practice recommendations.

Scope

The standards contained herein do not address every practice performed in a Drug Court. Unless there was reliable and convincing evidence demonstrating that a practice significantly improves outcomes, it was not incorporated into a best practice standard. This should, in no way, be interpreted as suggesting that omitted practices were viewed as unimportant or as less important than the practices that were included. Practices were omitted simply because the current state of the research was insufficient for the Committee to impose an affirmative obligation on the field to alter its operations. New practices will be added to the standards as additional studies are completed.

These standards were developed specifically for adult Drug Courts. This is not to suggest that adult Drug Courts are more effective or valued than other types of Drug Courts, such as juvenile Drug Courts, DWI courts, family Drug Courts, or veterans treatment courts. Adult Drug Courts simply have far more research on them than other types of problem-solving courts. When a sufficient body of research has identified best practices for other problem-solving court programs, NADCP will release best practice standards for those programs as well.

This document represents the first of two parts. Contained herein are best practice standards related to the following five topics:

I. Target Population
II. Historically Disadvantaged Groups
III. Roles and Responsibilities of the Judge
IV. Incentives, Sanctions, and Therapeutic Adjustments
V. Substance Abuse Treatment

Volume II, scheduled to be released in mid-2014, will contain five to seven additional standards focusing on drug and alcohol testing, ancillary services, census and caseloads, team functioning, professional training, and research and evaluation.

Standard I begins by addressing the appropriate target population for a Drug Court. It is essential to recognize that every standard that follows assumes the Drug Court is treating the intended participants. If this precondition is not met, then the ensuing standards might, or might not, be applicable. It is not possible to prescribe an effective course of action for a Drug Court until and unless its participant population has been carefully defined.

Aspirational and Obligatory

The terms *best practices* and *standards* are rarely used in combination. Best practices are aspirational whereas standards are obligatory and enforceable. Many professions choose instead to use terms such as *guidelines* or *principles* to allow for latitude in interpreting and applying the indicated practices (e.g., American Psychological Association, 2013). Other professions have focused on enforcing minimum standards for competent practice rather than defining best practices for the field. In other words, they have focused on defining the floor of acceptable practices rather than the ceiling of optimal practices.

The NADCP chooses to combine aspirational and obligatory language because best practice standards may be ambitious at present, but they are expected to become obligatory and enforceable within a reasonable period of time. Once best practices have been defined clearly for the field, it is assumed that Drug Courts will comport their operations accordingly. How long this process should take will vary from standard to standard. Drug Courts should be able to comply with some of the standards within a few months, if they are not already doing so; however, other standards might require three to five years to satisfy.

Conclusion

In an era of shrinking public resources and accelerating demands for community-based alternatives to incarceration, why would the NADCP put even greater responsibilities on Drug Courts to improve their services and operations? Shouldn't NADCP instead focus on serving more and more offenders with fewer resources?

The truth is that Drug Courts have always placed inordinate demands on themselves. Dissatisfied with what was currently being done and had always been done, Drug Courts pushed through the envelope and redesigned the criminal justice system. They brushed aside old paradigms and changed the very language of justice reform. Old terms such as *accountability* were redefined and reconceptualized, and new terms such as *therapeutic jurisprudence* and *proximal behaviors* were introduced into the criminal justice lexicon. Asking a lot of Drug Courts is nothing more than business as usual.

Best practice standards reflect the hard-won knowledge of the Drug Court field garnered from nearly a quarter century of earnest labor and honest self-appraisal. As more and more programs come on line, Drug Courts must take advantage of this institutional memory and avoid relearning the painful lessons of the past. Drug Courts cannot allow new programs to drift from the original

model or dilute its powerful effects. The price of membership in the Drug Court field is excellence.

The goal of these Best Practice Standards is not to constrain ingenuity or penalize divergence. Rather, the goal is to provide education and practice pointers for a maturing field, which the NADCP has always done for the benefit of Drug Court professionals, participants, and their communities.

REFERENCES

American Psychological Association. (2013). Guidelines for psychological practice in health care delivery systems. *American Psychologist, 68*(1), 1–6.

Carey, S.M., Mackin, J.R., & Finigan, M.W. (2012). What works? The Ten key components of Drug Court: Research-based best practices. *Drug Court Review*, *8(1),* 6–42.

Downey, P.M., & Roman, J.K. (2010). *A Bayesian meta-analysis of drug court cost-effectiveness*. Washington, DC: The Urban Institute.

Gutierrez, L., & Bourgon, G. (2012). Drug treatment courts: A quantitative review of study and treatment quality. *Justice Research & Policy, 14*(2), 47–77.

Marlowe, D.B. (2010). *Putting meat on the bones of the 10 Key Components. ALLRISE Magazine, 2*(2), 12.

Marlowe, D.B. (Ed.) (2012). Special Issue on Best Practices in Drug Courts. *Drug Court Review, 8*(1).

National Association of Drug Court Professionals (1997). *Defining drug courts: The key components* (NCJ No. 205621). Washington, DC: Author.

Office of National Drug Control Policy. (2012). *National drug control strategy, 2012*. Washington, DC: Author. *Available at* http://www.whitehouse.gov/sites/default/files/ondcp/2012_ndcs.pdf.

Shaffer, D.K. (2010). Looking inside the black box of drug courts: A meta-analytic review. *Justice Quarterly, 28*(3)*, 493–521.*

Zweig, J.M., Lindquist, C., Downey, P.M., Roman, J., & Rossman, S.B. (2012). Drug court policies and practices: How program implementation affects offender substance use and criminal behavior outcomes. *Drug Court Review*, *8*(1), 43–79.

I. TARGET POPULATION

Eligibility and exclusion criteria for the Drug Court are predicated on empirical evidence indicating which types of offenders can be treated safely and effectively in Drug Courts. Candidates are evaluated for admission to the Drug Court using evidence-based assessment tools and procedures.

A. Objective Eligibility & Exclusion Criteria

B. High-Risk and High-Need Participants

C. Validated Eligibility Assessments

D. Criminal History Disqualifications

E. Clinical Disqualifications

A. Objective Eligibility and Exclusion Criteria

Eligibility and exclusion criteria are defined objectively, specified in writing, and communicated to potential referral sources including judges, law enforcement, defense attorneys, prosecutors, treatment professionals, and community supervision officers. The Drug Court team does not apply subjective criteria or personal impressions to determine participants' suitability for the program.

B. High-Risk and High-Need Participants

The Drug Court targets offenders for admission who are addicted[1] to illicit drugs[2] or alcohol and are at substantial risk for reoffending or failing to complete a less intensive disposition, such as standard probation or pretrial supervision. These individuals are commonly referred to as high-risk and high-need offenders. If a Drug Court is unable to target only high-risk and high-need offenders, the program develops alternative tracks with services that are modified to meet the risk and need levels of its participants. If a Drug Court develops alternative tracks, it does not mix participants with different risk or need levels in the same counseling groups, residential treatment milieu, or housing unit.

C. Validated Eligibility Assessments

Candidates for the Drug Court are assessed for eligibility using validated risk-assessment and clinical-assessment tools. The risk-assessment tool has been demonstrated empirically to predict criminal recidivism or failure on community supervision and is

---

[1] Diagnostic terminology is in flux in light of recent changes to the 5th edition of the *Diagnostic and Statistical Manual of Mental Disorders* (DSM-5). The terms *addiction* and *dependence* are defined herein in accordance with the American Society of Addiction Medicine (ASAM), which focuses on a compulsion to use or inability to abstain from alcohol or other drugs: "Addiction is characterized by inability to consistently abstain, impairment in behavioral control, craving, diminished recognition of significant problems with one's behaviors and interpersonal relationships, and a dysfunctional emotional response." Available at http://www.asam.org/for-the-public/definition-of-addiction.

[2] Illicit drugs include addictive or intoxicating prescription medications that are taken for a nonprescribed or nonmedically indicated purpose.

equivalently predictive for women and racial or ethnic minority groups that are represented in the local arrestee population. The clinical-assessment tool evaluates the formal diagnostic symptoms of substance dependence or addiction. Evaluators are trained and proficient in the administration of the assessment tools and interpretation of the results.

D. Criminal History Disqualifications

Current or prior offenses may disqualify candidates from participation in the Drug Court if empirical evidence demonstrates offenders with such records cannot be managed safely or effectively in a Drug Court. Barring legal prohibitions, offenders charged with drug dealing or those with violence histories are not excluded automatically from participation in the Drug Court.

E. Clinical Disqualifications

If adequate treatment is available, candidates are not disqualified from participation in the Drug Court because of co-occurring mental health or medical conditions or because they have been legally prescribed psychotropic or addiction medication.

COMMENTARY

A. Objective Eligibility and Exclusion Criteria

Studies have found that the admissions process in many Drug Courts included informal or subjective selection criteria, multiple gatekeepers, and numerous opportunities for candidates to be rejected from the programs (Belenko et al., 2011). Removing subjective eligibility restrictions and applying evidence-based selection criteria significantly increases the effectiveness and cost-effectiveness of Drug Courts by allowing them to serve the most appropriate target population (Bhati et al., 2008; Sevigny et al., 2013).

Some Drug Courts may screen candidates for their *suitability* for the program based on the team's subjective impressions of the offender's motivation for change or readiness for treatment. Suitability determinations have been found to have no impact on Drug Court graduation rates or postprogram recidivism (Carey & Perkins, 2008; Rossman et al., 2011). Because they have the potential to exclude individuals from Drug Courts for reasons that are empirically invalid, subjective suitability determinations should be avoided.

B. High-Risk And High-Need Participants

A substantial body of research indicates which types of offenders are most in need of the full range of interventions embodied in the *Ten Key Components of Drug Courts* (NADCP, 1997). These are the offenders who are (1) addicted to or dependent on illicit drugs or alcohol and (2) at high risk for criminal recidivism or failure in less intensive rehabilitative dispositions. Drug Courts that focus their efforts on these individuals—commonly referred to as high-risk/high-need offenders — reduce crime approximately twice as much as those serving less serious offenders (Cissner et al., 2013; Fielding et al., 2002; Lowenkamp et al., 2005) and return approximately 50% greater cost savings to their communities (Bhati et al., 2008; Carey et al., 2008, 2012; Downey & Roman, 2010).

It may not always be feasible for Drug Courts to target high-risk and high-need offenders. To gain the cooperation of prosecutors or other stakeholders, some Drug Courts may need to begin by treating less serious offenders and then expand their eligibility criteria after they have proven the safety and effectiveness of their programs. In addition, some Drug Courts may not have statutory authorization or

adequate resources to treat high-risk or high-need offenders. Under such circumstances, research indicates the programs should modify their services to provide a lower intensity of supervision, substance abuse treatment, or both. Otherwise, the programs risk wasting resources or making outcomes worse for some of their participants (Lowenkamp & Latessa, 2004). Providing substance abuse treatment for nonaddicted substance abusers can lead to higher rates of reoffending or substance abuse or a greater likelihood of these individuals eventually becoming addicted (Lovins et al., 2007; Lowenkamp & Latessa, 2005; Szalavitz, 2010; Wexler et al., 2004). In particular, mixing participants with different risk or need levels together in treatment groups or residential facilities can make outcomes worse for the low-risk or low-need participants by exposing them to antisocial peers or interfering with their engagement in productive activities, such as work or school (DeMatteo et al., 2006; Lowenkamp & Latessa, 2004; McCord, 2003; Petrosino et al., 2000). A free publication from the NDCI provides evidence-based recommendations for developing alternative tracks in Drug Courts for low-risk and low-need participants.[3]

Some evidence suggests Drug Courts may have better outcomes if they target offenders either on a pre- or postadjudication basis and do not mix these populations (Shaffer, 2006). Other studies have found no differences in outcomes regardless of whether these populations were served alone or in combination (Carey et al., 2012). It is premature to conclude whether it is appropriate to mix pre- and postadjudication populations in Drug Courts; however, Drug Courts must be mindful of the fact that the populations may differ significantly in terms of their risk or need levels. They should not be treated in the same counseling groups or residential facilities if their treatment needs or criminal propensities are significantly different.

C. Validated Eligibility Assessments

Standardized assessment tools are significantly more reliable and valid than professional judgment for predicting success in correctional supervision and matching offenders to appropriate treatment and supervision services (Andrews et al., 2006; Miller & Shutt, 2001; Wormith & Goldstone, 1984). Drug Courts that employ standardized assessment tools to determine candidates' eligibility for the program have significantly better outcomes than Drug Courts that do not use standardized tools (Shaffer, 2010).

Eligibility assessments should be performed along the dimensions of both risk and need to match offenders to appropriate levels of criminal justice supervision and treatment services, respectively (Andrews & Bonta, 2010; Casey et al., 2011; Marlowe, 2009). Most substance abuse screening tools are not sufficient for this purpose because they do not accurately differentiate substance dependence or addiction from lesser degrees of substance abuse or substance involvement (Greenfield & Hennessy, 2008; Stewart, 2009). A structured psychiatric interview is typically required to make a valid diagnosis of substance dependence or addiction and thus to ensure that a Drug Court is serving the target population. Appendix A provides information on how to obtain risk and need assessment tools that have been validated for use with addicted individuals in substance abuse treatment or the criminal justice system.

D. Criminal History Disqualifications

Some Drug Courts serve only individuals charged with drug-possession offenses or may disqualify offenders who are charged with or have a history of a serious felony. Research reveals, however, that Drug Courts yielded nearly twice the cost savings when they served addicted individuals charged with felony theft and property crimes (Carey et al., 2008, 2012). Drug Courts that served only drug-possession cases typically offset crimes that did not involve high victimization or incarceration costs, such as petty theft, drug possession, trespassing, and traffic offenses (Downey & Roman, 2010). As a result, the investment costs of the programs were not recouped by the modest cost savings that were achieved from reduced recidivism. The most cost-effective Drug Courts focused their efforts on reducing serious felony offenses that are most costly to their communities.

Mixed outcomes have been reported for violent offenders in Drug Courts. Several studies found that participants who were charged with violent crimes or had histories of violence performed as well or better

[3] Alternative Tracks in Adult Drug Courts: Matching Your Program to the Needs of Your Clients. Available at http://www.ndci.org/sites/default/files/nadcp/AlternativeTracksInAdultDrugCourts.pdf.

than nonviolent participants in Drug Courts (Carey et al., 2008, 2012; Saum & Hiller, 2008; Saum et al., 2001). However, two meta-analyses reported significantly smaller effects for Drug Courts that admitted violent offenders (Mitchell et al., 2012; Shaffer, 2010). The most likely explanation for this discrepancy is that some of the Drug Courts might not have provided adequate services to meet the need and risk levels of violent offenders. If adequate treatment and supervision are available, there is no empirical justification for routinely excluding violent offenders from participation in Drug Courts.

Although research is sparse on this point, there also appears to be no justification for routinely excluding individuals charged with drug dealing from participation in Drug Courts, providing they are drug addicted. Evidence suggests such individuals can perform as well (Marlowe et al., 2008) or better (Cissner et al., 2013) than other participants in Drug Court programs. An important factor to consider in this regard is whether the offender was dealing drugs to support an addiction or solely for purposes of financial gain. If drug dealing serves to support an addiction, the participant might be a good candidate for a Drug Court.

E. Clinical Disqualifications

Appellate cases in some jurisdictions permit Drug Courts to exclude offenders who require more intensive psychiatric or medical services than the program is capable of delivering (Meyer, 2011). Assuming, however, that adequate services are available, there is no empirical justification for excluding addicted offenders with co-occurring mental health or medical problems from participation in Drug Courts. A national study of twenty-three adult Drug Courts, called the Multisite Adult Drug Court Evaluation (MADCE), found that Drug Courts were equivalently effective for a wide range of participants regardless of their mental health conditions (Rempel et al., 2012; Zweig et al., 2012). Another study of approximately seventy Drug Courts found that programs that excluded offenders with serious mental health issues were significantly less cost-effective and had no better impact on recidivism than Drug Courts that did not exclude such individuals (Carey et al., 2012). Because mentally ill offenders are likely to cycle in and out of the criminal justice system and to utilize expensive emergency room and crisis-management resources, intervening with these individuals in Drug Courts (assuming they are drug addicted and at high risk for treatment failure) has the potential to produce substantial cost savings (Rossman et al., 2012; Skeem et al., 2011).

It is unclear how severe the mental health problems were in the above-referenced studies because psychiatric diagnoses were not reported. A Mental Health Court, Co-Occurring Disorder Court or other psychiatric specialty program might be preferable to a Drug Court for treating an individual with a major psychiatric disorder, such as a psychotic or bipolar disorder. Research does not provide a clear indication of how to make this determination. The best course of action is to carefully assess offenders along the dimensions of risk and need and match them to the most suitable programs that are available in their community. It is not justifiable to have an across-the-board exclusion from Drug Court for addicted offenders who are suffering from mental health problems or conditions.

Finally, numerous controlled studies have reported significantly better outcomes when addicted offenders received medically assisted treatments including opioid antagonist medications such as naltrexone, opioid agonist medications such as methadone, and partial agonist medications such as buprenorphine (Chandler et al., 2009; Finigan et al., 2011; National Institute of Drug Abuse, 2006). Therefore, a valid prescription for such medications should not serve as the basis for a blanket exclusion from a Drug Court (Parrino, 2002). A unanimous resolution of the NADCP Board of Directors[4] provides that Drug Courts should engage in a fact-sensitive inquiry in each case to determine whether and under what circumstances to permit the use of medically assisted treatments. This inquiry should be guided in large measure by input from physicians with expertise in addiction psychiatry or addiction medicine [see also Standard V, Substance Abuse Treatment].

[4] Available at http://www.nadcp.org/sites/default/files/nadcp/NADCP%20Board%20Statement%20on%20MAT.pdf.

REFERENCES

Andrews, D.A., & Bonta, J. (2010). *The Psychology of Criminal Conduct* (5th ed.). New Providence, NJ: Anderson.

Andrews, D.A., Bonta, J., & Wormith, J.S. (2006). The recent past and near future of risk and/or need assessment. *Crime & Delinquency, 52*(1), 7–27.

Belenko, S., Fabrikant, N., & Wolff, N. (2011). The long road to treatment: Models of screening and admission into Drug Courts. *Criminal Justice & Behavior*, *38*(12), 1222–1243.

Bhati, A.S., Roman, J.K., & Chalfin, A. (2008). *To treat or not to treat: Evidence on the prospects of expanding treatment to drug-involved offenders.* Washington, DC: Urban Institute.

Carey, S.M., Finigan, M.W., & Pukstas, K. (2008). *Exploring the key components of drug courts: A comparative study of 18 adult drug courts on practices, outcomes and costs*. Portland, OR: NPC Research. *Available at* http://www.npcresearch.com/Files/NIJ_Cross-site_Final_Report_0308.pdf.

Carey, S.M., Mackin, J.R., & Finigan, M.W. (2012). What works? The ten key components of drug court: Research-based best practices. *Drug Court Review*, *7*(1), 6–42.

Carey, S.M., & Perkins, T. (2008). *Methamphetamine users in Missouri Drug Courts: Program elements associated with success* (Final report). Submitted to the Missouri Office of the State Court Administrator.

Casey, P.M., Warren, R.K., & Elek, J.K. (2011). *Using offender risk and needs assessment information at sentencing*. Williamsburg, VA: National Center for State Courts. *Available at* http://ncsc.contentdm.oclc.org/cgi-bin/showfile.exe?CISOROOT=/criminal&CISOPTR=196.

Chandler, R.K., Fletcher, B.W., & Volkow, N.D. (2009). Treating drug abuse and addiction in the criminal justice system: Improving public health and safety. *Journal of the American Medical Association, 301*,(2) 183–190.

Cissner, A., Rempel, M., Franklin, A.W., Roman, J.K., Bieler, S., Cohen, R., & Cadoret, C.R. (2013, March). *A statewide evaluation of New York's adult drug courts: Testing which policies work best*. Paper presented at the New York Association of Drug Treatment Court Professionals Training. *Available at* http://www.nyadtcp.org/userfiles/file/presentation/The%202012%20New%20York%20State%20Drug%20Court%20Evaluation.pdf.

DeMatteo, D.S., Marlowe, D.B., & Festinger, D.S. (2006). Secondary prevention services for clients who are low risk in drug court: A conceptual model. *Crime & Delinquency, 52*(1), 114–134.

Downey, P.M., & Roman, J.K. (2010). *A Bayesian meta-analysis of drug court cost-effectiveness*. Washington, DC: Urban Institute.

Fielding, J.E., Tye, G., Ogawa, P.L., Imam, I.J., & Long, A.M. (2002). Los Angeles County drug court programs: Initial results. *Journal of Substance Abuse Treatment, 23*(3), 217–224.

Finigan, M.W., Perkins, T., Zold-Kilbourn, P., Parks, J., & Stringer, M. (2011). Preliminary evaluation of extended-release naltrexone in Michigan and Missouri drug courts. *Journal of Substance Abuse Treatment*, *41*(3), 288–293.

Greenfield, S.F., & Hennessy, G. (2008). Assessment of the patient. In M. Galanter & H.D. Kleber (Eds.)., *Textbook of substance abuse treatment* (4th ed., pp. 55–78). Washington, DC: American Psychiatric Publishing.

Lovins, L.B., Lowenkamp, C.T., Latessa, E.J., & Smith, P. (2007). Application of the risk principle to female offenders. *Journal of Contemporary Criminal Justice, 23*(4), 383–398.

Lowenkamp, C.T., Holsinger, A.M., & Latessa, E.J. (2005). Are drug courts effective: A meta-analytic review. *Journal of Community Corrections, 15*(1)*,* 5–28.

Lowenkamp, C.T., & Latessa, E.J. (2004). Understanding the risk principle: How and why correctional interventions can harm low-risk offenders. *Topics in Community Corrections, 2004,* 3–8.

Lowenkamp, C.T., & Latessa, E.J. (2005). Increasing the effectiveness of correctional programming through the risk principle: Identifying offenders for residential placement. *Criminology & Public Policy, 4*(2), 263–290.

Marlowe, D.B. (2009). Evidence-based sentencing for drug offenders: An analysis of prognostic risks and criminogenic needs. *Chapman Journal of Criminal Justice, 1*(1), 167–201.

Marlowe, D.B., Festinger, D.S., Dugosh, K.L., Arabia, P.L., & Kirby, K.C. (2008). An effectiveness trial of contingency management in a felony preadjudication drug court. *Journal of Applied Behavior Analysis, 41*(4), 565–577.

McCord, J. (2003). Cures that harm: Unanticipated outcomes of crime prevention programs. *Annals of the American Academy of Political & Social Science, 587*(1), 16–30.

Meyer, W.G. (2011). Constitutional and legal issues in drug courts. In D.B. Marlowe & W.G. Meyer (Eds.), *The drug court judicial benchbook* (pp. 159–180). Alexandria, VA: National Drug Court Institute. *Available at* http://www.ndci.org/sites/default/files/nadcp/14146_NDCI_Benchbook_v6.pdf.

Miller, J.M., & Shutt, J.E. (2001). Considering the need for empirically grounded drug court screening mechanisms. *Journal of Drug Issues, 31*(1), 91–106.

Mitchell, O., Wilson, D.B., Eggers, A., & MacKenzie, D.L. (2012). Assessing the effectiveness of drug courts on recidivism: A meta-analytic review of traditional and nontraditional drug courts. *Journal of Criminal Justice, 40*(1), 60–71.

National Association of Drug Court Professionals (1997). *Defining drug courts: The key components* (NCJ No. 205621). Washington, DC: Author.

National Institute on Drug Abuse. (2006). *Principles of drug abuse treatment for criminal justice populations* [NIH Pub. No. 06-5316]. Bethesda, MD: Author.

Parrino, M.W. & McNicholas, L. (2002). Methadone maintenance and other pharmacotherapeutic interventions in the treatment of opioid dependence. *NDCI Drug Court Practitioner Fact Sheet 3*(1), 1–4.

Petrosino, A., Turpin-Petrosino, C., & Finckenauer, J.O. (2000). Well-meaning programs can have harmful effects! Lessons from experiments of programs such as Scared Straight. *Crime & Delinquency, 46*(3), 354–379.

Rempel, M., Green, M., & Kralstein, D. (2012). The impact of adult drug courts on crime and incarceration. *Journal of Experimental Criminology, 8*(3), 165–192.

Rossman, S.B., Rempel, M., Roman, J.K., Zweig, J.M., Lindquist, C.H., Green, M., Downey, P.M., Yahner, J., Bhati, A.S., & Farole, D.J. (2011). *The multisite adult drug court evaluation: The impact of drug courts, vol. 4.* Washington, DC: Urban Institute Justice Policy Center. *Available at* https://www.ncjrs.gov/pdffiles1/nij/grants/237112.pdf.

Rossman, S.B., Willison, J.B., Mallik-Kane, K., Kim, K., Debus-Sherrill, S., & Downey, P.M. (2012). *Criminal justice interventions for offenders with mental illness: Evaluation of mental health courts in Bronx and Brooklyn, New York*. Washington, DC: Urban Institute.

Saum, C.A., & Hiller, M.L. (2008). Should violent offenders be excluded from drug court participation? An examination of the recidivism of violent and nonviolent drug court participants. *Criminal Justice Review, 33*(3)*,* 291–307.

Saum, C.A., Scarpitti, F.R., & Robbins, C.A. (2001). Violent offenders in drug court. *Journal of Drug Issues, 31*(1)*,* 107–128.

Sevigny, E. L., Pollack, H. A., & Reuter, P. (2013). Can drug courts help to reduce prison and jail populations? *Annals of the American Academy of Political & Social Science, 647*, 190-212.

Shaffer, D.K. (2006). Reconsidering drug court effectiveness: A meta-analytic review (Doctoral dissertation, University of Cincinnati, 2006). *Dissertation Abstracts International*, 67, 09A (AAT No. 3231113).

Shaffer, D.K. (2010). Looking inside the black box of drug courts: A meta-analytic review. *Justice Quarterly, 28*(3)*, 493–521.*

Skeem, J.J., Manchak, S., & Peterson, J.K. (2011). Correctional policy for offenders with mental illness: Creating a new paradigm for recidivism reduction. *Law & Human Behavior, 35*(2), 110–126.

Stewart, S.H. (2009). Dependence and diagnosis. In P.M. Miller (Ed.), *Evidence-based addiction treatment* (pp. 77–88). New York: Elsevier.

Szalavitz, M. (2010, July 16). Does teen drug rehab cure addiction or create it? *Time Magazine: On-Line. Available at* http://time.com/time/printout/0,8816,2003160,00.html.

Wexler, H.K., Melnick, G., & Cao, Y. (2004). Risk and prison substance abuse treatment outcomes: A replication and challenge. *The Prison Journal, 84*(1), 106–120.

Wormith, J.S., & Goldstone, C.S. (1984). The clinical and statistical prediction of recidivism. *Criminal Justice & Behavior, 11*(1), 3–34.

Zweig, J.M., Lindquist, C., Downey, P.M., Roman, J., & Rossman, S.B. (2012). Drug court policies and practices: How program implementation affects offender substance use and criminal behavior outcomes. *Drug Court Review*, *7*(1), 43–79.

II. HISTORICALLY DISADVANTAGED GROUPS

Citizens who have historically experienced sustained discrimination or reduced social opportunities because of their race, ethnicity, gender, sexual orientation, sexual identity, physical or mental disability, religion, or socioeconomic status receive the same opportunities as other citizens to participate and succeed in the Drug Court.

A. Equivalent Access
B. Equivalent Retention
C. Equivalent Treatment
D. Equivalent Incentives & Sanctions
E. Equivalent Dispositions
F. Team Training

A. Equivalent Access

Eligibility criteria for the Drug Court are nondiscriminatory in intent and impact. If an eligibility requirement has the unintended effect of differentially restricting access for members of a historically disadvantaged group, the requirement is adjusted to increase the representation of such persons unless doing so would jeopardize public safety or the effectiveness of the Drug Court. The assessment tools that are used to determine candidates' eligibility for the Drug Court are valid for use with members of historically disadvantaged groups represented in the respective arrestee population.

B. Equivalent Retention

The Drug Court regularly monitors whether members of historically disadvantaged groups complete the program at equivalent rates to other participants. If completion rates are significantly lower for members of a historically disadvantaged group, the Drug Court team investigates the reasons for the disparity, develops a remedial action plan, and evaluates the success of the remedial actions.

C. Equivalent Treatment

Members of historically disadvantaged groups receive the same levels of care and quality of treatment as other participants with comparable clinical needs. The Drug Court administers evidence-based treatments that are effective for use with members of historically disadvantaged groups represented in the Drug Court population.

D. Equivalent Incentives and Sanctions

Except where necessary to protect a participant from harm, members of historically disadvantaged groups receive the same incentives and sanctions as other participants for comparable achievements or infractions. The Drug Court regularly monitors the delivery of incentives and sanctions to ensure they are administered equivalently to all participants.

E. Equivalent Dispositions

Members of historically disadvantaged groups receive the same legal dispositions as other participants for completing or failing to complete the Drug Court program.

F. Team Training

Each member of the Drug Court team attends up-to-date training events on recognizing implicit cultural biases and correcting disparate impacts for members of historically disadvantaged groups.

COMMENTARY

Drug Courts are first and foremost courts, and the fundamental principles of due process and equal protection apply to their operations (Meyer, 2011). Drug Courts have an affirmative legal and ethical obligation to provide equal access to their services and equivalent treatment for all citizens.

In June of 2010, the Board of Directors of the NADCP passed a unanimous resolution (hereafter minority resolution)[5] directing Drug Courts to examine whether unfair disparities exist in their programs for racial or ethnic minority[6] participants; and if so, to take reasonable corrective measures to eliminate those disparities (NADCP, 2010). The minority resolution places an affirmative obligation on Drug Courts to continually monitor whether minority participants have equal access to the programs, receive equivalent services in the programs, and successfully complete the programs at rates equivalent to nonminorities. It further instructs Drug Courts to adopt evidence-based assessment tools and clinical interventions, where they exist, that are valid and effective for use with minority participants and requires staff members to attend up-to-date training events on the provision of culturally sensitive and culturally proficient services.

The NADCP minority resolution focuses on racial and ethnic minority participants for two reasons. First, these groups are *suspect classes* pursuant to constitutional law and therefore receive heightened scrutiny and protections from the courts. Second, most of the available research on disproportionate impacts in Drug Courts has focused on African-American and Hispanic or Latino individuals because these individuals were represented in sufficient numbers in the studies for the evaluators to conduct separate analyses on their behalf. Nevertheless, the same principles of fundamental fairness apply to all historically disadvantaged groups that have experienced sustained periods of discrimination or reduced social opportunities. As a practical matter, Drug Courts can only be required to take remedial actions based on characteristics of participants that are readily observable or have been brought to the attention of the court. Such observable characteristics will typically include participants' gender, race or ethnicity.

A. Equivalent Access

Evidence suggests African-American and Hispanic or Latino citizens may be underrepresented by approximately 3% to 7% in Drug Courts. National studies have estimated that approximately 21% of Drug Court participants are African-American and 10% are Hispanic or Latino (Bureau of Justice Assistance, 2012; Huddleston & Marlowe, 2011). In contrast, approximately 28% of arrestees and probationers were African-American and approximately 13% of probationers were Hispanic or Latino. Additional research is needed to examine the representation of other historically disadvantaged groups in Drug Courts.

---

[5] Resolution of the Board of Directors on the Equivalent Treatment of Racial and Ethnic Minority Participants in Drug Courts, *available at* http://www.nadcp.org/sites/default/files/nadcp/NADCP%20Board%20Resolution%20-%20The%20Equivalent%20Treatment%20of%20Racial%20and%20Ethnic%20Minority%20Participants%20in%20Drug%20Courts%2006-01-10.pdf.

[6] The term *minority* refers here to racial or ethnic groups that historically were numerically in the minority within the U.S. population. Some of these racial or ethnic groups currently constitute a majority in certain communities and may be approaching a plurality of the U.S. population.

Some commentators have suggested that unduly restrictive eligibility criteria might be partly responsible for the lower representation of minority persons in Drug Courts (Belenko et al., 2011; O'Hear, 2009). It has been suggested, for example, that African-Americans or Hispanics may be more likely than Caucasians to have prior felony convictions or other entries in their criminal records that disqualify them from participation in Drug Court (National Association of Criminal Defense Lawyers [NACDL], 2009; O'Hear, 2009). Although there is no empirical evidence to confirm this hypothesis, Drug Courts must ensure that their eligibility criteria do not unnecessarily exclude minorities or members of other historically disadvantaged groups. If an eligibility criterion has the unintended impact of differentially restricting access to the Drug Court for such persons, then extra assurances are required that the criterion is necessary for the program to achieve effective outcomes or protect public safety. If less restrictive adjustments can be made to an eligibility requirement to increase the representation of members of a historically disadvantaged group without jeopardizing public safety or efficacy, the Drug Court is obligated to make those adjustments. Although an unintended discriminatory impact may not always be constitutionally objectionable (Washington v. Davis, 1976), it is nevertheless inconsistent with best practices in Drug Courts and with the NADCP minority resolution.

Drug Courts cannot assume that the assessment tools they use to determine candidates' eligibility for the program—which are often validated on samples comprising predominantly Caucasian males—are valid for use with minorities, females, or members of other demographic subgroups (Burlew et al., 2011; Huey & Polo, 2008). Studies have found that women and racial or ethnic minorities interpreted test items differently than other test respondents, making the test items less valid for the women or minorities (Carle, 2009; Perez & Wish, 2011; Wu et al., 2010). Therefore, where available, Drug Courts have a responsibility to select tools that have been validated for use with members of historically disadvantaged groups that are represented among the candidates for the program. If such tools do not exist, then at a minimum the Drug Court should elicit feedback from the participants about the clarity, relevance, and cultural sensitivity of the tools it is using. Ideally, the Drug Court should engage an evaluator to empirically validate the tools among the candidates for the program.

The Alcohol and Drug Abuse Institute Library at the University of Washington has an online catalog of screening and assessment tools created for use in substance abuse treatment.[7] Each instrument can be searched for research studies, if any, that have examined its validity and reliability among women and racial or ethnic minorities.

B. Equivalent Retention

Numerous studies have reported that a significantly smaller percentage of African-American or Hispanic participants graduated successfully from Drug Court as compared to non-Hispanic Caucasians (Finigan, 2009; Marlowe, 2013). In several of the studies, the magnitude of the discrepancy was as high as 25% to 40% (Belenko, 2001; Sechrest & Shicor, 2001; Wiest et al., 2007). These findings are not universal, however. A smaller but growing number of evaluations has found no differences in outcomes or even superior outcomes for racial minorities as compared to Caucasians (Brown, 2011; Cissner et al., 2013; Fulkerson, 2012; Saum et al., 2001; Somers et al., 2012; Vito & Tewksbury, 1998). Nevertheless, African-Americans appear less likely to succeed in a plurality of Drug Courts as compared to their nonracial minority peers.

To the extent such disparities exist, evidence suggests they might not be a function of race or ethnicity per se, but rather might be explained by broader societal burdens that are often borne disproportionately by minorities, such as lesser educational or employment opportunities or a greater infiltration of crack cocaine into some minority communities (Belenko, 2001; Dannerbeck et al., 2006; Fosados, et al., 2007; Hartley & Phillips, 2001; Miller & Shutt, 2001). When evaluators accounted statistically for these confounding factors, the influence of race or ethnicity disappeared (Dannerbeck et al., 2006). Interviews and focus groups conducted with racial minority participants have suggested that Drug Courts may be paying insufficient attention to employment and educational problems that are experienced disproportionately by

[7] Available at http://lib.adai.washington.edu/instruments/.

minority participants (Cresswell & Deschenes, 2001; DeVall & Lanier, 2012; Gallagher, 2013; Leukefeld et al., 2007).

These findings require Drug Courts to determine whether racial or ethnic minorities or members of other historically disadvantaged groups are experiencing poorer outcomes in their programs as compared to other participants and to investigate and remediate any disparities that are detected. One low-cost and effective strategy is to confidentially survey participants and staff members about their perceptions of disparate treatment and outcomes in the program (Casey et al., 2012; Sentencing Project, 2008). Programs that continually solicit feedback about their performance in the areas of cultural competence and cultural sensitivity learn creative ways to address the needs of their participants and produce better outcomes as a result (Szapocznik et al., 2007). Drug Courts are further encouraged to engage independent evaluators to objectively identify areas requiring improvement to meet the needs of minorities and members of other historically disadvantaged groups (Carey et al., 2012; Rubio et al., 2008).

C. Equivalent Treatment

Racial and ethnic minorities often receive lesser quality treatment than nonminorities in the criminal justice system (Brocato, 2013; Janku & Yan, 2009; Fosados et al., 2007; Guerrero et al., 2013; Huey & Polo, 2008; Lawson & Lawson, 2013; Marsh et al., 2009; Schmidt et al., 2006). A commonly cited example of this phenomenon relates to California Proposition 36, the Substance Abuse and Crime Prevention Act of 2000, a statewide diversion initiative for nonviolent drug possession offenders. A several-year study of Proposition 36 (Nicosia et al., 2012; Integrated Substance Abuse Programs, 2007) found that Hispanic participants were significantly less likely than Caucasians to be placed in residential treatment for similar patterns of drug abuse, and African-Americans were less likely to receive medically assisted treatment for addiction. To date, no empirical studies have determined whether there are such disparities in the quality of treatment in Drug Courts. The NADCP minority resolution directs Drug Courts to remain vigilant to potential differences in the quality or intensity of services provided to minority participants and to institute corrective measures where indicated.

Drug Courts must also ensure that the treatments they provide are valid and effective for members of historically disadvantaged groups in their programs. Because women and racial minorities are often underrepresented in clinical trials of addiction treatments, the treatments are frequently less beneficial for these individuals (Burlew et al., 2011; Calsyn et al., 2009). The Substance Abuse and Mental Health Services Administration (SAMHSA) maintains an internet directory of evidence-based treatments called the National Registry of Evidence-Based Programs and Practices (NREPP). The NREPP Web site may be searched specifically for interventions that have been evaluated among substantial numbers of racial and ethnic minority participants, women, and members of some other historically disadvantaged groups.[8]

A small but growing number of treatments have been tailored specifically to meet the needs of women or racial minority participants in Drug Courts. In one study, outcomes were improved significantly for young African-American male participants when an experienced African-American clinician delivered a curriculum that addressed issues commonly confronting these young men, such as negative racial stereotypes (Vito & Tewksbury, 1998). Efforts are underway to examine the intervention used in that study—habilitation, empowerment & accountability therapy (HEAT)—in a controlled experimental study.

Substantial evidence shows that women, particularly those with histories of trauma, perform significantly better in gender-specific substance abuse treatment groups (Dannerbeck et al., 2002; Grella, 2008; Liang & Long, 2013; Powell et al., 2012). This gender-specific approach has been demonstrated to improve outcomes for female Drug Court participants in at least one randomized controlled trial (Messina et al., 2012). Similarly, a study of approximately seventy Drug Courts found that programs offering gender-specific services reduced criminal recidivism significantly more than those that did not (Carey et al., 2012).

Studies indicate the success of culturally tailored treatments depends largely on the training and skills of the clinicians delivering the services (Castro et al., 2010; Hwang, 2006). Unless the clinicians attend

[8] NREPP, Find an Intervention: http://www.nrepp.samhsa.gov/AdvancedSearch.aspx.

comprehensive training workshops and receive ongoing supervision on how to competently deliver the interventions, outcomes are unlikely to improve for women and minority participants.

D. Equivalent Incentives and Sanctions

Some commentators have questioned whether racial or ethnic minority participants are sanctioned more severely than nonminorities in Drug Courts for comparable infractions. Anecdotal observations have been cited to support this concern (NACDL, 2009) and minority participants in at least one focus group did report feeling more likely than other participants to be ridiculed or laughed at during court sessions in response to violations (Gallagher, 2013). No empirical study, however, has borne out the assertion. To the contrary, what little research has been conducted suggests Drug Courts and other problem-solving courts appear to administer sanctions in a racially and ethnically even-handed manner (Arabia et al., 2008; Callahan et al., 2013; Frazer, 2006; Guastaferro & Daigle, 2012; Jeffries & Bond, 2012). Considerably more research is required to study this important issue in a systematic manner and in a representative range of Drug Courts. The NADCP minority resolution places an affirmative obligation on Drug Courts to continually monitor whether sanctions and incentives are being applied equivalently for minority participants and to take corrective actions if discrepancies are detected.

E. Equivalent Dispositions

Concerns have similarly been expressed that racial or ethnic minority participants might be sentenced more harshly than nonminorities for failing to complete Drug Court (Drug Policy Alliance, 2011; Justice Policy Institute, 2011; O'Hear, 2009). This is an important matter because, as discussed previously, minorities may be more likely than nonminorities to be terminated from Drug Courts. Although the matter is far from settled, evidence from at least one study suggests that participants who were terminated from Drug Court did receive harsher sentences than traditionally adjudicated defendants who were charged with comparable offenses (Bowers, 2008). There is no evidence, however, to indicate whether this practice differentially impacts minorities or members of other historically disadvantaged groups. In fact, one study in Australia found that indigenous minority Drug Court participants were *less* likely than nonminorities to be sentenced to prison (Jeffries & Bond, 2012). Nevertheless, due process and equal protection require Drug Courts to remain vigilant to the possibility of sentencing disparities in their programs and to take corrective actions where indicated.

F. Team Training

One of the most significant predictors of positive outcomes for racial and ethnic minority participants in substance abuse treatment is culturally sensitive attitudes on the part of the treatment staff, especially managers and supervisors (Ely & Thomas, 2001; Guerrero, 2010). When managerial staff value diversity and respect their clients' cultural backgrounds, the clients are retained significantly longer in treatment and services are delivered more efficiently (Guerrero & Andrews, 2011). Cultural-sensitivity training can enhance counselors' and supervisors' beliefs about the importance of diversity and the need to understand their clients' cultural backgrounds and influences (Cabaj, 2008; Westermeyer, & Dickerson, 2008).

Effective cultural-sensitivity curricula focus, in part, on identifying and examining the (often implicit or unconscious) biases that may be held by staff members about their clients (Greenwald & Banaji, 1995; Kang, 2005). Although the issue of implicit bias has not been studied in Drug Courts, it has been shown to negatively affect judicial decision-making in traditional criminal courts (Marsh, 2009; Rachlinski et al., 2009; Seamone, 2009). Cultural-sensitivity training can assist court staff to recognize and resolve prejudicial thoughts or beliefs they might hold but might not be aware of.

Merely sensitizing court staff to cultural concerns is not sufficient. Drug Courts need to go considerably further and teach staff concrete strategies to correct any problems that are identified and remediate disparities in services and outcomes. This includes teaching staff members how to apply research-based performance-monitoring procedures to identify and rectify disparate impacts (Casey et al., 2012; Rubio et al., 2008; Yu et al., 2009). One goal of cultural-sensitivity training is to underscore the importance of recognizing implicit bias; however, unless Drug Courts focus equally on finding concrete and feasible solutions to biases that are identified, little positive change is likely to occur.

REFERENCES

Arabia, P.L., Fox, G., Caughie, J., Marlowe, D.B., & Festinger, D.S. (2008). Sanctioning practices in an adult felony drug court. *Drug Court Review, 6*(1), 1–31.

Belenko, S. (2001). *Research on drug courts: A critical review: 2001 update*. New York: National Center on Addiction and Substance Abuse at Columbia University.

Belenko, S., Fabrikant, N., & Wolff, N. (2011). The long road to treatment: Models of screening and admission into Drug Courts. *Criminal Justice & Behavior*, *38(1)*, 1222–1243.

Bowers, J. (2008). Contraindicated drug courts. *UCLA Law Review*, *55 (4)*, 783–833.

Brocato, J. (2013). The impact of acculturation, motivation, and the therapeutic alliance on treatment retention and outcomes for Hispanic drug-involved probationers. *Journal of Ethnicity in Criminal Justice, 11*, 150-180.

Brown, R. (2011). Drug court effectiveness: A matched cohort study in the Dane County Drug Treatment Court. *Journal of Offender Rehabilitation, 50*(4), 191–201.

Bureau of Justice Assistance. (2012). *Program performance report: Enhancement grantees of the Adult Drug Court Discretionary Grant Program*. Washington, DC: Author. *Available at* https://www.bja.gov/Publications/DrugCt Enhancement_PPR_06-12.pdf.

Burlew, A.K., Weekes, J.C., Montgomery, L., Feaster, D.J., Robbins, M.S. Rosa, C.L., Ruglass, L.M., Venner, K.L., & Wu, L. (2011). Conducting research with racial/ethnic minorities: Methodological lessons from the NIDA Clinical Trials Network. *American Journal of Drug & Alcohol Abuse, 37*(5), 324–332.

Cabaj, R.P. (2008). Gay men and lesbians. In M. Galanter & H.D. Kleber (Eds), *Textbook of Substance Abuse Treatment* (4th Ed.; pp. 623–638). Arlington, VA: American Psychiatric Publishing.

Callahan, L., Steadman, H.J., Tillman, S., & Vesselinov, R. (2013). A multisite study of the use of sanctions and incentives in mental health courts. *Law & Human Behavior, 37*(1), 1–9.

Calsyn, D.A., Hatch-Maillette, M., Tross, S., Doyle, S.R., Crits-Christoph, P., Song, Y.S., Harrer, J.M., Lalos, G., & Berns, S.B. (2009). Motivational and skills training HIV/STI sexual risk reduction groups for men. *Journal of Substance Abuse Treatment, 37*(1), 138–150.

Carey, S.M., Mackin, J.R., & Finigan, M.W. (2012). What works? The ten key components of Drug Court: Research-based best practices. *Drug Court Review*, *8*(1), 6–42.

Carle, A.C. (2009, February). Assessing the adequacy of self-reported alcohol abuse measurement across time and ethnicity: Cross-cultural equivalence across Hispanics and Caucasians in 1992, nonequivalence in 2001–2002. *BioMed Central Public Health, 9*, 60. *Available at* http://www.biomedcentral.com/1471-2458/9/60.

Casey, P., Warren, R., Cheesman, F., & Elek, J. (2012). *Helping courts address implicit bias: Resources for education*. Williamsburg, VA: National Center for State Courts.

Castro, F.G., Barrera, M., & Steiker, L.K.H. (2010). Issues and challenges in the design of culturally adapted evidence-based interventions. *Annual Review of Clinical Psychology, 6*, 213–239.

Cissner, A., Rempel, M., Franklin, A.W., Roman, J.K., Bieler, S., Cohen, R., & Cadoret, C.R. (2013, March). *A statewide evaluation of New York's adult drug courts: Testing which policies work best*. Paper presented at the New York Association of Drug Treatment Court Professionals Training. *Available at* http://www.nyadtcp.org/userfiles/file/presentation/The%202012 %20New%20York%20State%20Drug%20Court%20Evaluation.pdf.

Cresswell, L.S., & Deschenes, E.P. (2001). Minority and nonminority perceptions of drug court program severity and effectiveness. *Journal of Drug Issues, 31*(1), 259–291.

Dannerbeck, A., Harris, G., Sundet, P., & Lloyd, K. (2006). Understanding and responding to racial differences in drug court outcomes. *Journal of Ethnicity in Substance Abuse, 5*(2), 1–22.

Dannerbeck, A., Sundet, P., & Lloyd, K. (2002). Drug courts: Gender differences and their implications for treatment strategies. *Corrections Compendium 27*(12), 1–26.

DeVall, K.E., & Lanier, C.L. (2012). Successful completion: An examination of factors influencing drug court completion for white and nonwhite male participants. *Substance Use & Misuse, 47*(10), 1106–1116.

Drug Policy Alliance. (2011). *Drug courts are not the answer: Toward a health-centered approach to drug use*. Los Angeles: Author.

Ely, R.J., & Thomas, D.A. (2001). The effects of diversity perspectives on work group processes and outcomes. *Administrative Science Quarterly 46*(2), 229–273.

Finigan, M.W. (2009). Understanding racial disparities in drug courts. *Drug Court Review, 7*(2), 135–142.

Fosados, R., Evans, E., & Hser, Y. (2007). Ethnic differences in utilization of drug treatment services and outcomes among Proposition 36 offenders in California. *Journal of Substance Abuse Treatment, 33*(4), 391–399.

Frazer, M.S. (2006). *The Impact of the community court model on defendant perceptions of fairness*. New York: Center for Court Innovation.

Fulkerson, A. (2012). Drug treatment court versus probation: An examination of comparative recidivism rates. *Southwest Journal of Criminal Justice, 8*(2), 30–45.

Gallagher, J.R. (2013). African American participants' views on racial disparities in drug court outcomes. *Journal of Social Work Practice in the Addictions, 13*(2), 143–162.

Greenwald, A., & Banaji, M. (1995). Implicit social cognition: Attitudes, self-esteem, and stereotypes. *Psychological Review*, *102*(1), 4–27.

Grella, C. (2008). Gender-responsive drug treatment services for women: A summary of current research and recommendations for drug court programs. In C. Hardin & J.N. Kushner (Eds.), *Quality improvement for drug courts: Evidence-based practices* (Monograph Series No. 9; pp. 63–74). Alexandria, VA: National Drug Court Institute.

Guastaferro, W.P., & Daigle, L.E. (2012). Linking noncompliant behaviors and programmatic responses: The use of graduated sanctions in a felony-level drug court. *Journal of Drug Issues, 42*(4), 396–419.

Guerrero E. (2010). Managerial capacity and adoption of culturally competent practices in outpatient substance abuse treatment organizations. *Journal of Substance Abuse Treatment, 39*(4), 329–339.

Guerrero E., & Andrews C.M. (2011). Cultural competence in outpatient substance abuse treatment: Measurement and relationship to wait time and retention. *Drug & Alcohol Dependence 119*(1), 13–22.

Guerrero, E.G., Marsh, J.C., Duan, L., Oh, C., Perron, B., & Lee, B. (2013). Disparities in completion of substance abuse treatment between and within racial and ethnic groups. *Health Services Research* (Online). doi: 10.1111/1475-6773.12031

Hartley, R.E., & Phillips, R.C. (2001). Who graduates from drug courts? Correlates of client success. *American Journal of Criminal Justice, 26*(1), 107–119.

Huddleston, W., & Marlowe, D.B. (2011). *Painting the current picture: A national report on drug courts and other problem solving court programs in the United States.* Alexandria, VA: National Drug Court Institute.

Huey, S.J., & Polo, A.J. (2008). Evidence-based psychosocial treatments for ethnic minority youth. *Journal of Clinical Child & Adolescent Psychology, 37*(1), 262–301.

Hwang, W. (2006). The psychotherapy adaptation and modification framework: Application to Asian Americans. *American Psychologist, 61*(7), 702–715.

Integrated Substance Abuse Programs. (2007, April 13). *Evaluation of the Substance Abuse and Crime Prevention Act: Final report*. Los Angeles, CA: UCLA. *Available at* http://www.uclaisap.org/Prop36/documents/SACPAEvaluationReport.pdf.

Janku, A.D., & Yan, J. (2009). Exploring patterns of court-ordered mental health services for juvenile offenders: Is there evidence of systematic bias? *Criminal Justice & Behavior, 36*(4), 402–419.

Jeffries, S., & Bond, C.E. W. (2012). Does a therapeutic court context matter? The likelihood of imprisonment for indigenous and nonindigenous offenders sentenced in problem-solving courts. *International Journal of Law, Crime & Justice, 41*(1), 100–114. *Available at* http://dx.doi.org/10.1016/j.ijlcj.2012.11.006.

Justice Policy Institute. (2011). *Addicted to courts: How a growing dependence on drug courts impacts people and communities*. Washington, DC: Author.

Kang, J. (2005). The Trojan horses of race. *Harvard Law Review*, *118*(5), 1489–1593.

Lawson, W.B., & Lawson, A. (2013). Disparities in mental health diagnosis and treatment among African Americans: Implications for the correctional systems. In B. Sanders, Y. Thomas, & B. Deeds (Eds.), *Crime, HIV and health: Intersections of criminal justice and public health concerns.* New York: Springer.

Leukefeld, C., Webster, J.M., Staton-Tindall, M., & Duvall, J. (2007). Employment and work among drug court clients: 12-month outcomes. *Substance Use & Misuse, 42*(7), 1109–1126.

Liang, B., & Long, M.A. (2013). Testing the gender effect in drug and alcohol treatment: Women's participation in Tulsa County drug and DUI programs. *Journal of Drug Issues*, *43*(3), 270-288.

Marlowe, D.B. (2013). Achieving racial and ethnic fairness in drug courts. *Court Review*, *49*(1), 40–47.

Marsh, S. (2009, summer). The lens of implicit bias. *Juvenile & Family Justice Today*, *18*, 16–19.

Marsh, J.C., Cao, D., Guerrero, E., & Shin, H.C. (2009). Need-service matching in substance abuse treatment: Racial/ethnic differences. *Evaluation & Program Planning, 32*(1), 43–51.

Messina, N., Calhoun, S., & Warda, U. (2012). Gender-responsive drug court treatment: A randomized controlled trial. *Criminal Justice & Behavior, 39*(12), 1539–1558.

Meyer, W.G. (2011). Constitutional and legal issues in drug courts. In D.B. Marlowe & W.G. Meyer (Eds.), *The drug court judicial benchbook* (pp. 159–180). Alexandria, VA: National Drug Court Institute. Available at http://www.ndci.org/sites/default/files/nadcp/14146_NDCI_Benchbook_v6.pdf.

Miller, J.M., & Shutt, J.E. (2001). Considering the need for empirically grounded drug court screening mechanisms. *Journal of Drug Issues, 31*(1), 91–106.

National Association of Criminal Defense Lawyers. (2009). *America's problem-solving courts: The criminal costs of treatment and the case for reform*. Washington, DC: Author.

National Association of Drug Court Professionals (1997). *Defining drug courts: The key components* (NCJ No. 205621). Washington, DC: Author.

National Association of Drug Court Professionals. (2010). *Resolution of the board of directors on the equivalent treatment of racial and ethnic minority participants in drug courts*. Alexandria, VA: Author. *Available at* http://www.nadcp.org/learn/positions-policy-statements-and-resolutions/board-resolutions.

Nicosia, N., MacDonald, J.M., & Pacula, R.L. (2012). *Does mandatory diversion to drug treatment eliminate racial disparities in the incarceration of drug offenders? An examination of California's Proposition 36*. Cambridge, MA: National Bureau of Economic Research. *Available at* http://www.nber.org/papers/w18518.

O'Hear, M.M. (2009). Rethinking drug courts: Restorative justice as a response to racial injustice. *Stanford Law & Policy Review, 20*(2), 101–137.

Perez, D.M., & Wish, E.D. (2011). Gender differences in the validity of the Substance Abuse Subtle Screening Inventory—3 (SASSI-3) with a criminal justice population. *International Journal of Offender Therapy & Comparative Criminology, 55*(3), 476–491.

Powell, C., Stevens, S., Dolce, B.L., Sinclair, K.O., & Swenson-Smith, C. (2012). Outcomes of a trauma-informed Arizona family drug court. *Journal of Social Work Practice in the Addictions, 12*(3), 219–241.

Rachlinski, J., Johnson, S., Wistrich, A., & Guthrie, C. (2009). Does unconscious racial bias affect trial court judges? *Notre Dame Law Review*, *84*(3), 1195–1246.

Rubio, D., Cheesman, F., & Webster, L. (2008). *Kentucky Drug Court statewide technical assistance project: Development of statewide adult drug court performance measures*. Denver, CO: National Center for State Courts.

Saum, C.A., Scarpitti, F.R., & Robbins, C.A. (2001). Violent offenders in drug court. *Journal of Drug Issues, 31*(1)*,* 107–128.

Schmidt, L., Greenfield, T., & Mulia, N. (2006). *Unequal treatment: Racial and ethnic disparities in alcoholism treatment services*. Bethesda, MD: National Institute on Alcohol Abuse and Alcoholism. *Available at* http://pubs.niaaa.nih.gov/publications/arh291/49-54.htm.

Seamone, E. (2009). Understanding the person beneath the robe: Practical methods for neutralizing harmful judicial bias. *Willamette Law Review*, 42(1), 1–76.

Sechrest, D.K., & Shicor, D. (2001). Determinants of graduation from a day treatment drug court in California: A preliminary study. *Journal of Drug Issues, 31*(1), 129–147.

Sentencing Project. (2008). *Reducing racial disparity in the criminal justice system: A manual for practitioners and policymakers*. Washington, DC: Author.

Somers, J.M., Rezansoff, S.N., & Moniruzzaman, A. (2012). *Mediators of drug treatment court outcomes in Vancouver Canada*. British Columbia, Canada: Simon Fraser University.

Szapocznik, J., Prado, G., Burlew, A.K., Williams, R.A., & Santisteban, D.A. (2007). Drug abuse in African-American and Hispanic adolescents: Culture, development, and behavior. *Annual Review of Clinical Psychology*, *3,* 77–105.

Vito, G., & Tewksbury, R. (1998). The impact of treatment: The Jefferson County (Kentucky) Drug Court program. *Federal Probation, 62*(2), 46–51.

Washington v. Davis, 426 U.S. 229 (1976).

Westermeyer, J., & Dickerson, D. (2008). Minorities. In M. Galanter & H.D. Kleber (Eds.), *Textbook of Substance Abuse Treatment* (4th Ed.; pp. 639–651). Washington, DC: American Psychiatric Publishing.

Wiest, K., Carey, S.M., Martin, S., Waller, M.S., Cox, A.A., Linhares, W., Compton, D., & Finigan, M. (2007). *Indiana drug courts: Vanderburgh County day reporting drug court, Process, outcome and cost evaluation* (Final Report). Portland, OR: NPC Research. *Available at* http://www.npcresearch.com/Files/Vanderburgh_Adult_Eval_Final.pdf.

Wu, L.T., Pan, J.J., Blazer, D.G., Tai, B., Stitzer, M.L., & Woody, G.E. (2010). Using a latent variable approach to inform gender and racial/ethnic differences in cocaine dependence: A National Drug Abuse Treatment Clinical Trials Network Study. *Journal of Substance Abuse Treatment, 38*(Suppl. 1), S70–S79.

Yu, J., Clark, L.P., Chandra, L., Dias, A., & Lai, T.F. (2009). Reducing cultural barriers to substance abuse treatment among Asian Americans: A case study in New York City. *Journal of Substance Abuse Treatment 37*(4), 398–406.

III. ROLES AND RESPONSIBILITIES OF THE JUDGE

The Drug Court judge stays abreast of current law and research on best practices in Drug Courts, participates regularly in team meetings, interacts frequently and respectfully with participants, and gives due consideration to the input of other team members.[9]

A. Professional Training
B. Length of Term
C. Consistent Docket
D. Participation in Pre-Court Staff Meetings
E. Frequency of Status Hearings
F. Length of Court Interactions
G. Judicial Demeanor
H. Judicial Decision Making

A. Professional Training

The Drug Court judge attends current training events on legal and constitutional issues in Drug Courts, judicial ethics, evidence-based substance abuse and mental health treatment, behavior modification, and community supervision. Attendance at annual training conferences and workshops ensures contemporary knowledge about advances in the Drug Court field.

B. Length of Term

The judge presides over the Drug Court for no less than two consecutive years to maintain the continuity of the program and ensure the judge is knowledgeable about Drug Court policies and procedures.

C. Consistent Docket

Participants ordinarily appear before the same judge throughout their enrollment in the Drug Court.

D. Participation in Pre-Court Staff Meetings

The judge regularly attends pre-court staff meetings during which each participant's progress is reviewed and potential consequences for performance are discussed by the Drug Court team.

---

[9] Studies in Drug Courts have not compared outcomes between judges and other judicial officers such as magistrates or commissioners. Barring evidence to the contrary, the standards contained herein are assumed to apply to all judicial officers working in Drug Courts.

E. Frequency of Status Hearings

Participants appear before the judge for status hearings no less frequently than every two weeks during the first phase of the program.[10] The frequency of status hearings may be reduced gradually after participants have initiated abstinence from alcohol and illicit drugs[11] and are regularly engaged in treatment. Status hearings are scheduled no less frequently than every four weeks until participants are in the last phase of the program.

F. Length of Court Interactions

The judge spends sufficient time during status hearings to review each participant's progress in the program. Evidence suggests judges should spend a minimum of approximately three minutes interacting with each participant in court.

G. Judicial Demeanor

The judge offers supportive comments to participants, stresses the importance of their commitment to treatment and other program requirements, and expresses optimism about their abilities to improve their health and behavior. The judge does not humiliate participants or subject them to foul or abusive language. The judge allows participants a reasonable opportunity to explain their perspectives concerning factual controversies and the imposition of sanctions, incentives, and therapeutic adjustments [see also Standard IV].

H. Judicial Decision Making

The judge is the ultimate arbiter of factual controversies and makes the final decision concerning the imposition of incentives or sanctions that affect a participant's legal status or liberty. The judge makes these decisions after taking into consideration the input of other Drug Court team members and discussing the matter in court with the participant or the participant's legal representative. The judge relies on the expert input of duly trained treatment professionals when imposing treatment-related conditions.

COMMENTARY

A. Professional Training

All team members in Drug Courts should attend annual training workshops on best practices in Drug Courts. The importance of training is emphasized specifically for judges because research indicates the judge exerts a unique and substantial impact on outcomes in Drug Courts (Carey et al., 2012; Jones, 2013; Jones & Kemp, 2013; Marlowe et al., 2006; Zweig et al., 2012).

Judges in Drug Courts have a professional obligation to remain abreast of legal, ethical and constitutional requirements related to Drug Court practices (Meyer, 2011; Meyer & Tauber, 2011). In addition, outcomes

[10] This assumes the Drug Court is treating the appropriate target population of high-risk and high-need participants [see Standard I, Target Population].

[11] Illicit drugs include addictive or intoxicating prescription medications taken for a nonprescribed or nonmedically indicated purpose.

are significantly better when the Drug Court judge attends annual training conferences on evidence-based practices in substance abuse and mental health treatment and community supervision (Carey et al., 2008, 2012; Shaffer, 2010). A national study of twenty-three adult Drug Courts, called the Multisite Adult Drug Court Evaluation (MADCE), found that Drug Courts produced significantly greater reductions in crime and substance abuse when the judges were rated by independent observers as being knowledgeable about substance abuse treatment (Zweig et al., 2012). Similarly, a statewide study in New York reported significantly better outcomes when Drug Court judges were perceived by the participants as being open to learning about the disease of addiction (Farole & Cissner, 2007).

The increasing availability of webinars and other distance-learning programs has made it considerably more affordable and feasible for judges to stay abreast of evidence-based practices. Organizations including the NDCI, Center for Court Innovation, National Center for State Courts, and American University offer, free of charge, live and videotaped webinars on various topics related to best practices in Drug Courts. Appendix B provides further information about these webinars.

B. Length of Term

A study of approximately seventy Drug Courts found nearly three times greater cost savings and significantly lower recidivism when the judges presided over the Drug Courts for at least two consecutive years (Carey et al., 2008, 2012). Significantly greater reductions in crime were also found when the judges were assigned to the Drug Courts on a voluntary basis and their term on the Drug Court bench was indefinite in duration (Carey et al., 2012). Evidence suggests many Drug Court judges are significantly less effective at reducing crime during their first year on the Drug Court bench than during ensuing years (Finigan et al., 2007). Presumably, this is because judges, like most professionals, require time and experience to learn how to perform their jobs effectively. For this reason, annually rotating assignments appear to be contraindicated for judges in Drug Courts.

C. Consistent Docket

Drug Courts that rotated their judicial assignments or required participants to appear before alternating judges had the poorest outcomes in several research studies (Finigan et al., 2007; National Institute of Justice, 2006). Participants in Drug Courts commonly lead chaotic lives, and they often require substantial structure and consistency in order to change their maladaptive behaviors. Unstable staffing patterns, especially when they involve the central figure of the judge, are apt to exacerbate rather than ameliorate the disorganization in participants' lives.

D. Participation in Pre-Court Staff Meetings

Studies have found that outcomes were significantly better in Drug Courts where the judges regularly attended pre-court staff meetings (Carey et al., 2008, 2012). Pre-court staff meetings are where team members share their observations and impressions about each participant's performance in the program and propose consequences for the judge to consider (McPherson & Sauder, 2013). The judge's presence at the staff meetings ensures that each team member's perspective is taken into consideration when important decisions are made in the case. Observational studies suggest that when judges do not attend pre-court staff meetings, they are less likely to be adequately informed or prepared when they interact with the participants during court hearings (Baker, 2012; Portillo et al., 2013).

E. Frequency of Status Hearings

A substantial body of experimental and quasi-experimental research establishes the importance of scheduling status hearings no less frequently than every two weeks (biweekly) during the first phase of a Drug Court. In a series of experiments, researchers randomly assigned Drug Court participants to either appear before the judge every two weeks for status hearings or to be supervised by their clinical case managers and brought into court only in response to repetitive rule violations. The results revealed that high-risk participants[12] had significantly better counseling attendance, drug abstinence, and graduation rates

[12] See Standard I indicating that high-risk offenders are the appropriate target population for a Drug Court.

when they were required to appear before the judge every two weeks (Festinger et al., 2002). This finding was replicated in misdemeanor and felony Drug Courts serving urban and rural communities (Jones, 2013; Marlowe et al., 2004a, 2004b). It was subsequently confirmed in prospective matching studies in which the participants were assigned at entry to biweekly hearings if they were determined to be high risk (Marlowe et al., 2006, 2007, 2008, 2009, 2012).

Similarly, a meta-analysis involving ninety-two adult Drug Courts (Mitchell et al., 2012) and another study of nearly seventy Drug Courts (Carey et al., 2012) found significantly better outcomes for Drug Courts that scheduled status hearings every two weeks during the first phase of the program. Scheduling status hearings at least once per month until the last phase of the program was also associated with significantly better outcomes and nearly three times greater cost savings (Carey et al., 2008, 2012).

F. Length of Court Interactions

In a study of nearly seventy adult Drug Courts, outcomes were significantly better when the judges spent an average of at least three minutes, and as much as seven minutes, interacting with the participants during court sessions (Carey et al., 2008, 2012). Shorter interactions may not allow the judge sufficient time to gauge each participant's performance in the program, intervene on the participant's behalf, impress upon the participant the importance of compliance with treatment, or communicate that the participant's efforts are recognized and valued by staff.

G. Judicial Demeanor

Studies have consistently found that Drug Court participants perceived the quality of their interactions with the judge to be among the most influential factors for success in the program (Farole & Cissner, 2007; Goldkamp et al., 2002; Jones & Kemp, 2013; National Institute of Justice, 2006; Satel, 1998; Saum et al., 2002; Turner et al., 1999). The MADCE study found that significantly greater reductions in crime and substance use were produced by judges who were rated by independent observers as being more respectful, fair, attentive, enthusiastic, consistent and caring in their interactions with the participants in court (Zweig et al., 2012). Similarly, a statewide study in New York reported significantly better outcomes for judges who were perceived by the participants as being fair, sympathetic, caring, concerned, understanding and open to learning about the disease of addiction (Farole & Cissner, 2007). In contrast, outcomes were significantly poorer for judges who were perceived as being arbitrary, jumping to conclusions, or not giving participants an opportunity to explain their sides of the controversies (Farole & Cissner, 2007; Zweig et al., 2012). Program evaluations have similarly reported that supportive comments from the judge were associated with significantly better outcomes in Drug Courts (Senjo & Leip, 2001) whereas stigmatizing, hostile, or shaming comments from the judge were associated with significantly poorer outcomes (Miethe et al., 2000).

These findings are consistent with a body of research on procedural fairness or procedural justice. The results of those studies indicated that criminal defendants and other litigants were more likely to have successful outcomes and favorable attitudes towards the court system when they were treated with respect by the judge, given an opportunity to explain their sides of the controversies, and perceived the judge as being unbiased and benevolent in intent (Burke, 2010; Burke & Leben, 2007; Frazer, 2006). This in no way prevents judges from holding participants accountable for their actions, or from issuing stern warnings or punitive sanctions when they are called for. The dispositive issue is not the outcome of the judge's decision, but rather how the decision was reached and how the participant was treated during the interaction.

H. Judicial Decision Making

Due process and judicial ethics require judges to exercise independent discretion when resolving factual controversies, administering sanctions or incentives that affect a participant's fundamental liberty interests, or ordering the conditions of supervision (Meyer, 2011). A Drug Court judge may not delegate these responsibilities to other members of the Drug Court team. For example, it is not permissible for a Drug Court team to vote on what consequences to impose on a participant unless the judge considers the results of the vote to be merely advisory. Judges are, however, required to consider probative evidence or relevant

information when making these determinations. Because judges are not trained to make clinical diagnoses or select treatment interventions, they ordinarily require expert input from treatment professionals to make treatment-related decisions. The collaborative nature of the Drug Court model brings together experts from several professional disciplines, including substance abuse treatment, to share their knowledge and observations with the judge, thus enabling the judge to make rational and informed decisions (Hora & Stalcup, 2008).

REFERENCES

Baker, K.M. (2012). Decision making in a hybrid organization: A case study of a southwestern drug court treatment program. *Law & Social Inquiry, 38*(1), 27–54.

Burke, K.S. (2010). Just what made drug courts successful? *New England Journal on Criminal & Civil Confinement, 36*(1), 39–58.

Burke, K., & Leben, S. (2007). Procedural fairness: A key ingredient in public satisfaction [White paper]. *Court Review, 44*, 4–24.

Carey, S.M., Finigan, M.W., & Pukstas, K. (2008). *Exploring the key components of drug courts: A comparative study of 18 adult drug courts on practices, outcomes and costs*. Portland, OR: NPC Research. *Available at* http://www.npcresearch.com/Files/NIJ_Cross-site_Final_Report_0308.pdf.

Carey, S.M., Mackin, J.R., & Finigan, M.W. (2012). What works? The ten key components of drug court: Research-based best practices. *Drug Court Review, 8*(1), 6–42.

Farole, D.J., & Cissner, A.B. (2007). Seeing eye to eye: Participant and staff perspectives on drug courts. In G. Berman, M. Rempel & R.V. Wolf (Eds.), *Documenting Results: Research on Problem-Solving Justice* (pp. 51–73). New York: Center for Court Innovation.

Festinger, D.S., Marlowe, D.B., Lee, P.A., Kirby, K.C., Bovasso, G., & McLellan, A.T. (2002). Status hearings in drug court: When more is less and less is more. *Drug & Alcohol Dependence, 68*(2), 151–157.

Finigan, M., Carey, S.M., & Cox, A. (2007). *The impact of a mature drug court over 10 years of operation: Recidivism and costs*. Portland, OR: NPC Research. *Available at* http://www.npcresearch.com/Files/10yr_STOP_Court_Analysis_Final_Report.pdf.

Frazer, M.S. (2006). *The impact of the community court model on defendant perceptions of fairness: A case study at the Red Hook Community Justice Center*. New York: Center for Court Innovation. *Available at* http://www.courtinnovation.org/sites/default/files/Procedural_Fairness.pdf.

Goldkamp, J.S., White, M.D., & Robinson, J.B. (2002). An honest chance: Perspectives on drug courts. *Federal Sentencing Reporter, 14*(6)*,* 369–372.

Hora, P.F., & Stalcup, T. (2008). Drug Treatment Courts in the twenty-first century: The evolution of the revolution in problem-solving courts. *Georgia Law Review, 42*(3), 717–811.

Jones, C. G. (2013). Early-phase outcomes from a randomized trial of intensive judicial supervision in an Australian drug court. *Criminal Justice & Behavior, 40*, 453-468.

Jones, C.G., & Kemp, R.I. (2013). The strength of the participant-judge relationship predicts better drug court outcomes. *Psychiatry, Psychology and Law* (Online). doi: 10.1080/13218719.2013.798392

Marlowe, D.B. (2006). Judicial supervision of drug-abusing offenders. *Journal of Psychoactive Drugs, 38*(Suppl. 3), 323–331.

Marlowe, D.B., Festinger, D.S., Arabia, P.L., Dugosh, K.L., Benasutti, K.M., & Croft, J.R. (2009). Adaptive interventions may optimize outcomes in drug courts: A pilot study. *Current Psychiatry Reports*, *11*(5), 370–376.

Marlowe, D.B., Festinger, D.S., Arabia, P.L., Dugosh, K.L., Benasutti, K.M., Croft, J.R., & McKay, J.R. (2008). Adaptive interventions in drug court: A pilot experiment. *Criminal Justice Review, 33*(3), 343–360.

Marlowe, D.B., Festinger, D.S., Dugosh, K.L., Benasutti, K.M., Fox, G. & Croft, J.R. (2012). Adaptive programming improves outcomes in drug court: An experimental trial. *Criminal Justice & Behavior, 39*(4), 514–532.

Marlowe, D.B., Festinger, D.S., Dugosh, K.L., Lee, P.A., & Benasutti, K.M. (2007). Adapting judicial supervision to the risk level of drug offenders: Discharge and six-month outcomes from a prospective matching study. *Drug & Alcohol Dependence, 88*(Suppl. 2), S4–S13.

Marlowe, D.B., Festinger, D.S., & Lee, P.A. (2004a). The judge is a key component of drug court. *Drug Court Review, 4*(2), 1–34.

Marlowe, D.B., Festinger, D.S., & Lee, P.A. (2004b). The role of judicial status hearings in drug court. In K. Knight & D. Farabee (Eds.), *Treating addicted offenders: A continuum of effective practices* (pp. 11-1–11-8). Kingston, NJ: Civic Research Institute.

Marlowe, D.B., Festinger, D.S., Lee, P.A., Dugosh, K.L., & Benasutti, K.M. (2006). Matching judicial supervision to clients' risk status in drug court. *Crime & Delinquency, 52*(1), 52–76.

McPherson, C. M., & Sauder, M. (2013). Logics in action: Managing institutional complexity in a drug court. *Administrative Science Quarterly, 58*(2), 165-196.

Meyer, W.G. (2011). Ethical obligations of judges in drug courts. In D.B. Marlowe & W.G. Meyer (Eds.), *The drug court judicial benchbook* (pp. 195–215). Alexandria, VA: National Drug Court Institute. *Available at* http://www.ndci.org/publications/more-publications/-drug-court-judicial-benchbook.

Meyer, W.G., & Tauber, J. (2011). The roles and responsibilities of the drug court judge. In D.B. Marlowe & W.G. Meyer (Eds.), *The drug court judicial benchbook* (pp. 45–61). Alexandria, VA: National Drug Court Institute. *Available at* http://www.ndci.org/publications/more-publications/-drug-court-judicial-benchbook.

Miethe, T.D., Lu, H., & Reese, E. (2000). Reintegrative shaming and recidivism risks in Drug Court: Explanations for some unexpected findings. *Crime & Delinquency, 46*(4)*,* 522–541.

Mitchell, O., Wilson, D.B., Eggers, A., & MacKenzie, D.L. (2012). Assessing the effectiveness of drug courts on recidivism: A meta-analytic review of traditional and nontraditional drug courts. *Journal of Criminal Justice, 40*(1), 60–71.

National Institute of Justice. (2006, June). *Drug courts: The second decade* [Special report, NCJ 211081]. Washington, DC: Office of Justice Programs, U.S. Dept. of Justice.

Portillo, S., Rudes, D.S., Viglione, J., & Nelson, M. (2013). Front-stage stars and backstage producers: The role of judges in problem-solving courts. *Victims & Offenders, 8* (1), 1–22.

Satel, S. (1998). Observational study of courtroom dynamics in selected drug courts. *National Drug Court Institute Review, 1*(1), 43–72.

Saum, C.A., Scarpitti, F.R., Butzin, C.A., Perez, V.W., Jennings, D., & Gray, A.R. (2002). Drug court participants' satisfaction with treatment and the court experience. *Drug Court Review, 4*(1), 39–83.

Senjo, S.R., & Leip, L.A. (2001). Testing and developing theory in drug court: A four-part logit model to predict program completion. *Criminal Justice Policy Review, 12*(1), 66–87.

Shaffer, D.K. (2010). Looking inside the black box of drug courts: A meta-analytic review. *Justice Quarterly, 28*(3)*, 493–521.*

Turner, S., Greenwood, P. Fain, T., & Deschenes, E. (1999). Perceptions of drug court: How offenders view ease of program completion, strengths and weaknesses, and the impact on their lives. *National Drug Court Institute Review, 2*(1), 61–85.

Zweig, J.M., Lindquist, C., Downey, P.M., Roman, J., & Rossman, S.B. (2012). Drug court policies and practices: How program implementation affects offender substance use and criminal behavior outcomes. *Drug Court Review, 8*(1), 43–79.

IV. INCENTIVES, SANCTIONS, AND THERAPEUTIC ADJUSTMENTS

Consequences for participants' behavior are predictable, fair, consistent, and administered in accordance with evidence-based principles of effective behavior modification.[13]

A. Advance Notice
B. Opportunity to Be Heard
C. Equivalent Consequences
D. Professional Demeanor
E. Progressive Sanctions
F. Licit Addictive or Intoxicating Substances
G. Therapeutic Adjustments
H. Incentivizing Productivity
I. Phase Promotion
J. Jail Sanctions
K. Termination
L. Consequences of Graduation & Termination

A. Advance Notice

Policies and procedures concerning the administration of incentives, sanctions, and therapeutic adjustments are specified in writing and communicated in advance to Drug Court participants and team members. The policies and procedures provide a clear indication of which behaviors may elicit an incentive, sanction, or therapeutic adjustment; the range of consequences that may be imposed for those behaviors; the criteria for phase advancement, graduation, and termination from the program; and the legal and collateral consequences that may ensue from graduation and termination. The Drug Court team reserves a reasonable degree of discretion to modify a presumptive consequence in light of the circumstances presented in each case.

B. Opportunity to Be Heard

Participants are given an opportunity to explain their perspectives concerning factual controversies and the imposition of incentives, sanctions, and therapeutic adjustments. If

[13] Herein, *incentives* refer to consequences for behavior that are desired by participants, such as verbal praise, phase advancement, social recognition, tangible rewards, or graduation. *Sanctions* refer to consequences that are disliked by participants, such as verbal reprimands, increased supervision requirements, community service, jail detention, or termination. *Therapeutic adjustments* refer to alterations to participants' treatment requirements that are intended to address unmet clinical or social service needs, and are not intended as an incentive or sanction. The generic term *consequence* encompasses incentives, sanctions and therapeutic adjustments.

a participant has difficulty expressing him or herself because of such factors as a language barrier, nervousness, or cognitive limitation, the judge permits the participant's attorney or legal representative to assist in providing such explanations. Participants receive a clear justification for why a particular consequence is or is not being imposed.

C. Equivalent Consequences

Participants receive consequences that are equivalent to those received by other participants in the same phase of the program who are engaged in comparable conduct.[14] Unless it is necessary to protect the individual from harm, participants receive consequences without regard to their gender, race, ethnicity, nationality, socioeconomic status, or sexual orientation [see Standard II, Historically Disadvantaged Groups].

D. Professional Demeanor

Sanctions are delivered without expressing anger or ridicule. Participants are not shamed or subjected to foul or abusive language.

E. Progressive Sanctions

The Drug Court has a range of sanctions of varying magnitudes that may be administered in response to infractions in the program. For goals that are difficult for participants to accomplish, such as abstaining from substance use[15] or obtaining employment, the sanctions increase progressively in magnitude over successive infractions. For goals that are relatively easy for participants to accomplish, such as being truthful or attending counseling sessions, higher magnitude sanctions may be administered after only a few infractions.

F. Licit Addictive or Intoxicating Substances

Consequences are imposed for the nonmedically indicated use of intoxicating or addictive substances, including alcohol, cannabis (marijuana) and prescription medications, regardless of the licit or illicit status of the substance. The Drug Court team relies on expert medical input to determine whether a prescription for an addictive or intoxicating medication is medically indicated and whether nonaddictive, nonintoxicating, and medically safe alternative treatments are available.

G. Therapeutic Adjustments

Participants do not receive punitive sanctions if they are otherwise compliant with their treatment and supervision requirements but are not responding to the treatment interventions. Under such circumstances, the appropriate course of action may be to reassess the individual and adjust the treatment plan accordingly. Adjustments to

---

[14] This assumes all participants have been assessed comparably as high risk and high need [see Standard I, Target Population].

[15] This assumes participants are addicted to or dependent on illicit drugs or alcohol [see Standard I, Target Population]. Individuals who do not have a serious drug or alcohol addiction have less difficulty achieving abstinence, and may receive higher magnitude sanctions for substance abuse during the early phases of the program.

treatment plans are based on the recommendations of duly trained treatment professionals.

H. Incentivizing Productivity

The Drug Court places as much emphasis on incentivizing productive behaviors as it does on reducing crime, substance abuse, and other infractions. Criteria for phase advancement and graduation include objective evidence that participants are engaged in productive activities such as employment, education, or attendance in peer support groups.

I. Phase Promotion

Phase promotion is predicated on the achievement of realistic and defined behavioral objectives, such as completing a treatment regimen or remaining drug-abstinent for a specified period of time. As participants advance through the phases of the program, sanctions for infractions may increase in magnitude, rewards for achievements may decrease, and supervision services may be reduced. Treatment is reduced only if it is determined clinically that a reduction in treatment is unlikely to precipitate a relapse to substance use. The frequency of drug and alcohol testing is not reduced until after other treatment and supervisory services have been reduced and relapse has not occurred. If a participant must be returned temporarily to the preceding phase of the program because of a relapse or related setback, the team develops a remedial plan together with the participant to prepare for a successful phase transition.

J. Jail Sanctions

Jail sanctions are imposed judiciously and sparingly. Unless a participant poses an immediate risk to public safety, jail sanctions are administered after less severe consequences have been ineffective at deterring infractions. Jail sanctions are definite in duration and typically last no more than three to five days. Participants are given access to counsel and a fair hearing if a jail sanction might be imposed because a significant liberty interest is at stake.

K. Termination

Participants may be terminated from the Drug Court if they no longer can be managed safely in the community or if they fail repeatedly to comply with treatment or supervision requirements. Participants are not terminated from the Drug Court for continued substance use if they are otherwise compliant with their treatment and supervision conditions, unless they are nonamenable to the treatments that are reasonably available in their community. If a participant is terminated from the Drug Court because adequate treatment is not available, the participant does not receive an augmented sentence or disposition for failing to complete the program.

L. Consequences of Graduation and Termination

Graduates of the Drug Court avoid a criminal record, avoid incarceration, or receive a substantially reduced sentence or disposition as an incentive for completing the program. Participants who are terminated from the Drug Court receive a sentence or disposition for

the underlying offense that brought them into the Drug Court. Participants are informed in advance of the circumstances under which they may receive an augmented sentence for failing to complete the Drug Court program.

COMMENTARY

A. Advance Notice

Numerous studies reported significantly better outcomes when Drug Courts developed a coordinated sanctioning strategy that was communicated in advance to team members and participants. A national study of twenty-three adult Drug Courts, called the Multisite Adult Drug Court Evaluation (MADCE), found significantly better outcomes for Drug Courts that had a written schedule of predictable sanctions that was shared with participants and staff members (Zweig et al., 2012). Another study of approximately forty-five Drug Courts found 72% greater cost savings for Drug Courts that shared their sanctioning regimen with all team members (Carey et al., 2008a, 2012). A meta-analysis of approximately sixty studies involving seventy Drug Courts found significantly better outcomes for Drug Courts that had a formal and predictable system of sanctions (Shaffer, 2010). Finally, statewide studies of eighty-six adult Drug Courts in New York (Cissner et al., 2013) and twelve adult Drug Courts in Virginia (Cheesman & Kunkel, 2012) found significantly better outcomes for Drug Courts that provided participants with written sanctioning guidelines and followed the procedures in the guidelines.

Meta-analyses of voucher-based positive reinforcement programs have similarly reported superior outcomes for programs that communicated their policies and procedures to participants and staff members (Griffith et al., 1999; Lussier et al., 2006). To be most effective, Drug Courts should describe to participants the expectations for earning positive reinforcement and the manner in which rewards will be administered (Burdon et al., 2001; Stitzer, 2008).

Evidence from the MADCE also suggests that Drug Courts should remind participants frequently about what is expected of them in the program and the likely consequences of success or failure (Zweig et al., 2012). Significantly higher retention rates were produced in another study when staff members in Drug Courts consistently reminded participants about their responsibilities in treatment and the consequences that would ensue from graduation or termination (Young & Belenko, 2002).

Drug Courts should not, however, apply a rigid template when administering sanctions and incentives. Two of the above studies reported significantly better outcomes when the Drug Court team reserved a reasonable degree of discretion to modify a presumptive consequence in light of the facts presented in each case (Carey et al., 2012; Zweig et al., 2012). This empirical finding is consistent with legal and ethical requirements that Drug Court judges must exercise independent discretion when resolving factual controversies and imposing punitive consequences [See Standard III, Roles and Responsibilities of the Judge].

Because certainty is a critical factor in behavior modification programs (Marlowe & Kirby, 1999), discretion should generally be limited to modifying the magnitude of the consequence as opposed to withholding a consequence altogether. Drug Courts that intermittently failed to impose sanctions for infractions had significantly poorer outcomes in at least one large statewide study (Cissner et al., 2013). Withholding a consequence is appropriate only if subsequent information suggests an infraction or achievement did not in fact occur. For example, a sanction should be withheld if a participant's absence from treatment had been excused in advance by staff.

B. Opportunity to Be Heard
Equivalent Consequences
Professional Demeanor

A substantial body of research on procedural justice or procedural fairness reveals that criminal defendants are most likely to react favorably to an adverse judgment or punitive sanction if they believe fair procedures were followed in reaching the decision. The best outcomes were achieved when defendants were (1) given a reasonable opportunity to explain their side of the dispute, (2) treated in an equivalent manner to similar people in similar circumstances and (3) accorded respect and dignity throughout the process (Burke & Leben, 2007; Frazer, 2006; Tyler, 2007).

In the MADCE study, outcomes were significantly better when participants perceived the judge as fair and when independent observers rated the judge's interactions with the participants as respectful, fair, consistent, and predictable (Rossman et al., 2011). In contrast, outcomes were significantly poorer for judges who were rated as being arbitrary or not giving participants an opportunity to explain their side of the controversy (Farole & Cissner, 2007; Rossman et al., 2011). Stigmatizing, hostile, and shaming comments from the judge have also been associated with significantly poorer outcomes in Drug Courts (Gallagher, 2013; Miethe et al., 2000).

C. Equivalent Consequences

See Commentary B above.

D. Professional Demeanor

See Commentary B above.

E. Progressive Sanctions

Sanctions are less effective at low and high magnitudes than in the intermediate range (Marlowe & Kirby, 1999; Marlowe & Wong, 2008). Sanctions that are weak in magnitude can cause *habituation* in which the individual becomes accustomed, and thus less responsive, to punishment. Sanctions that are severe in magnitude can lead to *ceiling effects* in which the program runs out of sanctions before treatment has had a chance to take effect. The most effective Drug Courts develop a wide and creative range of intermediate-magnitude sanctions that can be ratcheted upward or downward in response to participants' behaviors (Marlowe, 2007). The NDCI publishes, free of charge, lists of sanctions and incentives of varying magnitudes that have been collected from hundreds of Drug Courts around the country.[16]

Significantly better outcomes are achieved when the sanctions for failing to meet difficult goals increase progressively in magnitude over successive infractions (Harrell & Roman, 2001; Harrell et al., 1999; Hawken & Kleiman, 2009; Kilmer et al., 2012; National Institute on Drug Abuse, 2006). Providing gradually escalating sanctions for difficult goals gives treatment a chance to take effect and prepares participants to meet steadily increasing responsibilities in the program. In contrast, applying high-magnitude sanctions for failing to meet easy goals avoids habituation (Marlowe, 2011).

F. Licit Addictive or Intoxicating Substances

Consequences should be imposed for the nonmedically indicated use of intoxicating and addictive substances, including alcohol, cannabis (marijuana), and prescription medications, regardless of the licit or illicit status of the substance. Ingestion of alcohol and cannabis gives rise to further criminal activity (Bennett et al., 2008; Boden et al., 2013; Friedman et al., 2001; Pedersen & Skardhamar, 2010; Reynolds et al., 2011), precipitates relapse to other drugs of abuse (Aharonovich et al., 2005), increases the likelihood that participants will fail out of Drug Court (Sechrest & Shicor, 2001), and reduces the efficacy of rewards and sanctions that are used in Drug Courts to improve participants' behaviors (Lane et al., 2004; Thompson et al., 2012). Permitting the continued use of these substances is contrary to evidence-based practices in

[16] List of Incentives and Sanctions, available at http://www.ndcrc.org/content/list-incentives-and-sanctions.

substance abuse treatment and interferes with the central goals of a Drug Court. The use of any addictive or intoxicating substance should be authorized only if it is determined by competent medical evidence to be medically indicated, if safe and effective alternative treatments are not reasonably available, and if the participant is carefully monitored by a physician with training in addiction psychiatry or addiction medicine. There is a serious risk of morbidity, mortality, or illegal diversion of medications when addiction medications are prescribed by general medical practitioners for addicted patients (Bazazi et al., 2011; Bohnert et al., 2011; Daniulaityte et al., 2012; Johanson et al., 2012).

G. Therapeutic Adjustments

Individuals who are addicted to alcohol or other drugs commonly experience severe cravings to use the substance and may suffer from painful or uncomfortable withdrawal symptoms when they discontinue use (American Psychiatric Association, 2000; American Society of Addiction Medicine, 2011). These symptoms often reflect neurological or neurochemical impairment in the brain (Baler & Volkow, 2006; Dackis & O'Brien, 2005; NIDA, 2006). If a Drug Court imposes substantial sanctions for substance use early in treatment, the team is likely to run out of sanctions and reach a ceiling effect before treatment has had a chance to take effect. Therefore, Drug Courts should ordinarily adjust participants' treatment requirements in response to positive drug tests during the early phases of the program. Participants might, for example, require medication, residential treatment, or motivational-enhancement therapy to improve their commitment to abstinence (Chandler et al., 2009). Because judges are not trained to make such decisions, they must rely on the expertise of duly trained clinicians when adjusting treatment conditions [see also Standard III, Roles and Responsibilities of the Judge]. After participants have received adequate treatment and have stabilized, it becomes appropriate to apply progressively escalating sanctions for illicit drug or alcohol use.

The question might arise about what to do for a participant who is complying with most of his or her obligations in the program, but is continuing to abuse substances over an extended period. If multiple adjustments to the treatment plan have been inadequate to initiate abstinence, it is possible the participant might not be amenable to the treatments that are available in the Drug Court. Under such circumstances, it may become necessary to discharge the participant; however, the participant should not be punished or receive an augmented sentence for trying, but failing, to respond to treatment (see subsection K below). Alternatively, the team might discover that the participant was willfully failing to apply him or herself in treatment. Under those circumstances, it would be appropriate to apply punitive sanctions for the willful failure to comply with treatment.

H. Incentivizing Productivity

Drug Courts achieve significantly better outcomes when they focus as much on incentivizing productive behaviors as they do on reducing undesirable behaviors. In the MADCE, significantly better outcomes were achieved by Drug Courts that offered higher and more consistent levels of praise and positive incentives from the judge (Zweig et al., 2012). Several other studies found that a 4:1 ratio of incentives to sanctions was associated with significantly better outcomes among drug offenders (Gendreau, 1996; Senjo & Leip, 2001; Wodahl et al., 2011). Support for the 4:1 ratio must be viewed with caution because it was derived from post hoc (after the fact) correlations rather than from controlled studies. By design, sanctions are imposed for poor performance and incentives are provided for good performance; therefore, a greater proportion of incentives might not have caused better outcomes, but rather better outcomes might have elicited a greater proportion of incentives. Nevertheless, although this correlation does not prove causality, it does suggest that Drug Courts are more likely to be successful if they make positive incentives readily available to their participants.

It is essential to recognize that punishment and positive reinforcement serve different, but complementary, functions. Punishment is used to reduce undesirable behaviors, such as substance abuse and crime, whereas positive reinforcement is used to increase desirable behaviors, such as treatment attendance and employment. Therefore, they are most likely to be effective when administered in combination (DeFulio et al., 2013). The effects of punishment typically last only as long as the sanctions are forthcoming, and undesirable behaviors often return precipitously after the sanctions are withdrawn (Marlowe & Kirby,

1999; Marlowe & Wong, 2008). For this reason, Drug Courts that rely exclusively on punishment to reduce drug abuse and crime will rarely produce lasting gains after graduation.

Treatment gains are most likely to be sustained if positive reinforcement is used to increase participant involvement in productive activities, such as employment or recreation, which can compete against drug abuse and crime after graduation. Studies have revealed that Drug Courts achieved significantly greater reductions in recidivism and greater cost savings when they required their participants to have a job, enroll in school, or live in sober housing as a condition of graduation from the program (Carey et al., 2012). How high a Drug Court should set the bar for graduation depends on the level of functioning of its participants. For seriously impaired participants, finding a safe place to live might be the most that can reasonably be expected after only a year or so of treatment. Other participants, however, might be capable of obtaining a job or a GED after a year. At a minimum, Drug Courts must ensure that their participants are engaged in a sufficient level of prosocial activities to keep them stable and abstinent after they have left the structure of the Drug Court program. The community reinforcement approach (CRA; Budney et al., 1998; Godley & Godley, 2008) is one example of an evidence-based counseling intervention that Drug Courts can use to incentivize participant involvement in prosocial activities.

I. Phase Promotion

Drug Courts have significantly better outcomes when they have a clearly defined phase structure and concrete behavioral requirements for advancement through the phases (Carey et al., 2012; Shaffer, 2006; Wolfer, 2006). The purpose of phase advancement is to reward participants for their accomplishments and put them on notice that the expectations for their behavior have been raised accordingly (Marlowe, 2011). Therefore, phase advancement should be predicated on the achievement of clinically important milestones that mark substantial progress towards recovery. Phase advancement should not be based simply on the length of time that participants have been enrolled in the program.

As participants make progress in treatment, they become better equipped to resist illicit drugs and alcohol and to engage in productive activities. Therefore, as they move through the phases of the program, the consequences for infractions should increase accordingly and supervision services may be reduced. Because addiction is a chronic and relapsing medical condition (McLellan et al., 2000), treatment must be reduced only if it is determined clinically that doing so would be unlikely to precipitate a relapse. Finally, a basic tenet of behavior modification provides that the effects of treatment should be assessed continually until all components of the intervention have been withdrawn (Rusch & Kazdin, 1981). Therefore, drug and alcohol testing should be the last supervisory obligation that is lifted to ensure relapse does not occur as other treatment and supervision services are withdrawn.

Reducing treatment or supervision before participants have been stabilized sufficiently puts the participants at serious risk for relapse or other behavioral setbacks. A relapse occurring soon after a phase promotion is often a sign that services were reduced too abruptly. The appropriate course of action is to return the participant temporarily to the preceding phase and plan for a more effective phase transition. Returning the participant to the beginning of the first phase of treatment is usually not appropriate because this may exacerbate what is referred to as the *abstinence violation effect* (AVE) (Marlatt, 1985). When addicted individuals experience a lapse after an extended period of abstinence, they may conclude, wrongly, that they have accomplished nothing in treatment and will never be successful at recovery. This counterproductive all-or-nothing thinking may put them at further risk for a full relapse or for dropping out of treatment (Collins & Lapp, 1991; Marlatt & Witkiewitz, 2005; Stephens et al., 1994). Returning the participant to the first phase of treatment could be misinterpreted as corroborating this erroneous thinking. The goal of the Drug Court should be to counteract the AVE and help the participant learn from the experience and avoid making the same mistake again.

J. Jail Sanctions

The certainty and immediacy of sanctions are far more influential to outcomes than the magnitude or severity of the sanctions (Harrell & Roman, 2001; Marlowe et al., 2005; Nagin & Pogarsky, 2011). As was noted earlier, sanctions that are too high in magnitude can lead to ceiling effects in which outcomes may become stagnant or may even be made worse.

Drug Courts are significantly more effective and cost-effective when they use jail sanctions sparingly (Carey et al., 2008b; Hepburn & Harvey, 2007). Research in Drug Courts indicates that jail sanctions produce diminishing returns after approximately three to five days (Carey et al., 2012; Hawken & Kleiman, 2009). A multisite study found that Drug Courts that had a policy of applying jail sanctions of longer than one week were associated with increased recidivism and negative cost-benefits (Carey et al., 2012). Drug Courts that relied on jail sanctions of longer than two weeks were two and a half times less effective at reducing crime and 45% less cost-effective than Drug Courts that tended to impose shorter jail sanctions.

Because jail sanctions involve the loss of a fundamental liberty interest, Drug Courts must ensure that participants receive a fair hearing on the matter (Meyer, 2011). Given that many controversies in Drug Courts involve uncomplicated questions of fact, such as whether a drug test was positive or whether the participant missed a treatment session, truncated hearings can often be held on the same day and provide adequate procedural due process protections.

K. Termination

Participants may be terminated from the Drug Court if they pose an immediate risk to public safety, are unwilling or unable to engage in treatment, or are too impaired to benefit from the treatments that are available in their community. If none of these conditions are met, then in most cases the most effective course of action will be to adjust a nonresponsive participant's treatment or supervision requirements or apply escalating sanctions.

Drug Courts have significantly poorer outcomes and are considerably less cost-effective when they terminate participants for drug or alcohol use. In a multisite study, Drug Courts that had a policy of terminating participants for positive drug tests or new arrests for drug possession offenses had 50% higher criminal recidivism and 48% lower cost savings than Drug Courts that responded to new drug use by increasing treatment or applying sanctions of lesser severity (Carey et al., 2012). The results of another meta-analysis similarly revealed significantly poorer outcomes for Drug Courts that had a policy of terminating participants for positive drug tests (Shaffer, 2010). Because termination from Drug Court for continued substance use is costly and does not improve outcomes, participants should be terminated only when necessary to protect public safety or if continued efforts at treatment are unlikely to be successful.

If a participant is terminated from Drug Court because adequate treatment was unavailable to meet his or her clinical needs, fairness dictates the participant should receive credit for the efforts in the program and should not receive an augmented sentence or disposition for the unsuccessful termination. To do otherwise is likely to dissuade addicted offenders and their defense attorneys from choosing the Drug Court option. Defense attorneys are understandably reluctant to advise their clients to enter Drug Court when there is a serious risk their client could receive an enhanced sentence despite his or her best efforts in treatment (Bowers, 2007; Justice Policy Institute, 2011; National Association of Criminal Defense Lawyers, 2009).

L. Consequences of Graduation and Termination

Studies consistently find that Drug Courts have better outcomes when they exert *leverage* over their participants, meaning the participants can avoid a serious sentence or disposition if they complete the program (Cissner et al., 2013; Goldkamp et al., 2001; Longshore et al., 2001; Mitchell et al., 2012; Rempel & DeStefano, 2001; Rossman et al., 2011; Shaffer, 2010; Young & Belenko, 2002). Conversely, outcomes are typically poor if minimal consequences are enacted for withdrawing from or failing to complete the program (Cissner et al., 2013; Burns & Peyrot, 2008; Carey et al., 2008b; Gottfredson et al., 2003; Rempel & DeStefano, 2001; Rossman et al., 2011; Young & Belenko, 2002). If it is the policy of a Drug Court to resume traditional legal proceedings as if terminated participants had never attempted Drug Court, the odds are substantially diminished that the program will be successful.

Legal precedent and empirical research offer little guidance for deciding when to impose more than the presumptive sentence for the underlying offense if an offender fails a diversion program such as a Drug Court. At a minimum, participants and their legal counsel must be informed of the possibility that an augmented sentence could be imposed when they execute a waiver to enter the Drug Court (Meyer, 2011). Drug Courts should make every effort to spell out in the waiver agreement what factors the judge is likely

to take into account when deciding whether to augment the presumptive sentence if a participant is terminated or withdraws from the program.

REFERENCES

Aharonovich, E., Liu, X., Samet, S., Nunes, E., Waxman, R., & Hasin, D. (2005). Postdischarge cannabis use and its relationship to cocaine, alcohol, and heroin use: A prospective study. *American Journal of Psychiatry, 162*(8)*,* 1507–1514.

American Psychiatric Association. (2000). *Diagnostic and statistical manual of mental disor*ders (4th ed., text rev.). Washington, DC: American Psychiatric Press.

American Society of Addiction Medicine. (2011). *Public policy statement: Definition of addiction*. *Available at* http://www.asam.org/for-the-public/definition-of-addiction.

Baler, R.D., & Volkow, N.D. (2006). Drug addiction: The neurobiology of disrupted self-control. *Trends in Molecular Medicine, 12*(12), 559–566.

Bazazi, A.R., Yokell, M., Fu, J.J., Rich, J.S., & Zaller, N.D. (2011). Illicit use of buprenorphine/naloxone among injecting and noninjecting opioid users. *Journal of Addiction Medicine, 5*(3), 175–180.

Bennett, T., Holloway, K., & Farrington, D. (2008). The statistical association between drug misuse and crime: A meta-analysis. *Aggression & Violent Behavior, 13*(2), 107–118.

Boden, J.M., Fergusson, D.M., & Horwood, L.J. (2013). Alcohol misuse and criminal offending: Findings from a 30-year longitudinal study. *Drug & Alcohol Dependence, 128*(1–2), 30–36.

Bohnert, A.S., Valenstein, M., Bair, M.J., Ganoczy, D., McCarthy, J.F., Ilgen, M.A., & Blow, F.C. (2011). Association between opioid prescribing patterns and opioid overdose-related deaths. *Journal of the American Medical Association, 305*(13), 1315-1321.

Bowers, J. (2007). Contraindicated drug courts. *UCLA Law Review, 55*, 783-831.

Budney, A.J., Higgins, S.T., Mercer, D.E., & Carpenter, G. (1998). *A community reinforcement approach: Treating cocaine addiction* [NIH Pub. No. 98-4309]. In series *Therapy manuals for drug abuse: Manual 2.* Rockville, MD: National Institute on Drug Abuse. *Available at* http://archives.drugabuse.gov/TXManuals/CRA/CRA1.html.

Burdon, William M., John M. Roll, Michael L. Prendergast, & Richard A. Rawson. (2001). Drug courts and contingency management. *Journal of Drug Issues, 31*(1)*,* 73–90.

Burke, K., & Leben, S. (2007). Procedural fairness: A key ingredient in public satisfaction [White paper]. *Court Review, 44*(1–2), 4–25.

Burns, S.L., & Peyrot, M. (2008). Reclaiming discretion: Judicial sanctioning strategy in court-supervised drug treatment. *Journal of Contemporary Ethnography, 37*(6), 720–744.

Carey, S.M., Finigan, M.W., & Pukstas, K. (2008a). *Exploring the key components of drug courts: A comparative study of 18 adult drug courts on practices, outcomes and costs*. Portland, OR: NPC Research. *Available at* http://www.npcresearch.com/Files/NIJ_Cross-site_Final_Report_0308.pdf.

Carey, S.M., Mackin, J.R., & Finigan, M.W. (2012). What works? The ten key components of Drug Court: Research-based best practices. *Drug Court Review*, *8*(1), 6–42.

Carey, S.M., Pukstas, K., Waller, M.S., Mackin, R.J., & Finigan, M.W. (2008b). *Drug courts and state mandated drug treatment programs: Outcomes, costs and consequences*. Portland, OR: NPC Research. *Available at* http://www.npcresearch.com/Files/Prop36_Drug_Court_Executive_Summary_0308.pdf.

Chandler, R.K., Fletcher, B.W., & Volkow, N.D. (2009). Treating drug abuse and addiction in the criminal justice system: Improving public health and safety. *Journal of the American Medical Association, 301*(2), 183–190.

Cheesman, F.L., & Kunkel, T.L. (2012). *Virginia Adult Drug Treatment Courts: Cost benefit analysis*. Williamsburg, VA: National Center for State Courts.

Cissner, A., Rempel, M., Franklin, A.W., Roman, J.K., Bieler, S., Cohen, R., & Cadoret, C.R. (2013, March). *A statewide evaluation of New York's adult drug courts: Testing which policies work best*. Paper presented at the New York Association of Drug Treatment Court Professionals Training. *Available at* http://www.nyadtcp.org/userfiles/file/presentation/The%202012%20New%20York%20State%20Drug%20Court%20Evaluation.pdf.

Collins, L.R., & Lapp, W.M. (1991). Restraint and attributions: Evidence of the abstinence violation effect in alcohol consumption. *Cognitive Therapy & Research, 15*(1), 69–84.

Dackis, C., & O'Brien, C. (2005). Neurobiology of addiction: Treatment and public policy ramifications. *Nature Neuroscience, 8*(11), 1431–1436.

Daniulaityte, R., Falck, R., & Carlson, R. G. (2012). Illicit use of buprenorphine in a community sample of young adult non-medical users of pharmaceutical opioids. *Drug and Alcohol Dependence, 122*(3), 201–207.

DeFulio, A., Stitzer, M., Roll, J., Petry, N., Nuzzo, P., Schwartz, R.P., & Stabile, P. (2013). Criminal justice referral and incentives in outpatient substance abuse treatment. *Journal of Substance Abuse Treatment, 45*(1), 70–75.

Farole, D.J., & Cissner, A.B. (2007). Seeing eye to eye: Participant and staff perspectives on drug courts. In G. Berman, M. Rempel & R.V. Wolf (Eds.), *Documenting Results: Research on Problem-Solving Justice* (pp. 51–73). New York: Center for Court Innovation.

Frazer, M.S. (2006). *The impact of the community court model on defendant perceptions of fairness: A case study at the Red Hook Community Justice Center.* New York: Center for Court Innovation. *Available at* http://www.courtinnovation.org/sites/default/files/Procedural_Fairness.pdf.

Friedman, A.S., Glassman, K., & Terras, A. (2001). Violent behavior as related to use of marijuana and other drugs. *Journal of Addictive Diseases, 20*(1), 49–72.

Gallagher, J.R. (2013). African American participants' views on racial disparities in drug court outcomes. *Journal of Social Work Practice in the Addictions, 13*(2)*,* 143–162.

Gendreau, P. (1996). The principles of effective intervention with offenders. In A. Harland (Ed.), *Choosing correctional options that work* (pp. 117–130). Thousand Oaks, CA: Sage.

Godley, M.D., & Godley, S.H. (2008). *Adolescent Community Reinforcement Approach (A-CRA). Available at* http://nrepp.samhsa.gov/ViewIntervention.aspx?id=41.

Goldkamp, J.S., White, M.D., & Robinson, J.B. (2001). Do Drug Courts work? Getting inside the Drug Court black box. *Journal of Drug Issues, 31*(1), 27–72.

Gottfredson, D.C., Najaka, S.S., & Kearley, B., (2003). Effectiveness of drug treatment courts: Evidence from a randomized trial. *Criminology & Public Policy, 2*(2), 171–196.

Griffith, J.D., Rowan-Szal, G.A., Roark, R.R., & Simpson, D.D. (1999). Contingency management in outpatient methadone treatment: A meta-analysis. *Drug & Alcohol Dependence, 58*(1), 55–66.

Harrell, A., Cavanagh, S., & Roman, J. (1999). *Findings From the Evaluation of the D.C. Superior Court Drug Intervention Program: Final Report.* Washington, DC: The Urban Institute.

Harrell, A., & Roman, J. (2001). Reducing drug use and crime among offenders: The impact of graduated sanctions. *Journal of Drug Issues, 31*(1)*,* 207–231.

Hawken, A., & Kleiman, M. (2009). *Managing drug involved probationers with swift and certain sanctions: Evaluating Hawaii's HOPE* (NCJRS No. 229023)*.* Washington, DC: National Institute of Justice. *Available at* http://www.ncjrs.gov/pdffiles1/nij/grants/229023.pdf.

Hepburn, J.R., & Harvey, A.N. (2007). The effect of the threat of legal sanction on program retention and completion: Is that why they stay in drug court?. *Crime & Delinquency, 53*(2), 255–280.

Johanson, C., Arfken, C. L., di Menza, S., & Schuster, C. R. (2012). Diversion and abuse of buprenorphine: Findings from national surveys of treatment patients and physicians. *Drug and Alcohol Dependence, 120*(1), 190–195.

Justice Policy Institute. (2011). *Addicted to courts: How a growing dependence on drug courts impacts people and communities*. Washington, DC: Author.

Kilmer, B., Nicosia, N., Heaton, P., & Midgette, G. (2012). Efficacy of frequent monitoring with swift, certain, and modest sanctions for violations: Insights from South Dakota's 24/7 Sobriety Project. *American Journal of Public Health, 103*(1), e37–e43.

Lane, S.D., Cherek, D.R., Pietras, C.J., & Tcheremissine, O.V. (2004). Acute marijuana effects on response–reinforcer relations under multiple variable-interval schedules. *Behavioural Pharmacology*, *15*(4), 305–309.

Longshore, D.L., Turner, S., Wenzel, S.L., Morral, A.R., Harrell, A., McBride, D., Deschenes,E., & Iguchi, M.Y. (2001). Drug Courts: A conceptual framework. *Journal of Drug Issues 31*(1), 7–25.

Lussier, J.P., Heil, S.H., Mongeon, J.A., Badger, G.J., & Higgins, S.T. (2006). A meta-analysis of voucher-based reinforcement therapy for substance use disorders. *Addiction, 101*(2), 192–203.

Marlatt, G.A. (1985). Cognitive factors in the relapse process. In G. A. Marlatt & J. R. Gordon (Eds.), *Relapse prevention: Maintenance strategies in the treatment of addictive behaviors* (pp. 128-200). New York: Guilford.

Marlatt, G.A., & Witkiewitz, K. (2005). Relapse prevention for alcohol and drug problems. In G. A. Marlatt & D. M. Donovan (Eds.), *Relapse prevention: Maintenance strategies in the treatment of addictive behaviors* (2nd ed.; pp. 1-44). New York: Guilford.

Marlowe, D.B. (2007). Strategies for administering rewards and sanctions. In J.E. Lessenger & G.F. Roper (Eds.), *Drug courts: A new approach to treatment and rehabilitation* (pp. 317–336). New York: Springer.

Marlowe, D.B. (2011). Applying incentives and sanctions. In B. Marlowe & W.G. Meyer (Eds.), *The drug court judicial benchbook* (pp.139–157). Alexandria, VA: National Drug Court Institute. *Available at* http://www.ndci.org/sites/default/files/nadcp/14146_NDCI_Benchbook_v6.pdf.

Marlowe, D.B., Festinger, D.S., Foltz, C., Lee, P.A., & Patapis, N.S. (2005). Perceived deterrence and outcomes in drug court. *Behavioral Sciences & the Law, 23*(2), 183–198.

Marlowe, D.B., & Kirby, K.C. (1999). Effective use of sanctions in drug courts: Lessons from behavioral research. *National Drug Court Institute Review, 2*(1), 1–31.

Marlowe, D.B., & Wong, C.J. (2008). Contingency management in adult criminal drug courts. In S.T. Higgins, K. Silverman, & S.H. Heil (Eds.), *Contingency management in substance abuse treatment* (pp. 334–354). New York: Guilford Press.

McLellan, A. T., Lewis, D. L., O'Brien, C. P., & Kleber, H. D. (2000). Drug dependence, a chronic medical illness: Implications for treatment, insurance, and outcomes evaluation. *Journal of the American Medical Association, 284*, 1689-1695.

Meyer, W.G. (2011). Constitutional and legal issues in drug courts. In D.B. Marlowe & W.G. Meyer (Eds.), *The drug court judicial benchbook* (pp. 159–180). Alexandria, VA: National Drug Court Institute. Available at http://www.ndci.org/sites/default/files/nadcp/14146_NDCI_Benchbook_v6.pdf.

Miethe, T.D., Lu, H., & Reese, E. (2000). Reintegrative shaming and recidivism risks in Drug Court: Explanations for some unexpected findings. *Crime & Delinquency, 46*(4)*,* 522–541.

Mitchell, O., Wilson, D.B., Eggers, A., & MacKenzie, D.L. (2012). Assessing the effectiveness of drug courts on recidivism: A meta-analytic review of traditional and nontraditional drug courts. *Journal of Criminal Justice, 40*(1), 60–71.

Nagin, D.S., & Pogarsky, G. (2001). Integrating celerity, impulsivity, and extralegal sanction threats into a general deterrence: Theory and evidence. *Criminology, 39*(4), 865–892.

National Association of Criminal Defense Lawyers. (2009). *America's problem-solving courts: The criminal costs of treatment and the case for reform*. Washington, DC: Author.

National Institute on Drug Abuse. (2006). *Principles of drug abuse treatment for criminal justice populations* (NIH Pub. No. 06–5316). Bethesda, MD: Author.

Pedersen, W., & Skardhamar, T. (2010). Cannabis and crime: Findings from a longitudinal study. *Addiction, 105*(1), 109–118.

Rempel, M., & DeStefano, C.D. (2001). Predictors of engagement in court-mandated treatment: Findings at the Brooklyn Treatment Court, 1996–2000. *Journal of Offender Rehabilitation, 33*(4), 87–124.

Reynolds, M.D., Tarter, R.E., Kirisci, L., & Clark, D.B. (2011). Marijuana but not alcohol use during adolescence mediates the association between transmissible risk for substance use disorder and number of lifetime violent offenses. *Journal of Criminal Justice,* 39(3), 218-223.

Rossman, S.B., Rempel, M., Roman, J.K., Zweig, J.M., Lindquist, C.H., Green, M., Downey, P.M., Yahner, J., Bhati, A.S., & Farole, D.J. (2011). *The multisite adult drug court evaluation: The impact of drug courts, vol. 4.* Washington, DC: Urban Institute Justice Policy Center. *Available at* https://www.ncjrs.gov/pdffiles1/nij/grants/237112.pdf.

Rusch, F.R., & Kazdin, A.E. (1981). Toward a methodology of withdrawal designs for the assessment of response maintenance. *Journal of Applied Behavior Analysis, 14*(2), 131–140.

Sechrest, D.K., & Shicor, D. (2001). Determinants of graduation from a day treatment drug court in California: A preliminary study. *Journal of Drug Issues, 31*, 129–147.

Senjo, S.R., & Leip, L.A. (2001). Testing and developing theory in Drug Court: A four-part logit model to predict program completion. *Criminal Justice Policy Review, 12*(1), 66–87.

Shaffer, D.K. (2006). Reconsidering drug court effectiveness: A meta-analytic review (Doctoral dissertation, University of Cincinnati, 2006). *Dissertation Abstracts International*, 67, 09A (AAT No. 3231113).

Shaffer, D.K. (2010). Looking inside the black box of drug courts: A meta-analytic review. *Justice Quarterly, 28*(3), 493–521.

Stephens, R.S., Curtin, L., Simpson, E. E., & Roffman, R.A. (1994). Testing the abstinence violation effect construct with marijuana cessation. *Addictive Behaviors, 19*(1), 23–32.

Stitzer, M.L. (2008). Motivational incentives in drug courts. In C. Hardin & J.N. Kushner (Eds.), *Quality improvement for drug courts: Evidence-based practices* (pp. 97–105). Alexandria, VA: National Drug Court Institute.

Thompson, L.L., Claus, E.D., Mikulich-Gilbertson, S.K., Banich, M.T., Crowley, T., Krmpotich, T., Miller, D., & Tanabe, J. (2012). Negative reinforcement learning is affected in substance dependence. *Drug & Alcohol Dependence, 123*(1), 84–90.

Tyler, T.R. (2007). Procedural justice and the courts. *Court Review, 44* (1–2), 26–31.

Wodahl, E.J., Garland, B., Culhane, S.E., & McCarty, W.P. (2011). Utilizing behavioral interventions to improve supervision outcomes in community-based corrections. *Criminal Justice & Behavior, 38*(4), 386–405.

Wolfer, L. (2006). Graduates speak: A qualitative exploration of drug court graduates' views of the strengths and weaknesses of the program. *Contemporary Drug Problems, 33*(2), 303–320.

Young, D., & Belenko, S. (2002). Program retention and perceived coercion in three models of mandatory drug treatment. *Journal of Drug Issues,* 22(1), 297–328.

Zweig, J.M., Lindquist, C., Downey, P.M., Roman, J., & Rossman, S.B. (2012). Drug court policies and practices: How program implementation affects offender substance use and criminal behavior outcomes. *Drug Court Review*, *8*(1), 43–79.

V. SUBSTANCE ABUSE TREATMENT

Participants receive substance abuse treatment based on a standardized assessment of their treatment needs.[17] Substance abuse treatment is not provided to reward desired behaviors, punish infractions, or serve other nonclinically indicated goals. Treatment providers[18] are trained and supervised to deliver a continuum of evidence-based interventions that are documented in treatment manuals.

A. Continuum of Care
B. In-Custody Treatment
C. Team Representation
D. Treatment Dosage & Duration
E. Treatment Modalities
F. Evidence-Based Treatments
G. Medications
H. Provider Training & Credentials
I. Peer Support Groups
J. Continuing Care

A. Continuum of Care

The Drug Court offers a continuum of care for substance abuse treatment including detoxification, residential, sober living, day treatment, intensive outpatient and outpatient services. Standardized patient placement criteria govern the level of care that is provided. Adjustments to the level of care are predicated on each participant's response to treatment and are not tied to the Drug Court's programmatic phase structure. Participants do not receive punitive sanctions or an augmented sentence if they fail to respond to a level of care that is substantially below or above their assessed treatment needs.

B. In-Custody Treatment

Participants are not incarcerated to achieve clinical or social service objectives such as obtaining access to detoxification services or sober living quarters.

---

[17] The provisions of this Standard assume participants have been reliably diagnosed as dependent on or addicted to illicit drugs, alcohol or prescription medications that are taken for a nonprescribed or nonmedically indicated purpose [see Standard I, Target Population]. If a Drug Court is unable to provide the level of services specified herein, it may need to alter its eligibility criteria to serve a nonaddicted population.

[18] The terms *treatment provider* or *clinician* refer to any professional administering substance abuse treatment in a Drug Court, including licensed or certified addiction counselors, social workers, nurses, psychologists, and psychiatrists. The term *clinical case manager* refers to a clinically trained professional who may perform substance abuse assessments, make referrals for substance abuse treatment, or report on participant progress in treatment during court hearings or staff meetings, but does not provide substance abuse treatment.

C. Team Representation

One or two treatment agencies are primarily responsible for managing the delivery of treatment services for Drug Court participants. Clinically trained representatives from these agencies are core members of the Drug Court team and regularly attend team meetings and status hearings. If more than two agencies provide treatment to Drug Court participants, communication protocols are established to ensure accurate and timely information about each participant's progress in treatment is conveyed to the Drug Court team.

D. Treatment Dosage and Duration

Participants receive a sufficient dosage and duration of substance abuse treatment to achieve long-term sobriety and recovery from addiction. Participants ordinarily receive six to ten hours of counseling per week during the initial phase of treatment and approximately 200 hours of counseling over nine to twelve months; however, the Drug Court allows for flexibility to accommodate individual differences in each participant's response to treatment.

E. Treatment Modalities

Participants meet with a treatment provider or clinical case manager for at least one individual session per week during the first phase of the program. The frequency of individual sessions may be reduced subsequently if doing so would be unlikely to precipitate a behavioral setback or relapse. Participants are screened for their suitability for group interventions, and group membership is guided by evidence-based selection criteria including participants' gender, trauma histories and co-occurring psychiatric symptoms. Treatment groups ordinarily have no more than twelve participants and at least two leaders or facilitators.

F. Evidence-Based Treatments

Treatment providers administer behavioral or cognitive-behavioral treatments that are documented in manuals and have been demonstrated to improve outcomes for addicted persons involved in the criminal justice system. Treatment providers are proficient at delivering the interventions and are supervised regularly to ensure continuous fidelity to the treatment models.

G. Medications

Participants are prescribed psychotropic or addiction medications based on medical necessity as determined by a treating physician with expertise in addiction psychiatry, addiction medicine, or a closely related field.

H. Provider Training and Credentials

Treatment providers are licensed or certified to deliver substance abuse treatment, have substantial experience working with criminal justice populations, and are supervised regularly to ensure continuous fidelity to evidence-based practices.

I. Peer Support Groups

Participants regularly attend self-help or peer support groups in addition to professional counseling. The peer support groups follow a structured model or curriculum such as the 12-step or Smart Recovery models.[19] Before participants enter the peer support groups, treatment providers use an evidence-based preparatory intervention, such as 12-step facilitation therapy, to prepare the participants for what to expect in the groups and assist them to gain the most benefits from the groups.

J. Continuing Care

Participants complete a final phase of the Drug Court focusing on relapse prevention and continuing care. Participants prepare a continuing-care plan together with their counselor to ensure they continue to engage in prosocial activities and remain connected with a peer support group after their discharge from the Drug Court. For at least the first ninety days after discharge from the Drug Court, treatment providers or clinical case managers attempt to contact previous participants periodically by telephone, mail, e-mail, or similar means to check on their progress, offer brief advice and encouragement, and provide referrals for additional treatment when indicated.

COMMENTARY

A. Continuum of Care

Outcomes are significantly better in Drug Courts that offer a continuum of care for substance abuse treatment which includes residential treatment and recovery housing in addition to outpatient treatment (Carey et al., 2012; Koob et al., 2011; McKee, 2010). Participants who are placed initially in residential treatment should be stepped down gradually to day treatment or intensive outpatient treatment and subsequently to outpatient treatment (Krebs et al., 2009). Moving patients directly from residential treatment to a low frequency of standard outpatient treatment has been associated with poor outcomes in substance abuse treatment studies (McKay, 2009a; Weiss et al., 2008). Broadly speaking, standard outpatient treatment is typically less than nine hours per week of services, intensive outpatient treatment is typically between nine and nineteen hours, and day treatment is typically over twenty hours but does not include overnight stays (Mee-Lee & Gastfriend, 2008).

Significantly better results are achieved when substance abuse patients are assigned to a level of care based on a standardized assessment of their treatment needs as opposed to relying on professional judgment or discretion (Andrews & Bonta, 2010; Babor & Del Boca, 2002; Karno & Longabaugh, 2007; Vieira et al., 2009). The most commonly used placement criteria are the *American Society of Addiction Medicine Patient Placement Criteria for the Treatment of Substance-Related Disorders* (ASAM-PPC; Mee-Lee et al., 2001). Studies have confirmed that patients who received the indicated level of care according to the ASAM-PPC had significantly higher treatment completion rates and fewer instances of relapse to substance use than patients who received a lower level of care than was indicated by the ASAM-PPC (for example, patients who received outpatient treatment when the ASAM-PPC indicated a need for residential treatment; De Leon et al., 2010; Gastfriend et al., 2000; Gregoire, 2000; Magura et al., 2003; Mee-Lee & Gastfriend, 2008). Patients who received a higher level of care than was indicated by the ASAM-PPC had equivalent or

[19] Drug Courts must offer a secular alternative to 12-step programs such as Narcotics Anonymous because appellate courts have interpreted these programs to be deity-based, thus implicating the First Amendment (Meyer, 2011).

worse outcomes than those receiving the indicated level of care, and the programs were rarely cost-effective (Magura et al., 2003).

In the criminal justice system, mismatching offenders to a higher level of care than they require has been associated frequently with negative or iatrogenic effects in which outcomes were made worse. In several studies, offenders who received residential treatment when a lower level of care would have sufficed had significantly higher rates of treatment failure and criminal recidivism than offenders with comparable needs who were assigned to outpatient treatment (Lovins et al., 2007; Lowenkamp & Latessa, 2005; Wexler et al., 2004). The negative impact of receiving an excessive level of care appears to be most pronounced for offenders below the age of twenty-five years, perhaps because youthful offenders are more vulnerable to antisocial peer influences (DeMatteo et al., 2006; Lowenkamp & Latessa, 2004; McCord, 2003; Petrosino et al., 2000; Szalavitz, 2010). Particular caution is required, therefore, to ensure younger Drug Court participants are not placed erroneously into residential substance abuse treatment.

As was discussed earlier, evidence suggests racial and ethnic minority offenders may be more likely than nonminorities to receive a lower level of care than is warranted from their assessment results (Integrated Substance Abuse Programs, 2007; Janku & Yan, 2009). To prevent this from occurring in Drug Courts, a unanimous resolution of the NADCP Board of Directors requires Drug Courts to monitor whether minorities and members of other historically disadvantaged groups are receiving services equivalent to other participants in the program and to take remedial measures, where indicated, to correct any discrepancies [see Standard II, Historically Disadvantaged Groups].

Some Drug Courts may begin all participants in the same level of care, or may routinely taper down the level of care as participants move through the phases of the program. The research cited above shows clearly that such practices are not justified on the bases of clinical necessity or cost. Participants should not be assigned to a level of care without first confirming through a standardized and validated assessment that their clinical needs warrant that level of care.

If a Drug Court is unable to provide adequate levels of care to meet the needs of addicted individuals, then the program might consider adjusting its eligibility criteria to serve a less clinically disordered population, such as offenders who abuse but are not addicted to drugs or alcohol. At a minimum, participants should not be punished for failing to respond to a level of care that research indicates is insufficient to meet their treatment needs. If a participant is terminated from Drug Court for failing to respond to an inadequate level of treatment, fairness dictates the participant should receive credit for his or her efforts in the program and should not receive an augmented sentence or disposition for the unsuccessful termination. To do otherwise is likely to dissuade addicted offenders and their defense attorneys from choosing the Drug Court option. As was noted earlier, evidence suggests defense attorneys are reluctant to advise their clients to enter Drug Court when there is a serious chance the client could receive an enhanced sentence despite his or her best efforts in treatment (Bowers, 2007; Justice Policy Institute, 2011; National Association of Criminal Defense Lawyers, 2009).

B. In-Custody Treatment

Relying on in-custody substance abuse treatment can reduce the cost-effectiveness of a Drug Court by as much as 45% (Carey et al., 2012). Most studies have reported minimal gains from providing substance abuse treatment within jails or prisons (Pearson & Lipton, 1999; Pelissier et al., 2007; Wilson & Davis, 2006). Although specific types of in-custody programs, such as therapeutic communities (TCs), have been shown to improve outcomes for jail or prison inmates (Mitchell et al., 2007), most of the benefits of those programs were attributable to the fact that they increased the likelihood the offenders would complete outpatient treatment after their release from custody (Bahr et al., 2012; Martin et al., 1999; Wexler et al., 1999). The long-term benefits of the TCs were accounted for primarily by the offender's subsequent exposure to community-based treatment. Once an offender has engaged in community-based treatment, rarely will there be a clinical rationale for transferring him or her to in-custody treatment. Placing a participant in custody might be appropriate to protect public safety or to punish willful infractions such as intentionally failing to attend treatment sessions; however, in-custody treatment will rarely serve the goals of treatment effectiveness or cost-effectiveness.

Some Drug Courts may place participants in jail as a means of providing detoxification services or to keep them "off the streets" when adequate treatment is unavailable in the community. Although this practice may be necessary in rare instances to protect participants from immediate self-harm, it is inconsistent with best practices, unduly costly, and unlikely to produce lasting benefits. As soon as a treatment slot becomes available, the participant should be released immediately from custody and transferred to the appropriate level of care in the community.

C. Team Representation

Outcomes are significantly better in Drug Courts that rely on one or two primary treatment agencies to manage the provision of treatment services for participants (Carey et al., 2008, 2012; Shaffer, 2006; Wilson et al., 2006). Criminal recidivism may be reduced by as much as two fold when representatives from these primary agencies are core members of the Drug Court team and regularly attend staff meetings and court hearings (Carey et al., 2012). This arrangement helps to ensure that timely information about participants' progress in treatment is communicated to the Drug Court team and treatment-related issues are taken into consideration when decisions are reached in staff meetings and status hearings.

For practical reasons, large numbers of treatment providers cannot attend staff meetings and court hearings on a routine basis. Therefore, for Drug Courts that are affiliated with large numbers of treatment agencies, communication protocols must be established to ensure timely treatment information is reported to the Drug Court team. Clinical case managers from the primary treatment agencies are often responsible for ensuring that this process runs efficiently and timely information is conveyed to fellow team members. Particularly when Drug Courts are affiliated with large numbers of treatment providers, outcomes may be enhanced by having those treatment providers communicate frequently with the court via e-mail or similar electronic means (Carey et al., 2012).

D. Treatment Dosage and Duration

The success of Drug Courts is attributable, in part, to the fact that they significantly increase participant exposure to substance abuse treatment (Gottfredson et al., 2007; Lindquist et al., 2009). The longer participants remain in treatment and the more sessions they attend, the better their outcomes (Banks & Gottfredson, 2003; Gottfredson et al., 2007; Gottfredson et al., 2008; Peters et al., 2002; Shaffer, 2010; Taxman & Bouffard, 2005). The best outcomes are achieved when addicted offenders complete a course of treatment extending over approximately nine to twelve months (270 to 360 days; Peters et al., 2002; Huebner & Cobbina, 2007).[20] On average, participants will require approximately six to ten hours of counseling per week during the first phase of the program (Landenberger & Lipsey, 2005) and 200 hours of counseling over the course of treatment (Bourgon & Armstrong, 2005; Sperber et al., 2013).[21] The most effective Drug Courts publish general guidelines concerning the anticipated length and dosage of treatment; however, they retain sufficient flexibility to accommodate individual differences in each participant's response to treatment (Carey et al., 2012).

E. Treatment Modalities

Outcomes are significantly better in Drug Courts that require participants to meet with a treatment provider or clinical case manager for at least one individual session per week during the first phase of the program (Carey et al., 2012; Rossman et al., 2011). Most participants are unstable clinically and in a state of crisis when they first enter a Drug Court. Group sessions may not provide sufficient time and opportunities to address each participant's clinical and social service needs. Individual sessions reduce the likelihood that participants will fall through the cracks during the early stages of treatment when they are most vulnerable to cravings, withdrawal symptoms, and relapse.

---

[20] This is a separate matter from the average term of enrollment in a Drug Court, which evidence suggests should be approximately twelve to eighteen months (Carey et al., 2012; Shaffer, 2010).

[21] This assumes the Drug Court is treating individuals who are addicted to drugs or alcohol and at high risk for criminal recidivism or treatment failure [see Standard I, Target Population].

Group counseling may also improve outcomes in Drug Courts, but only if the groups apply evidence-based practices and participants are screened for their suitability for group-based services. Research indicates counseling groups are most effective with six to twelve participants and two facilitators (Brabender, 2002; Sobell & Sobell, 2011; Velasquez et al., 2001; Yalom, 2005). Groups with more than twelve members have fewer verbal interactions, spend insufficient time addressing individual members' concerns, are more likely to fragment into disruptive cliques or subgroups, and are more likely to be dominated by antisocial, forceful or aggressive members (Brabender, 2002; Yalom, 2005). Groups with fewer than four members commonly experience excessive attrition and instability (Yalom, 2005). If a Drug Court cannot form stable groups with at least four members, relying on individual counseling rather than groups to deliver treatment services may be preferable.

For groups that are treating externalizing or acting-out behaviors, such as crime and substance abuse, two facilitators are often needed to monitor and control the group interactions (Sobell & Sobell, 2011). The main facilitator can direct the format and flow of the sessions, while the cofacilitator may set limits on disruptive participants, review participants' homework assignments, or take part in role-plays such as illustrating effective drug-refusal strategies. Although the main facilitator should be a trained and certified treatment professional, the cofacilitator may be a trainee or recent hire to the program. Using trainees or inexperienced staff members as cofacilitators can reduce the costs of having two facilitators and provides an excellent training opportunity for the new staff members.

Evidence reveals group interventions may be contraindicated for certain types of participants, such as those suffering from serious brain injury, paranoia, sociopathy, major depression, or traumatic disorders (Yalom, 2005). Individuals with these characteristics may need to be treated on an individual basis or in specialized groups that can focus on their unique needs and vulnerabilities (Drake et al., 2008; Ross, 2008). Better outcomes have been achieved, for example, in Drug Courts (Messina et al., 2012; Liang & Long, 2013) and other substance abuse treatment programs (Grella, 2008; Mills et al., 2012) that developed specialized groups for women with trauma histories. Researchers have identified substantial percentages of Drug Court participants who may require specialized group services for comorbid mental illness (Mendoza et al., 2013; Peters, 2008; Peters et al., 2012) or trauma histories (Sartor et al., 2012).

Not all substance abuse treatment participants may benefit from group counseling. Interviews with participants who were terminated from Drug Courts found that many of them attributed their failure, in part, to their dissatisfaction with group-based services (Fulkerson et al., 2012). This theme has arisen frequently in focus groups with young, African-American, male Drug Court participants (Gallagher, 2013). Although there is no proof that dissatisfaction with group counseling was the actual cause of these individuals' failure in the programs, the findings do suggest that Drug Courts should consider whether participants are suited for group-based services and prepare them for what to expect in the groups before assigning them to the interventions.

F. Evidence-Based Treatments

A substantial body of research spanning several decades reveals that outcomes from correctional rehabilitation are significantly better when (1) offenders receive behavioral or cognitive-behavioral counseling interventions, (2) the interventions are carefully documented in treatment manuals, (3) treatment providers are trained to deliver the interventions reliably according to the manual, and (4) fidelity to the treatment model is maintained through continuous supervision of the treatment providers (Andrews et al., 1990; Andrews & Bonta, 2010; Gendreau, 1996; Hollins, 1999; Landenberger & Lipsey, 2005; Lowenkamp et al., 2006; Lowenkamp et al., 2010; Smith et al., 2009). Adherence to these principles has been associated with significantly better outcomes in Drug Courts (Gutierrez & Bourgon, 2012) and in other drug abuse treatment programs (Prendergast et al., 2013).

Behavioral treatments reward offenders for desirable behaviors and sanction them for undesirable behaviors. The systematic application of graduated incentives and sanctions in Drug Courts is an example of a behavior therapy technique (Defulio et al., 2013; Marlowe & Wong, 2008). Cognitive-behavioral therapies (CBT) take an active problem-solving approach to managing drug- and alcohol-related problems. Common CBT techniques include correcting participants' irrational thoughts related to substance abuse (e.g., "I will never amount to anything anyway, so why bother?"), identifying participants' triggers or risk

factors for drug use, scheduling participants' daily activities to avoid coming into contact with their triggers, helping participants to manage cravings and other negative affects without recourse to substance abuse, and teaching participants effective problem-solving techniques and drug-refusal strategies.

Examples of manualized CBT curricula that have been proven to reduce criminal recidivism among offenders include Moral Reconation Therapy (MRT), Reasoning and Rehabilitation (R&R), Thinking for a Change (T4C), relapse prevention therapy (RPT) and the Matrix Model (Cullen et al., 2012; Dowden et al., 2003; Ferguson & Wormith, 2012; Landenberger & Lipsey, 2005; Lipsey et al., 2001; Lowenkamp et al., 2009; Marinelli-Casey et al., 2008; Milkman & Wanberg, 2007; Pearson et al., 2002; Wilson et al., 2005). Some of these CBT curricula were developed to address criminal offending generally and were not developed specifically to treat substance abuse or addiction. However, the Matrix Model and RPT were developed for the treatment of addiction and MRT has been adapted successfully to treat drug-abusing offenders (Bahr et al., 2012; Wanberg & Milkman, 2006) and Drug Court participants (Cheesman & Kunkel, 2012; Heck, 2008; Kirchner & Goodman, 2007). The Substance Abuse and Mental Health Services Administration (SAMHSA) maintains an Internet directory of evidence-based treatments called the *National Registry of Evidence-Based Programs and Practices* (NREPP).[22] Drug Court professionals can search the NREPP Web site, free of charge, to identify substance abuse treatments that have been demonstrated to improve outcomes for addicted offenders.

Outcomes from CBT are enhanced significantly when counselors are trained to deliver the curriculum in a reliable manner as specified in the manual (Goldstein et al., 2013; Southam-Gerow & McLeod, 2013). A minimum of three days of preimplementation training, periodic booster sessions, and monthly individualized supervision and feedback are required for probation officers and treatment providers to administer evidence-based practices reliably (Bourgon et al., 2010; Edmunds et al., 2013; Robinson et al., 2012; Schoenwald et al., 2013). In addition, outcomes are better when counselors give homework assignments to the participants that reinforce the material covered in the sessions (Kazantzis et al., 2000; McDonald & Morgan, 2013). Examples of homework assignments include having participants keep a journal of their thoughts and feelings related to substance abuse, requiring participants to develop and follow through with a preplanned activity schedule, or having them write an essay on a drug-related topic (Sobell & Sobell, 2011).

G. Medications

Medically assisted treatment (MAT) can significantly improve outcomes for addicted offenders (Chandler et al., 2009; National Center on Addiction & Substance Abuse, 2012; National Institute on Drug Abuse, 2006). Buprenorphine or methadone maintenance administered prior to and immediately after release from jail or prison has been shown to significantly increase opiate-addicted inmates' engagement in treatment; reduce illicit opiate use; reduce rearrests, technical parole violations, and reincarceration rates; and reduce mortality and hepatitis C infections (Dolan et al., 2005; Gordon et al., 2008; Havnes et al., 2012; Kinlock et al., 2008; Magura et al., 2009). These medications are referred to as agonists or partial agonists because they stimulate the central nervous system (CNS) in a similar manner to illicit drugs. Because they can be addictive and may produce euphoria in nontolerant individuals, they may be resisted by some criminal justice professionals. Positive outcomes have also been reported for antagonist medications, such as naltrexone, which are nonaddictive and nonintoxicating. Naltrexone blocks the effects of opiates and partially blocks the effects of alcohol without producing psychoactive effects of its own. Studies have reported significant reductions in heroin use and rearrest rates for opiate-addicted probationers and parolees who received naltrexone (Cornish et al., 1997; Coviello et al., 2012; O'Brien & Cornish, 2006). In addition, at least two small-scale studies reported better outcomes in DWI Drug Courts or DWI probation programs for alcohol-dependent participants who received an injectable form of naltrexone called Vivitrol (Finigan et al., 2011; Lapham & McMillan, 2011).

[22] Simply being listed on the NREPP does not guarantee an intervention is effective. Drug Courts need to review the studies and ratings on the Web site to determine how reliable and powerful the effects were, and whether the intervention was examined in a similar context to that of a Drug Court. Registry available at http://www.samhsa.gov/newsroom/advisories/1012071342.aspx.

A recent national survey found that nearly half of Drug Courts do not use medications in their programs (Matusow et al., 2013). One of the primary barriers to using medications was reportedly a lack of awareness of or familiarity with medical treatments. For this reason, the NADCP Board of Directors issued a unanimous resolution directing Drug Courts to learn the facts about MAT and obtain expert consultation from duly trained addiction psychiatrists or addiction physicians.[23] Drug Courts should ordinarily discourage their participants from obtaining addictive or intoxicating medications from general medical practitioners, because this practice can pose an unacceptable risk of morbidity, mortality, or illegal diversion of the medications (Bazazi et al., 2011; Bohnert et al., 2011; Daniulaityte et al., 2012; Johanson et al., 2012).

H. Provider Training and Credentials

Treatment providers are significantly more likely to administer evidence-based assessments and interventions when they are professionally credentialed and have an advanced educational degree in a field directly related to substance abuse treatment (Kerwin et al., 2006; McLellan et al., 2003; National Center on Addiction & Substance Abuse, 2012; Olmstead et al., 2012). Studies have found that clinicians with higher levels of education and clinical certification were more likely to hold favorable views toward the adoption of evidence-based practices (Arfken et al., 2005) and to deliver culturally competent treatments (Howard, 2003). A large-scale study found that clinically certified professionals significantly outperformed noncertified staff members in conducting standardized clinical assessments (Titus et al., 2012). Clinicians are also more likely to endorse treatment philosophies favorable to client outcomes if they are educated about the neuroscience of addiction (Steenbergh et al., 2012).

As was previously discussed, treatment providers must be supervised regularly to ensure continuous fidelity to evidence-based treatments. Providers are better able to administer evidence-based practices when they receive three days of preimplementation training, periodic booster trainings, and monthly individualized supervision and feedback (Bourgon et al., 2010; Edmunds et al., 2013; Robinson et al., 2012). Finally, research suggests treatment providers are more likely to be effective if they have substantial experience working with criminal offenders and are accustomed to functioning in a criminal justice environment (Lutze & van Wormer, 2007).

I. Peer Support Groups

Participation in self-help or peer-support groups is consistently associated with better long-term outcomes following a substance abuse treatment episode (Kelly et al., 2006; Moos & Timko, 2008; Witbrodt et al., 2012). Contrary to some beliefs, individuals who are court mandated to attend self-help groups perform as well or better than nonmandated individuals (Humphreys et al., 1998). The critical variable appears to be how long the participants were exposed to the self-help interventions and not their original level of intrinsic motivation (Moos & Timko, 2008). Many people (more than 40%) drop out prematurely from self-help groups, in part because they are unmotivated or insufficiently motivated to maintain sobriety (Kelly & Moos, 2003). Therefore, Drug Courts need to find effective ways to leverage continued participant involvement in self-help groups.

Simply attending self-help groups is not sufficient to achieve successful outcomes. Sustained benefits are more likely to be attained if participants engage in recovery-relevant activities such as developing a sober-support social network (Kelly et al., 2011a), engaging in spiritual practices (Kelly et al., 2011b; Robinson et al., 2011), and learning effective coping skills from fellow group members (Kelly et al., 2009). Because it is very difficult for Drug Courts to mandate and monitor compliance with these types of recovery activities, they must find other means of encouraging and reinforcing participant engagement in recovery-related exercises. Evidence-based interventions have been developed, documented in treatment manuals, and proven to improve participant engagement in self-help groups and recovery activities. Examples of validated interventions include 12-step facilitation therapy (Ries et al., 2008), which teaches participants about what to expect and how to gain the most benefits from 12-step meetings. In addition, *intensive referrals* improve outcomes by assertively linking participants with support-group volunteers who may

[23] Available at http://www.nadcp.org/sites/default/files/nadcp/NADCP%20Board%20Statement%20on%20MAT.pdf.

escort them to the groups, answer any questions they might have, and provide them with support and camaraderie (Timko & DeBenedetti, 2007).

J. Continuing Care

Vulnerability to relapse remains high for at least three to six months after completion of substance abuse treatment (Marlatt, 1985; McKay, 2005). One year after treatment, an average of 40% to 60% of treatment graduates will have relapsed to substance abuse (McLellan et al., 2000). Therefore, preparation for aftercare or continuing care is a critical component of Drug Courts.

In one multisite study, Drug Courts that included a formal phase focusing on relapse prevention and aftercare preparation had more than three times greater cost-benefits and significantly greater reductions in recidivism than those that offered minimal services during the last phase of the program or neglected aftercare preparation (Carey et al., 2008). Drug Courts that required their participants to plan for engaging in prosocial activities after graduation, such as employment or schooling, were found to be more effective and significantly more cost effective than those that did not plan for postgraduation activities (Carey et al., 2012). Another study found that drug-abusing probationers who received aftercare services were nearly three times more likely to be abstinent from all drugs of abuse after six months than those who did not receive aftercare services (Brown et al, 2001).

As was described earlier, RPT is a manualized, cognitive-behavioral counseling intervention that has been demonstrated to extend the effects of substance abuse treatment (Dowden et al., 2003; Dutra et al, 2008). Participants in RPT learn to identify their personal triggers or risk factors for relapse, take measures to avoid coming into contact with those triggers, and rehearse strategies to deal with high-risk situations that arise unavoidably. Drug Courts that teach formal RPT skills are likely to significantly extend the effects of their program beyond graduation (Carey et al., 2012).

Studies have also examined ways to remain in contact with participants after they have been discharged from a treatment program. For example, researchers have extended the benefits of substance abuse treatment by making periodic telephone calls to participants (McKay, 2009a), although not all studies have reported success with this approach (McKay et al., 2013). In addition, treatment benefits have been extended by inviting participants back to the program for brief recovery management check-ups (Scott & Dennis, 2012), providing assertive case management involving periodic home visits (Godley et al., 2006), and reinforcing participants with praise or small gifts for continuing to attend aftercare sessions (Lash et al., 2004). The aftercare strategies that have been successful typically continued for at least 90 days and had trained counselors, nurses, or case managers contact the participants briefly to check on their progress, probe for potential warning signs of an impending relapse, offer advice and encouragement, and make suitable referrals if a return to treatment appeared warranted (McKay, 2009b).

Although some of these measures might be cost-prohibitive for many Drug Courts, and participants might be reluctant to remain engaged with the criminal justice system after graduation, research suggests brief telephone calls, letters, or e-mails can be helpful in extending the effects of a Drug Court at minimal cost to the program and with minimal inconvenience to the participants. Anecdotal reports from Drug Court graduates and staff members have also suggested that involving graduates in alumni groups might be another promising, yet understudied, method for extending the benefits of Drug Courts (Burek, 2011; McLean, 2012).

REFERENCES

Andrews, D.A., & Bonta, J. (2010). *The psychology of criminal conduct* (5th ed.). Waltham, MA: Anderson Publishing.

Andrews, D.A., Zinger, I., Hoge, R.D., Bonta, J., Gendreau, P., & Cullen, F.T. (1990). Does correctional treatment work? A clinically relevant and psychologically informed meta-analysis. *Criminology, 28*(3), 369–404.

Arfken C., Agius E., Dickson M., Anderson H., Hegedus A. (2005). Clinicians' beliefs and awareness of substance abuse treatments in research and nonresearch-affiliated programs. *Journal of Drug Issue*s, 35(3), 547–558.

Babor, T., & Del Boca, F. (Vol. Eds.) (2002). *Treatment matching in alcoholism: International research monographs in the addictions.* In G. Edwards (Series Ed.). Cambridge, UK: Cambridge University Press.

Bahr, S.J., Masters, A.L., & Taylor, B.M. (2012). What works in substance abuse treatment programs for offenders? *The Prison Journal, 92*(2), 155–174.

Banks, D., & Gottfredson, D.C. (2003). The effects of drug treatment and supervision on time to rearrest among drug treatment court participants. *Journal of Drug Issues*, *33*(2), 385–412.

Bazazi, A.R., Yokell, M., Fu, J.J., Rich, J.S., & Zaller, N.D. (2011). Illicit use of buprenorphine/naloxone among injecting and noninjecting opioid users. *Journal of Addiction Medicine, 5*(3), 175–180.

Bohnert, A.S., Valenstein, M., Bair, M.J., Ganoczy, D., McCarthy, J.F., Ilgen, M.A., & Blow, F.C. (2011). Association between opioid prescribing patterns and opioid overdose-related deaths. *Journal of the American Medical Association, 305*(13), 1315-1321.

Bourgon, G., & Armstrong, B. (2005). Transferring the principles of effective treatment into a "real world" prison setting. *Criminal Justice & Behavior, 32*(1), 3–25.

Bourgon, G., Bonta, J., Rugge, T., Scott, T.L., & Yessine, A. (2010). The role of program design, implementation, and evaluation in evidence-based 'real world' community supervision. *Federal Probation, 74*(1), 2–15.

Bowers, J. (2007). Contraindicated drug courts. *UCLA Law Review, 55*(4), 783–831.

Brabender, V. (2002). *Introduction to group therapy*. New York: John Wiley & Sons.

Brown, B.S., O'Grady, K.E., Battjes, R.J., Farrell, E.V., & Smith, N.P., & Nurco, D.N., (2001). Effectiveness of a stand-alone aftercare program for drug-involved offenders. *Journal of Substance Abuse Treatment*, *21*(4), 185–192.

Burek, E. (2011, Fall). The importance of Drug Court alumni groups. *AllRise Magazine*, p. 21.

California Substance Abuse and Crime Prevention Act. (2000). 2000 Cal. Legis. Serv. Prop 36 (West), codified in Cal. Penal Code § 1210 *et seq*.

Carey, S.M., Finigan, M.W., & Pukstas, K. (2008). *Exploring the key components of drug courts: A comparative study of 18 adult drug courts on practices, outcomes, and costs*. Portland, OR: NPC Research. *Available at https://www.ncjrs.gov/pdffiles1/nij/grants/223853.pdf*.

Carey, S.M., Mackin, J.R., & Finigan, M.W. (2012). What works? The 10 key components of Drug Court: Research-based best practices. *Drug Court Review*, *8*(1), 6–42.

Chandler, R.K., Fletcher, B.W., & Volkow, N.D. (2009). Treating drug abuse and addiction in the criminal justice system: Improving public health and safety. *Journal of the American Medical Association, 301*(2)*,* 183–190.

Cheesman, F.L., & Kunkel, T.L. (2012). *Virginia adult drug treatment courts: Cost benefit analysis*. Williamsburg, VA: National Center for State Courts.

Cornish, J.W., Metzger, D., Woody, G.E., Wilson, D., McLellan, A.T., Vandergrift, B., & O'Brien, C.P. (1997). Naltrexone pharmacotherapy for opioid dependent federal probationers. *Journal of Substance Abuse Treatment, 14*(6), 529–534.

Coviello, D.M., Cornish, J.W., Lynch, K.G., Boney, T.Y., Clark, C.A., Lee, J.D., et al. (2012). A multisite pilot study of extended-release injectable naltrexone treatment for previously opioid-dependent parolees and probationers. *Substance Abuse, 33*(1), 48–59.

Cullen, A.E., Clarke, A.Y., Kuipers, E., Hodgins, S., Dean, K., & Fahy, T. (2012). A multisite randomized trial of a cognitive skills program for male mentally disordered offenders: Violence and antisocial behavior outcomes. *Journal of Consulting & Clinical Psychology, 80*(6), 1114–1120.

Daniulaityte, R., Falck, R., & Carlson, R. G. (2012). Illicit use of buprenorphine in a community sample of young adult non-medical users of pharmaceutical opioids. *Drug and Alcohol Dependence, 122*(3), 201–207.

DeFulio, A., Stitzer, M., Roll, J., Petry, N., Nuzzo, P., Schwartz, R.P., & Stabile, P. (2013). Criminal justice referral and incentives in outpatient substance abuse treatment. *Journal of Substance Abuse Treatment, 45*(1), 70–75.

De Leon, G., Melnick, G., & Cleland, C.M. (2010). Matching to sufficient treatment: Some characteristics of undertreated (mismatched) clients. *Journal of Addictive Diseases, 29*(1), 59–67.

DeMatteo, D. S., Marlowe, D. B., & Festinger, D. S. (2006). Secondary prevention services for clients who are low risk in drug court: A conceptual model. *Crime & Delinquency, 52*, 114-134.

Dolan, K.A., Shearer, J., White, B., Zhou, J., Kaldor, J., & Wodak, A.D. (2005). Four-year follow-up of imprisoned male heroin users and methadone treatment: Mortality, reincarceration and hepatitis C infection. *Addiction, 100*(6), 820–828.

Dowden, C., Antonowicz, D., & Andrews, D.A. (2003). The effectiveness of relapse prevention with offenders: A meta-analysis. *International Journal of Offender Therapy & Comparative Criminology, 47*(5), 516–528.

Drake, R.E., O'Neal, E., L., & Wallach, M.A. (2008). A systematic review of psychosocial research on psychosocial interventions for people with co-occurring severe mental and substance use disorders. *Journal of Substance Abuse Treatment*, *34*(1), 123–138.

Dutra, L., Stathopoulou, G., Basden, S.L., Leyro, T.M., Powers, M.B., & Otto, M.W. (2008). A meta-analytic review of psychosocial interventions for substance use disorders. *American Journal of Psychiatry*, *165*(2), 179–187.

Edmunds, J.M., Beidas, R.S., & Kendall, P.C. (2013). Dissemination and implementation of evidence-based practices: Training and consultation as implementation strategies. *Clinical Psychology Science and Practice, 20*(2), 152–165.

Ferguson, L.M., & Wormith, S. (2012). A meta-analysis of Moral Reconation Therapy. *International Journal of Offender Therapy & Comparative Criminology: OnLineFirst*. doi: 10.1177/0306624X12447771

Finigan, M.W., Perkins, T., Zold-Kilbourn, P., Parks, J., & Stringer, M. (2011). Preliminary evaluation of extended-release naltrexone in Michigan and Missouri drug courts. *Journal of Substance Abuse Treatment*, *41*(3), 288–293.

Fulkerson, A., Keena, L.D., & O'Brien, E. (2012). Understanding success and nonsuccess in the Drug Court. *International Journal of Offender Therapy & Comparative Criminology: OnLineFirst.* doi: 10.1177/0306624X12447774

Gallagher, J.R. (2013). African American participants' views on racial disparities in drug court outcomes. *Journal of Social Work Practice in the Addictions, 13*(2), 143–162.

Gastfriend, D.R., Lu, S., & Sharon, E. (2000). Placement matching: Challenges and technical progress. *Substance Use & Misuse*, *35*(12–14), 2191–2213.

Gendreau, P. (1996). Offender rehabilitation: What we know and what needs to be done. *Criminal Justice & Behavior, 23*(1), 144–161.

Godley, M.D., Godley, S.H., Dennis, M.L., Funk, R.R., & Passetti, L.L. (2006). The effect of assertive continuing care linkage, adherence, and abstinence following residential treatment for adolescents with substance use disorders. *Addiction*, *102*(1), 81–93.

Goldstein, N.E., Kemp, K.A., Leff, S.S., & Lochman, J.E. (2013). Guidelines for adapting manualized interventions for new target populations: A step-wise approach using anger management as a model. *Clinical Psychology: Science & Practice, 19*(4), 385–401.

Gordon, M.S., Kinlock, T.W., Schwartz, R.P., & O'Grady, K.E. (2008). A randomized clinical trial of methadone maintenance for prisoners: Findings at 6 months post-release. *Addiction, 103*(8), 1333–1342.

Gottfredson, D.C., Kearley, B.W., & Bushway, S.D. (2008). Substance use, drug treatment, and crime: An examination of intra-individual variation in a drug court population. *Journal of Drug Issues*, *38*(2), 601–630.

Gottfredson, D.C., Kearley, B.W., Najaka, S.S., & Rocha, C.M. (2007). How drug treatment courts work: An analysis of mediators. *Journal of Research on Crime & Delinquency, 44*(1), 3–35.

Gregoire, T.K. (2000). Factors associated with level of care assignments in substance abuse treatment. *Journal of Substance Abuse Treatment*, *18*(3), 241–248.

Grella, C. (2008). Gender-responsive drug treatment services for women: A summary of current research and recommendations for drug court programs. In C. Hardin & J.N. Kushner (Eds.), *Quality improvement for drug courts: Evidence-based practices* (Monograph Series No. 9; pp. 63–74). Alexandria, VA: National Drug Court Institute.

Gutierrez, L., & Bourgon, G. (2012). Drug treatment courts: A quantitative review of study and treatment quality. *Justice Research & Policy, 14*(2), 47–77.

Havnes, I., Bukten, A., Gossop, M., Waal, H., Stangeland, P., & Clausen, T. (2012). Reductions in convictions for violent crime during opioid maintenance treatment: A longitudinal national cohort study. *Drug and Alcohol Dependence, 124*(3), 307–310.

Heck, C. (2008). MRT: Critical component of a local drug court program. *Cognitive Behavioral Treatment Review*, *17*(1), 1–2.

Hollins, C.R. (1999). Treatment programs for offenders: Meta-analysis, "what works," and beyond. *International Journal of Law & Psychiatry, 22*(3–4), 361–372.

Howard, D.L. (2003). Culturally competent treatment of African American clients among a national sample of outpatient substance abuse treatment units. *Journal of Substance Abuse Treatment, 24*(2), 89–102.

Huebner, B.M., & Cobbina, J. 2007). The effect of drug use, drug treatment participation, and treatment completion on probationer recidivism. *Journal of Drug Issues, 37*(3), 619–641.

Humphreys, K., Kaskutas, L.A., & Weisner, C. (1998). The relationship of pretreatment Alcoholics Anonymous affiliation with problem severity, social resources, and treatment history. *Drug & Alcohol Dependence, 49*(2), 123–131.

Integrated Substance Abuse Programs. (2007, April 13). *Evaluation of the Substance Abuse and Crime Prevention Act: Final report*. Los Angeles, CA: UCLA. *Available at* http://www.uclaisap.org/Prop36/documents/SACPAEvaluationReport.pdf.

Janku, A.D., & Yan, J. (2009). Exploring patterns of court-ordered mental health services for juvenile offenders: Is there evidence of systematic bias? *Criminal Justice & Behavior, 36*(4), 402–419.

Johanson, C., Arfken, C. L., di Menza, S., & Schuster, C. R. (2012). Diversion and abuse of buprenorphine: Findings from national surveys of treatment patients and physicians. *Drug and Alcohol Dependence, 120*(1), 190–195.

Justice Policy Institute. (2011). *Addicted to courts: How a growing dependence on drug courts impacts people and communities*. Washington, DC: Author.

Karno, M.P., & Longabaugh, R. (2007). Does matching matter? Examining matches and mismatches between patient attributes and therapy techniques in alcoholism treatment. *Addiction, 102*(4), 587–596.

Kazantzis, N., Deane, F.P., & Ronan, K.R. (2000). Homework assignments in cognitive and behavioral therapy: A meta-analysis. *Clinical Psychology: Science & Practice, 7*(2), 189–202.

Kelly, J.F., Magill, M., & Stout, R.L. (2009). How do people recover from alcohol dependence? A systematic review of the research on mechanisms of behavior change in Alcoholics Anonymous. *Addiction Research & Theory, 17*(3), 236–259.

Kelly, J.F., & Moos, R. (2003). Dropout from 12-step groups: Prevalence, predictors, and counteracting treatment influences. *Journal of Substance Abuse Treatment, 24*(3), 241–250.

Kelly, J.F., Stout, R.L., Magill, M., & Tonigan, J.S. (2011a). The role of Alcoholics Anonymous in mobilizing adaptive social network changes: A prospective lagged meditational analysis. *Drug & Alcohol Dependence*, *114*(2), 119–126.

Kelly, J.F., Stout, R.L., Magill, M., Tonigan, J.S., & Pagano, M.E. (2011b). Spirituality in recovery: A lagged mediational analysis of Alcoholics Anonymous' principal theoretical mechanism of behavior change. *Alcoholism: Clinical & Experimental Research, 35*(3), 454–463.

Kelly, J.F., Stout, R., Zywiak, W., & Schneider, R. (2006). A 3-year study of addiction mutual-help group participation following intensive outpatient treatment. *Alcoholism: Clinical & Experimental Research, 30*(8), 1381–1392.

Kerwin, M.E., Walker-Smith, K., & Kirby, K.C. (2006). Comparative analysis of state requirements for the training of substance abuse and mental health counselors. *Journal of Substance Abuse Treatment, 30*(3), 173–181.

Kinlock, T.W., Gordon, M.S., Schwartz, R.P., & O'Grady, K.E. (2008). A study of methadone maintenance for male prisoners: Three-month postrelease outcomes. *Criminal Justice & Behavior, 35*(1)*,* 34–47.

Kirchner, R.A., & Goodman, E. (2007). Effectiveness and impact of the Thurston County, Washington Drug Court program. *Cognitive Behavioral Treatment Review*, *16*(2), 1–4.

Koob, J., Brocato, J., & Kleinpeter, C. (2011). Enhancing residential treatment for drug court participants. *Journal of Offender Rehabilitation, 50*(5), 252–271.

Krebs, C.P., Strom, K.J., Koetse, W.H., & Lattimore, P.K. (2009). The impact of residential and nonresidential drug treatment on recidivism among drug-involved probationers. *Crime & Delinquency, 55*(3), 442–471.

Landenberger, N.A., & Lipsey, N.W. (2005). The positive effects of cognitive-behavioral program for offenders: A meta-analysis of factors associated with effective treatment. *Journal of Experimental Criminology*, 1(4), 451–476.

Lapham, S.C., & McMillan, G.P. (2011). Open-label pilot study of extended-release naltrexone to reduce drinking and driving among repeat offenders. *Journal of Addiction Medicine, 5*(3), 163–169.

Lash, S.J., Burden, J.L., Monteleone, B.R., & Lehmann, L.P. (2004). Social reinforcement of substance abuse treatment aftercare participation: Impact on outcome*. Addictive Behaviors*, *29*(2), 337–342.

Liang, B., & Long, M.A. (2013). Testing the gender effect in drug and alcohol treatment: Women's participation in Tulsa County drug and DUI programs. *Journal of Drug Issues*, *43*(3), 270–288.

Lindquist, C.H., Krebs, C.P., Warner, T.D., & Lattimore, P.K. (2009). An exploration of treatment and supervision intensity among drug court and non-drug court participants*. Journal of Offender Rehabilitation, 48*(3), 167–193.

Lipsey, M.W., Chapman, G.L., & Landenberger, N.A. (2001). Cognitive-behavioral programs for offenders. *Annals of the American Academy of Political & Social Science, 578*(1), 144–157.

Lovins, L.B., Lowenkamp, C.T., Latessa, E.J., & Smith, P. (2007). Application of the risk principle to female offenders. *Journal of Contemporary Criminal Justice, 23*(4), 383–398.

Lowenkamp, C.T., Flores, A.W., Holsinger, A.M., Makarios, M.D., & Latessa, E.J. (2010). Intensive supervision programs: Does program philosophy and the principles of effective intervention matter? *Journal of Criminal Justice, 38*(4), 368–375.

Lowenkamp, C.T., Hubbard, D., Makarios, M., & Latessa, E. (2009). A quasi-experimental evaluation of Thinking For a Change: A real world application. *Criminal Justice & Behavior*, 36(2), 137–146.

Lowenkamp, C.T., & Latessa, E.J. (2004). Understanding the risk principle: How and why correctional interventions can harm low-risk offenders. *Topics in Community Corrections: Assessment Issues for Managers,* pp. 3–8.

Lowenkamp, C.T., & Latessa, E.J. (2005). Increasing the effectiveness of correctional programming through the risk principle: Identifying offenders for residential placement. *Criminology & Public Policy, 4*(2), 263–290.

Lowenkamp, C.T., Latessa, E.J., & Smith, P. (2006). Does correctional program quality really matter? The impact of adhering to the principles of effective intervention. *Criminology & Public Policy, 5*(3), 575–594.

Lutze, F.E., & van Wormer, J.G. (2007). The nexus between drug and alcohol treatment program integrity and drug court effectiveness: Policy recommendations for pursuing success. *Criminal Justice Policy Review, 18*(3), 226–245.

Magura, S., Lee, J.D., Hershberger, J., Joseph, H., Marsch, L., Shropshire, C., & Rosenblum, A. (2009). Buprenorphine and methadone maintenance in jail and post-release: A randomized clinical trial. *Drug & Alcohol Dependence, 99*(1)*,* 222–230.

Magura, S., Staines, G., Kosanke, N., Rosenblum, A., Foote, J., DeLuca, A., & Bali, P. (2003). Predictive validity of the ASAM patient placement criteria for naturalistically matched vs. mismatched alcoholism patients. *American Journal on Addictions*, *12*(5), 386–97.

Marinelli-Casey, P., Gonzales, R., Hillhouse, M., Ang, A., Zweben, J., Cohen, J., Hora, P.F., & Rawson. R.A. (2008). Drug court treatment for methamphetamine dependence: Treatment response and posttreatment outcomes. *Journal of Substance Abuse Treatment*, 34(2), 242–248.

Marlatt, G.A. (1985). Relapse prevention: Theoretical rationale and overview of the model. In G.A. Marlatt & J.R. Gordon (Eds.), *Relapse Prevention* (pp. 3–70). New York: Guilford Press.

Marlowe, D.B., & Wong, C.J. (2008). Contingency management in adult criminal drug courts. In S.T. Higgins, K. Silverman, & S.H. Heil (Eds.), *Contingency management in substance abuse treatment* (pp. 334–354). New York: Guilford Press.

Martin, S.S., Butzin, C.A., Saum, C.A., & Inciardi, J.A. (1999). Three-year outcomes of therapeutic community treatment for drug-involved offenders in Delaware: From prison to work release to aftercare. *The Prison Journal, 79*(3), 294–320.

Matusow, H., Dickman, S.L., Rich, J.D., Fong, C., Dumont, D.M., Hardin, C., Marlowe, D., & Rosenblum, A. (2013). Medication assisted treatment in U.S. drug courts: Results from a nationwide survey of availability, barriers and attitudes. *Journal of Substance Abuse Treatment*. *44*(5), 473–480.

McCord, J. (2003). Cures that harm: Unanticipated outcomes of crime prevention programs. *Annals of the American Academy of Political & Social Science, 587*(1), 16–30.

McDonald, B. R., & Morgan, R. D. (2013). Enhancing homework compliance in correctional psychotherapy. *Criminal Justice & Behavior, 40*(7), 814–828.

McKay, J.R. (2005). Is there a case for extended interventions for alcohol and drug use disorders? *Addiction, 100*(11), 1594–1610.

McKay, J.R. (2009a). Continuing care research: What we have learned and where we are going. *Journal of Substance Abuse Treatment, 36*(2), 131–145.

McKay, J.R. (2009b). *Treating substance use disorders with adaptive continuing care*. Washington, DC: American Psychological Association.

McKay, J.R., Van Horn, D., Ivey, M., Drapkin, M.L., Rennert, L., & Lynch, K.G. (2013). Enhanced continuing care provided in parallel to intensive outpatient treatment does not improve outcomes for patients with cocaine dependence. *Journal of Studies on Alcohol, 74*, 642-651.

McKee, M. (2010). *San Francisco drug court transitional housing program outcome study*. San Francisco: SF Collaborative Courts. *Available at* http://www.sfsuperiorcourt.org/sites/default/files/pdfs/2676%20Outcome%20on%20SF%20Drug%20Court%20Transitional%20Housing%20Program.pdf.

McLean, A. (2012, Fall). The value of alumni groups: A graduate's viewpoint. *AllRise Magazine*, Fall, p. 27.

McLellan, A.T., Carise, D., & Kleber, H.D. (2003). Can the national addiction treatment infrastructure support the public's demand for quality care? *Journal of Substance Abuse Treatment, 25*(2), 117–121.

McLellan, A.T., Lewis, D.C., O'Brien, C.P., & Kleber, H.D. (2000). Drug dependence, a chronic medical illness: Implications for treatment, insurance, and outcomes evaluation. *Journal of the American Medical Association, 284*(13), 1689–1695.

Mee-Lee, D., & Gastfriend, D.R. (2008). Patient placement criteria. In M. Galanter & H.D. Kleber (Eds.), *Textbook of Substance Abuse Treatment* (4th Ed., pp. 79–91). Arlington, VA: American Psychiatric Publishing.

Mee-Lee, D., Shulman, G.D., Fishman, M., Gastfriend, D.R., & Griffith, J.H. (Eds.). (2001). *ASAM patient placement criteria for the treatment of substance-related disorders* (2nd ed.-revised). Chevy Chase, MD: American Society of Addiction Medicine. *Available at* http://www.asam.org/publications/patient-placement-criteria/ppc-2r.

Mendoza, N.S., Trinidad, J.R., Nochajski, T.H., & Farrell, M.C. (2013). Symptoms of depression and successful drug court completion. *Community Mental Health Journal* (Online). doi: 10.1007/s10597-013-9595-5

Messina, N., Calhoun, S., & Warda, U. (2012). Gender-responsive drug court treatment: A randomized controlled trial. *Criminal Justice & Behavior, 39*(12), 1539–1558.

Meyer, W.G. (2011). Constitutional and legal issues in Drug Courts. In D.B. Marlowe & W.G. Meyer (Eds.), *The drug court judicial benchbook* (pp. 159–180). Alexandria, VA: National Drug Court Institute. Available at http://www.ndci.org/sites/default/files/nadcp/14146_NDCI_Benchbook_v6.pdf.

Milkman, H., & Wanberg, K. (2007). *Cognitive-behavioral treatment: A review and discussion for corrections professionals* (NIC No. 021657). Washington, DC: National Institute of Corrections, U.S. Dept. of Justice.

Mills, K.L., Teesson, M., Back, S.E., Brady, K.T., Baker, A.L., Hopwood, S., Sannibale, C., Barrett, E.L., Merz, S., Rosenfeld, J., & Ewer, P.L. (2012). Integrated exposure-based therapy for co-occurring posttraumatic stress disorder and substance dependence: A randomized controlled trial. *Journal of the American Medical Association, 308*(7), 690–699.

Mitchell, O., Wilson, D.B., & MacKenzie, D.L. (2007). Does incarceration-based drug treatment reduce recidivism? A meta-analytic synthesis of the research. *Journal of Experimental Criminology, 3*(4), 353–375.

Moos, R.H., & Timko, C. (2008). Outcome research on 12-step and other self-help programs. In M. Galanter & H.D. Kleber (Eds.), *Textbook of Substance Abuse Treatment* (4th Ed., pp. 511–521). Arlington, VA: American Psychiatric Publishing.

National Association of Criminal Defense Lawyers. (2009). *America's problem-solving courts: The criminal costs of treatment and the case for reform*. Washington, DC: Author.

National Center on Addiction and Substance Abuse. (2012). *Addiction medicine: Closing the gap between science and practice*. New York: Columbia University.

National Institute on Drug Abuse. (2006). *Principles of drug abuse treatment for criminal justice populations: A research based guide* (NIH Publication No. 06-5316). Bethesda, MD: Author.

O'Brien, C.P., & Cornish, J.W. (2006). Naltrexone for probationers and parolees. *Journal of Substance Abuse Treatment*, *31*(2), 107–111.

Olmstead, T.A., Abraham, A.J., Martino, S., & Roman, P.M. (2012). Counselor training in several evidence-based psychosocial addiction treatments in private US substance abuse treatment centers. *Drug & Alcohol Dependence, 120*(1), 149–154.

Pearson, F.S., & Lipton, D.S. (1999). A meta-analytic review of the effectiveness of corrections-based treatments for drug abuse. *The Prison Journal, 79*(4), 384–410.

Pearson, F.S., Lipton, D.S., Cleland, C.M., & Yee, D.S. (2002). The effects of behavioral/cognitive-behavioral programs on recidivism. *Crime & Delinquency*, 48(3), 476–496.

Pelissier, B., Jones, N., & Cadigan, T. (2007). Drug treatment aftercare in the criminal justice system: A systematic review. *Journal of Substance Abuse Treatment, 32*(3), 311—320.

Peters, R.H. (2008). Co-occurring disorders. In C. Hardin & J.N. Kushner (Eds.), *Quality improvement for drug courts: Evidence-based practices* (Monograph Series No. 9; pp. 51–61). Alexandria, VA: National Drug Court Institute.

Peters, R.H., Haas, A.L., & Hunt, W.M. (2002). Treatment "dosage" effects in drug court programs. *Journal of Offender Rehabilitation*, 33(4), 63–72.

Peters, R.H., Kremling, J., Bekman, N.M., & Caudy, M.S. (2012). Co-occurring disorders in treatment-based courts: Results of a national survey. *Behavioral Sciences & the Law*, *30*(6), 800–820.

Petrosino, A., Turpin-Petrosino, C., & Finckenauer, J.O. (2000). Well-meaning programs can have harmful effects! Lessons from experiments of programs such as Scared Straight. *Crime & Delinquency, 46*(3), 354–379.

Prendergast, M.L., Pearson, F.S., Podus, D., Hamilton, Z.K., & Greenwell, L. (2013). The Andrews' principles of risk, needs, and responsivity as applied in drug treatment programs: Meta-analysis of crime and drug use outcomes. *Journal of Experimental Criminology: Online First*. doi: 10.1007/s11292-013-9178-z

Ries, R.K., Galanter, M., & Tonigan, J.S. (2008). Twelve-Step Facilitation: An adaptation for psychiatric practitioners and patients. In M. Galanter & H.D. Kleber (Eds.), *Textbook of Substance Abuse Treatment* (4th Ed., pp. 373–386). Arlington, VA: American Psychiatric Publishing.

Robinson, C.R., Lowenkamp, C.T., Holsinger, A.M., VanBenschoten, S., Alexander, M., & Oleson, J.C. (2012). A random study of Staff Training Aimed at Reducing Rearrest (STARR): Using core correctional practices in probation interactions. *Journal of Crime & Justice*. *35*(2) 167–188.

Robinson, E.A., Krentzman, A.R., Webb, J.R., & Bowler, K.J. (2011). Six-month changes in spirituality and religiousness in alcoholics predict drinking outcomes at nine months. *Journal of Studies on Alcohol & Drugs, 72*(4), 660–668.

Ross, S. (2008). The mentally ill substance abuser. In M. Galanter & H.D. Kleber (Eds.), *Textbook of Substance Abuse Treatment* (4th ed., pp. 537–554). Washington, DC: American Psychiatric Publishing.

Rossman, S.B., Rempel, M., Roman, J.K., Zweig, J.M., Lindquist, C.H., Green, M., Downey, P.M., Yahner, J., Bhati, A.S., & Farole, D.J. (2011). *The multisite adult drug court evaluation: The impact of drug courts, vol. 4.* Washington, DC: Urban Institute Justice Policy Center. *Available at* https://www.ncjrs.gov/pdffiles1/nij/grants/237112.pdf.

Sartor, C.E., McCutcheon, V.V., O'Leary, C.C., Van Buren, D.J., Allsworth, J.E., Jeffe, D.B., & Cottler, L.B. (2012). Lifetime trauma exposure and posttraumatic stress disorder in women sentenced to drug court. *Psychiatry Research, 200*(2–3), 602–608.

Schoenwald, S. K., Mehta, T. G., Frazier, S. L., & Shernoff, E. S. (2013). Clinical supervision in effectiveness and implementation research. *Clinical Psychology: Science and Practice, 20*(1), 44–59.

Scott, C.K., & Dennis, M.L. (2012). The first 90 days following release from jail: Findings from the Recovery Management Checkups for Women Offenders (RMCWO) experiment. *Drug & Alcohol Dependence, 125*(1–2), 110–118.

Shaffer, D.K. (2006). Reconsidering drug court effectiveness: A meta-analytic review (Doctoral dissertation, University of Cincinnati, 2006). *Dissertation Abstracts International*, 67, 09A (AAT No. 3231113).

Shaffer, D.K. (2010). Looking inside the black box of drug courts: A meta-analytic review. *Justice Quarterly, 28*(3)*, 493–521.*

Smith, P., Gendreau, P., & Swartz, K. (2009). Validating the principles of effective intervention: A systematic review of the contributions of meta-analysis in the field of corrections. *Victims & Offenders, 4*(2), 148–169.

Sobell, L.C., & Sobell, M.B. (2011). *Group therapy for substance use disorders: A motivational cognitive-behavioral approach*. New York: Guilford.

Southam-Gerow, M. A., & McLeod, B. D. (2013). Advances in applying treatment integrity research for dissemination and implementation science: Introduction to special issue. *Clinical Psychology: Science & Practice, 20*(1), 113.

Sperber, K.G., Latessa, E., & Makarios, M.D. (2013). Examining the interaction between level of risk and dosage of treatment. *Criminal Justice & Behavior, 40*(3), 338–348.

Steenbergh, T.A., Runyan, J.D., Daugherty, D.A., & Winger, J.G. (2012). Neuroscience exposure and perceptions of client responsibility among addiction counselors. *Journal of Substance Abuse Treatment*, *42*(4), 421–8.

Szalavitz, M. (2010, July 16). Does teen drug rehab cure addiction or create it? *Time Magazine: On-Line. Available at* http://time.com/time/printout/0,8816,2003160,00.html.

Taxman, F.S., & Bouffard, J.A. (2005). Treatment as a part of drug court: The impact on graduation rates. *Journal of Offender Rehabilitation, 42*(1), 23–50.

Timko, C., & DeBenedetti, A. (2007). A randomized controlled trial of intensive referral to 12-step self-help groups: One-year outcomes. *Drug & Alcohol Dependence*, 90(2), 270–279.

Titus, J.C., Smith, D., C., Dennis, M.L., Ives, M., Twanow, L, & White, M.K. (2012). Impact of a training and certification program on the quality of interviewer-collected self-report assessment data. *Journal of Substance Abuse Treatment, 42(*2), 201–212.

Velasquez, M.M., Maurer, G.G., Crouch, C., & DiClemente, C.C. (2001). *Group treatment for substance abuse: A stages-of-change therapy manual.* New York: Guilford.

Vieira, T.A., Skilling, T.A., & Peterson-Badali, M. (2009). Matching court-ordered services with treatment needs: Predicting treatment success with young offenders. *Criminal Justice & Behavior, 36*(4), 385–401.

Wanberg, K.W., & Milkman, H.B. (2006). *Criminal conduct & substance abuse treatment: Strategies for self-improvement and change* (2nd ed.). Thousand Oaks, CA: Sage.

Weiss, R.D., Potter, J.S., & Iannucci, R.A. (2008). Inpatient treatment. In M. Galanter & H.D. Kleber (Eds.), *Textbook of Substance Abuse Treatment* (4th Ed., pp. 445–458). Arlington, VA: American Psychiatric Publishing.

Wexler, H.K., Melnick, G., & Cao, Y. (2004). Risk and prison substance abuse treatment outcomes: A replication and challenge. *The Prison Journal, 84*(1), 106–120.

Wexler, H.K., Melnick, G., Lowe, L., & Peters, J. (1999). Three-year reincarceration outcomes for Amity in-prison therapeutic community and aftercare in California. *The Prison Journal, 79*(3), 321–336.

Wilson, D.B., Bouffard, L.A., & MacKenzie, D.L. (2005). A quantitative review of structured, group-oriented, cognitive-behavioral programs for offenders. *Criminal Justice & Behavior, 32*(2), 172–204.

Wilson, D.B., Mitchell, O. & MacKenzie, D.L. (2006). A systematic review of drug court effects on recidivism. *Journal of Experimental Criminology*, *2*(4), 459–487.

Wilson, J.A., & Davis, R.C. (2006). Good intentions meet hard realities: An evaluation of the Project Greenlight Reentry Program. *Criminology & Public Policy, 5*(2), 303–338.

Witbrodt, J., Mertens, J., Kaskutas, L.A., Bond, J., Chi, F., & Weisner, C. (2012). Do 12-step meeting attendance trajectories over 9 years predict abstinence? *Journal of Substance Abuse Treatment*, *43*(1), 30–43.

Yalom, I.D. (2005). *The theory and practice of group psychotherapy* (5th ed.). New York: Basic Books.

Zweig, J.M., Lindquist, C., Downey, P.M., Roman, J., & Rossman, S.B. (2012). Drug court policies and practices: How program implementation affects offender substance use and criminal behavior outcomes. Drug Court Review, *8*(1), 43–79.

APPENDIX A

VALIDATED RISK AND NEED ASSESSMENT TOOLS

This list provides examples of risk and need assessment tools that have been validated for use with addicted individuals in substance abuse treatment or the criminal justice system. It is not an exhaustive list. Further information about these and other assessment tools can be obtained online from the Alcohol and Drug Abuse Institute Library at the University of Washington at http://lib.adai.washington.edu/instruments/.

RISK ASSESSMENT TOOLS

Level of Service Inventory—Revised (LSI-R)

https://ecom.mhs.com/(S(zhkd5d55qlwc3lr2gzqq5w55))/product.aspx?gr=saf&prod=lsi-r&id=overview

Wisconsin Risk and Need Assessment Scale (WRN)

http://www.j-satresources.com/Toolkit/Adult/adf6e846-f4dc-4b1e-b7b1-2ff28551ce85

Risk and Needs Triage (RANT)

http://www.trirant.org/

Correctional Offender Management Profiling for Alternative Sanctions (COMPAS)

http://www.northpointeinc.com/products/northpointe-software-suite

Ohio Risk Assessment System (ORAS)

http://www.uscourts.gov/uscourts/FederalCourts/PPS/Fedprob/2010-06/02_creation_validation_of_oras.html

Federal Post Conviction Risk Assessment (PCRA)

http://www.uscourts.gov/FederalCourts/ProbationPretrialServices/Supervision/PCRA.aspx

Risk Prediction Index (RPI)

http://www.fjc.gov/public/pdf.nsf/lookup/0013.pdf/$file/0013.pdf

Risk-Need-Responsivity Simulation Tool

http://www.gmuace.org/tools/

CLINICAL DIAGNOSTIC TOOLS

Global Appraisal of Individual Needs (GAIN)

http://www.gaincc.org/

Texas Christian University (TCU) Drug Screen II

http://www.ibr.tcu.edu/pubs/datacoll/Forms/ddscreen-95.pdf

Structured Clinical Interview for the DSM-IV (SCID)

http://www.scid4.org/

Psychiatric Research Interview for Substance and Mental Disorders (PRISM)

http://www.columbia.edu/~dsh2/prism/

Diagnostic Interview Schedule (DIS)

http://www.enotes.com/drugs-alcohol-encyclopedia/diagnostic-interview-schedule-dis

Drug Abuse Screening Test (DAST-20)

http://www.camh.ca/en/education/about/camh_publications/Pages/drug_abuse_screening_test.aspx

APPENDIX B

ON-LINE WEBINARS ON BEST PRACTICES IN DRUG COURTS

National Drug Court Institute (NDCI)

http://www.ndci.org/training/online-trainings-webinars

National Drug Court Resource Center (NDCRC)

http://www.ndcrc.org/

Center for Court Innovation (CCI)

http://drugcourtonline.org/

National Center for State Courts (NCSC) &
Justice Programs Office at American University
Translating Drug Court Research into Practice (R2P)

http://research2practice.org/

NADCP
National Association of
Drug Court Professionals

1029 North Royal Street
Suite 201
Alexandria, VA 22314

703.575.9400
703.575.9402 **Fax**

www.AllRise.org

ADULT DRUG COURT
BEST PRACTICE STANDARDS

VOLUME II

NATIONAL ASSOCIATION OF DRUG COURT PROFESSIONALS
ALEXANDRIA, VIRGINIA

Printed in the United States of America.

Drug Courts perform their duties without manifestation, by word or conduct, of bias or prejudice, including, but not limited to, bias or prejudice based upon race, gender, national origin, disability, age, sexual orientation, language, or socioeconomic status.

ADULT DRUG COURT BEST PRACTICE STANDARDS COMMITTEE

COMMITTEE CO-CHAIRS

Douglas B. Marlowe, JD, PhD
Chief of Science, Law, and Policy
NADCP
Alexandria, Virginia

Carson L. Fox, Jr., JD
Chief Operating Officer
NADCP
Alexandria, Virginia

COMMITTEE MEMBERS

P. Karen Blackburn, MA
Program Administrator
Administrative Office of Pennsylvania Courts
Pennsylvania Supreme Court
Philadelphia, Pennsylvania

Peter Bochert
Statewide Drug Court Coordinator
New Mexico Administrative Office of the Courts
Santa Fe, New Mexico

Shannon M. Carey, PhD
Copresident
Sr. Research Associate
NPC Research
Portland, Oregon

Paul L. Cary, MS
Scientific Director
Toxicology Laboratory
University of Missouri Health Care
Columbia, Missouri

Fred L. Cheesman II, PhD
Principal Court Research Consultant
National Center for State Courts
Williamsburg, Virginia

Michael W. Finigan, PhD
President (Ret.)
NPC Research
Portland, Oregon

Hon. Karen Freeman-Wilson
Mayor
City of Gary, Indiana

Carolyn D. Hardin, MPA
Senior Director
National Drug Court Institute
Alexandria, Virginia

Mary Kay Hudson, LSW
Director of Court Services
Indiana Judicial Center
Indianapolis, Indiana

Deborah Koetzle, PhD
Associate Professor & Executive Officer
Doctoral Program in Criminal Justice
John Jay College of Criminal Justice/CUNY
New York, New York

Mike Loeffler, JD
Fellow, NDCI
Sr. Assistant District Attorney
Bristow, Oklahoma

Austine M. Long, JD
Program Attorney
Indigent Defense Education
University of North Carolina School of Government
Chapel Hill, North Carolina

John N. Marr, MS
Executive Minister
Boones Creek Christian Church
Johnson City, Tennessee

Hon. William G. Meyer (Ret.)
Managing Arbiter
Judicial Arbiter Group, Inc.
Denver, Colorado

Valerie Raine, JD
Statewide Drug Court Coordinator
New York Unified Court System
New York, New York

Hon. Robert G. Rancourt
Minnesota District Court Judge
Minnesota Judicial Branch
Center City, Minnesota

Aaron Roussell, PhD
Assistant Professor
Department of Criminal Justice & Criminology
Washington State University
Pullman, Washington

Richard H. Schwermer, JD
Assistant State Court Administrator
Utah Administrative Office of the Courts
Salt Lake City, Utah

Jacqueline Van Wormer, PhD
Assistant Professor
Department of Criminal Justice & Criminology
Washington State University
Pullman, Washington

Carol A. Venditto, MPA
Statewide Drug Court Manager (Ret.)
Administrative Office of the Courts
Trenton, New Jersey

Terrence D. Walton, MSW, CSAC
Chief of Standards
NADCP
Alexandria, Virginia

NADCP BOARD OF DIRECTORS RESEARCH & STANDARDS COMMITTEE

Mary Kay Hudson
Director of Court Services
Indiana Judicial Center
Indianapolis, Indiana

Judi M. Kosterman, PhD (Committee Chair)
Senior Vice President
WestCare Foundation
Reno, Nevada

Connie M. Payne
Executive Officer, Statewide Services
Kentucky Administrative Office of the Courts
Frankfort, Kentucky

Charles R. Robinson
Chief Probation Officer-Director
Travis County Community Supervision and Corrections Department
Austin, Texas

Hon. Robert T. Russell
Judge
Erie County Court
Buffalo, New York

OBSERVERS

Ruby Qazilbash, MPA
Associate Deputy Director
Bureau of Justice Assistance
Washington, DC

Holly K. Rogers, MA
Public Health Advisor
Substance Abuse & Mental Health Services Administration
Rockville, Maryland

PEER REVIEWERS

Susan Alameda
Kenneth Arnold
Karen Barnes
Erica Bartlett
Michelle Bartley
Gray Barton
Chet Bell
Kim Bingham
Francine Byrne
Scott Carlson
Alex Casale
Michelle Cern
Hartwell Dowling
James Eberspacher
David Festinger
Karen Gennette
Socorro Gonzalez
Dana Graham
Jennifer Grandal
Steve Hanson
Helen Harberts
Cary Heck
Paula Hendrix
Ronald Ibarra
Anne Dannerbeck Janku
Michael Jewell
Robert Kirchner
Melissa Knopp
Jeff Kushner
Liz Ledbetter
Wendy Lindley
Jaki Livingston
Christopher Lowenkamp
Melanie May
Gerald Melnick
Pamela Miller
Marilyn Moe
Jessica Parks
Roger Peters
Chris Pleasanton
Noreen Plumage
Angela Plunkett
Anna Powers
Kari Powers
Vanessa Price
Michael Rempel
Brenidy Rice
Charles Robinson
Ken Robinson
Michelle Rock
Scott Ronan
Michael Roosevelt
Shelli Rossman
Robert Russell
Ronald Thrasher
Robert Ward
Henry Weber
Nisha Wilson
Shane Wolf
Kristin Wood
Yolanda Woodhouse
Michele Worobiec
Carrie Zoller

EDITORIAL

Jennifer L. Carson
Production Editor
Editcetera
Berkeley, CA

NATIONAL ASSOCIATION OF DRUG COURT PROFESSIONALS
BOARD OF DIRECTORS

CHAIR

Hon. Keith Starrett
U.S. District Court Judge
Hattiesburg, Mississippi

NADCP BOARD OF DIRECTORS

Hon. Jeffrey S. Bagley
Cumming, Georgia

Hon. Michael J. Barrasse
Scranton, Pennsylvania

Jonathan W. Blodgett
Salem, Massachusetts

Hon. Richard S. Gebelein
Wilmington, Delaware

Hon. Pamela Gray
Washington, DC

Hon. Robert B. Helfrich
Hattiesburg, Mississippi

Domingo Herraiz
Washington, DC

Earl Hightower
Studio City, California

Mary Kay Hudson
Indianapolis, Indiana

Mack Jenkins
San Diego, California

Hon. Ronald Eagleye Johnny (Ret.)
Nixon, Nevada

Judi M. Kosterman, PhD
Reno, Nevada

Hon. Russell B. Laine
Algonquin, Illinois

Hon. Leonia J. Lloyd
Detroit, Michigan

Hon. Stephen V. Manley
San Jose, California

Connie M. Payne
Frankfort, Kentucky

Hon. Ruben G. Reyes
Lubbock, Texas

Lynn P. Richardson
Dallas, Texas

Charles R. Robinson
Austin, Texas

Hon. Charles B. Simmons
Greenville, South Carolina

EMERITUS BOARD MEMBERS

Hon. Louis J. Presenza (Ret.)
Philadelphia, Pennsylvania

Hon. Robert G. Rancourt
Center City, Minnesota

Hon. Robert T. Russell
Buffalo, New York

Hon. John Schwartz (Ret.)
Rochester, New York

NATIONAL ASSOCIATION OF DRUG COURT PROFESSIONALS

Carolyn D. Hardin
Interim Chief Executive Officer
1029 N. Royal Street, Suite 201
Alexandria, Virginia 22314
Tel. (703) 575-9400, Fax (703) 575-9402
www.allrise.org

THE NATIONAL ASSOCIATION OF DRUG COURT PROFESSIONALS

It takes innovation, passion, teamwork, and strong judicial leadership for a community to achieve success in rehabilitating persons with severe substance use disorders and concurrent criminal involvement. That is why since 1994, the National Association of Drug Court Professionals (NADCP) has worked tirelessly at the national, state, and local levels to develop and enhance Drug Courts, which combine treatment and accountability to support and compel drug-addicted persons charged with serious crimes to change their lives.

Now an international movement, Drug Courts are the shining example of what works in the criminal justice system. Today over 2,900 Drug Courts operate in the U.S. and another thirteen countries have also implemented the model. Drug Courts are applied widely to adult criminal cases, juvenile delinquency and truancy cases, and family court cases involving parents at risk of losing custody of their children as a result of substance use problems.

In the twenty-six years since the first Drug Court was founded in Miami/Dade County, Florida, more research has been published on the effects of Drug Courts than virtually all other criminal justice programs combined. The scientific community has put Drug Courts under a microscope and concluded that Drug Courts significantly reduce drug abuse and crime and do so at far less cost than any other justice strategy. Drug Courts improve communities by successfully getting justice-involved individuals clean and sober, stopping drug-related crime, reuniting broken families, intervening with juveniles before they embark on a debilitating life of addiction and crime, and preventing impaired driving.

This success has motivated NADCP to champion new generations of the Drug Court model, including but not limited to Veterans Treatment Courts, Reentry Courts, and Mental Health Courts. Veterans Treatment Courts link critical services and provide the structure needed for military veterans who are involved in the justice system as a result of substance abuse or mental illness to resume productive lives after combat. Reentry Courts assist individuals leaving our nation's jails and prisons to succeed on probation or parole and avoid a recurrence of drug abuse and crime. And Mental Health Courts treat and monitor those with severe and persistent mental illness who often find their way into the justice system because of their illness.

Today the award-winning NADCP is the premier national membership, training, and advocacy organization for the Drug Court model, representing over 27,000 multidisciplinary justice professionals and community leaders. NADCP hosts the largest annual training conference on drugs and crime in the nation and provides 130 training and technical assistance events each year through its professional service branches, the National Drug Court Institute, the National Center for DWI Courts, and Justice for Vets: The National Veterans Treatment Court Clearinghouse. NADCP publishes numerous scholastic and practitioner publications critical to the growth and fidelity of the Drug Court model, and works tirelessly on Capitol Hill, in the media, and in state legislatures to improve the response of the American justice system to help persons suffering from drug addiction and mental illness through effective policy, legislation, appropriations, and public education.

ACKNOWLEDGMENTS

Producing the first two volumes of the ***Adult Drug Court Best Practice Standards*** has been a tremendous undertaking, which would not have been possible but for the dedication and contributions of so many seasoned and generous professionals. This exhaustive project has been continuing for more than six years. The five standards contained in Volume II and the five preceding standards in Volume I are the products of countless hours of effort from a host of dedicated professionals who volunteered their time, energy, and intellects to the endeavor.

First, I want to thank the committee of volunteer practitioners, researchers, and subject-matter experts who developed the topics and materials contained in these standards. Second, I thank the peer reviewers who provided invaluable and meticulous feedback on each standard. Finally, I thank the NADCP Board of Directors for its leadership and vision in supporting this time- and labor-intensive effort. I reserve special recognition for Dr. Douglas Marlowe, who, as he did with Volume I, labored over every aspect of the document to ensure that it provides guidance that is clear, rooted convincingly in scientific research, and as practical as possible for Drug Court professionals.

I could not be more excited as we release this next volume. In the twenty-six years since the first Drug Court was founded, a vast body of research has proven not only that Drug Courts work, but also how they work and for whom. We now know how to structure and implement our Drug Courts to achieve the best outcomes, and it is a great privilege and honor to share this hard-won knowledge with the Drug Court field. With science guiding the hands of a compassionate and dedicated field of educated professionals, Drug Courts are poised to give hope and the gift of recovery to millions of deserving citizens, enhance public safety in our communities, and make the best use of taxpayer dollars.

Clearly the work is not done. The material contained herein must be disseminated widely to the Drug Court field and translated into day-to-day Drug Court operations. Much effort lies ahead to train practitioners on the content of the standards and put the recommended procedures into effect. In addition, future volumes of the standards will address other aspects of Drug Court procedures as new research findings become available. NADCP stands ready to deliver the requisite training, technical assistance, and knowledge development needed to enact the standards, expand the field's knowledge of best practices, and produce the best possible results for our participants and our communities.

Carolyn D. Hardin
Interim Chief Executive Officer
National Association of Drug Court Professionals

ADULT DRUG COURT
BEST PRACTICE STANDARDS

INTRODUCTION 1

VI COMPLEMENTARY TREATMENT AND SOCIAL SERVICES 5

Participants receive complementary treatment and social services for conditions that co-occur with substance abuse and are likely to interfere with their compliance in Drug Court, increase criminal recidivism, or diminish treatment gains.

VII DRUG AND ALCOHOL TESTING 26

Drug and alcohol testing provides an accurate, timely, and comprehensive assessment of unauthorized substance use throughout participants' enrollment in the Drug Court.

VIII MULTIDISCIPLINARY TEAM 38

A dedicated multidisciplinary team of professionals manages the day-to-day operations of the Drug Court, including reviewing participant progress during pre-court staff meetings and status hearings, contributing observations and recommendations within team members' respective areas of expertise, and delivering or overseeing the delivery of legal, treatment and supervision services.

IX CENSUS AND CASELOADS 51

The Drug Court serves as many eligible individuals as practicable while maintaining continuous fidelity to best practice standards.

X MONITORING AND EVALUATION 59

The Drug Court routinely monitors its adherence to best practice standards and employs scientifically valid and reliable procedures to evaluate its effectiveness.

APPENDIX C COMPLEMENTARY NEEDS ASSESSMENTS 75

APPENDIX D EVIDENCE-BASED COMPLEMENTARY TREATMENT AND SOCIAL SERVICES 78

APPENDIX E MANAGEMENT INFORMATION SYSTEMS FOR DRUG COURT EVALUATIONS 79

ADULT DRUG COURT
BEST PRACTICE STANDARDS

INTRODUCTION

Until Drug Courts define appropriate standards of practice, they will be held accountable, fairly or unfairly, for the worst practices in the field. Scientists will continue to analyze the effects of weak Drug Courts alongside those of exceptional Drug Courts, thus diluting the benefits of Drug Courts. Critics will continue to tarnish the reputation of Drug Courts by attributing to them the most noxious practices of the feeblest programs. Only by defining the bounds of acceptable and exceptional practices will Drug Courts be in a position to disown poor-quality or harmful programs and set effective benchmarks for new and existing programs to achieve.

—Adult Drug Court Best Practice Standards, Volume I (NADCP, 2013; p. 1)

Volume I

In 2013, NADCP released Volume I of the *Adult Drug Court Best Practice Standards* (Standards). This landmark document was the product of more than four years of exhaustive work reviewing scientific research on best practices in substance abuse treatment and correctional rehabilitation and distilling that vast literature into measurable and enforceable practice recommendations for Drug Court professionals.

The response from the Drug Court field was immediate and profound. In the ensuing two years, twenty out of twenty-five states (80%) responding to a national survey indicated they have adopted the Standards for purposes of credentialing, funding, or training new and existing Drug Courts in their jurisdictions. The parlance of the field is literally evolving as evidence-based terminology permeates Drug Court policies and procedures. Drug Court professionals now speak routinely about targeting high-risk and high-need participants [Standard I], ensuring equivalent access and services for members of historically disadvantaged groups [Standard II], enhancing perceptions of procedural fairness during court hearings [Standard III], distinguishing proximal from distal behavioral goals and responding to participant conduct accordingly [Standard IV], and delivering evidence-based treatments matched to participants' clinical needs and prognoses for success in treatment [Standard V].

Any concerns that the Standards might sit on a shelf and collect dust vanished rapidly. Drug Courts are changing their policies and procedures in accordance with scientific findings and improving their outcomes as a result.

Volume II

Volume I marked the beginning of an ongoing process of self-evaluation and self-correction initiated by and for the Drug Court field. Before the ink dried on Volume I, NADCP launched subsequent efforts to bring Volume II to print, and those efforts have now reached fruition. Volume II picks up seamlessly where Volume I left off and describes best practices for Drug Courts on the following topics:

VI. Complementary Treatment and Social Services. Drug Court participants often have a range of service needs extending well beyond substance abuse treatment. Standard VI addresses an array of co-occurring needs encountered frequently in Drug Courts, including best practices for delivering mental health treatment, trauma-informed services, criminal thinking interventions, family counseling, vocational or educational counseling, and prevention education to reduce health-risk behaviors.

VII. Drug and Alcohol Testing. Unless Drug Courts have accurate and timely information as to whether participants are maintaining abstinence from illicit drugs and alcohol, they have no way to apply incentives, sanctions, or treatment adjustments effectively. Standard VII describes best practices for detecting unauthorized substance use in a population that is often highly motivated and surprisingly adept at avoiding detection by standard testing methods.

VIII. Multidisciplinary Team. Recent studies have shed considerable light on the workings of the Drug Court team. Standard VIII reviews the latest research indicating which professional disciplines should be represented on the team, how team members should share information and expertise, and how often and under what circumstances team members should receive preparatory instruction and continuing-education training on Drug Court best practices.

IX. Census and Caseloads. Drug Courts need to "go to scale" and treat all eligible individuals involved in the criminal justice system. Yet studies suggest outcomes may decline if caseloads increase without ensuring that programs have sufficient resources to maintain fidelity to best practices. Standard IX identifies milestones related to the size of the Drug Court census and caseloads for supervision officers and clinicians that should trigger a reexamination of a Drug Court's resources and adherence to best practices.

X. Monitoring and Evaluation. Drug Courts are successful in large measure because they recognized the importance of research and evaluation from their inception. Not all studies, however, employ adequate scientific methodology, thus contributing a good deal of "noise" and confusion to the scientific literature on Drug Courts. Standard X describes best practices for monitoring a Drug Court's adherence to best practices and evaluating its impacts on substance abuse, crime, participants' emotional health, and other important outcomes.

Procedures

NADCP employed the same procedures for developing Volume II as were employed for Volume I. The standards were drafted by a diverse and multidisciplinary committee comprising Drug Court practitioners, subject-matter experts, researchers, and state and federal policymakers. Each draft standard was peer-reviewed subsequently by at least thirty practitioners and researchers with expertise in the relevant subject matter. The peer reviewers rated the standards on the dimensions of *clarity* (what specific practices were required), *justification* (why those practices were required), and *feasibility* (how difficult it would be for Drug Courts to implement the practices). All of the standards received ratings from good to excellent and were viewed as achievable by most Drug Courts within a reasonable period of time. How long this process should take will vary from standard to standard. Drug Courts should be able to comply with some of the standards within a few months if they are not already doing so; however, other standards may require three to five years to satisfy.

None of the requirements contained in the Standards will come as a surprise to Drug Court professionals who have attended a training workshop or conference within the past five years. The research supporting these standards has been disseminated widely to the Drug Court field via conference presentations, webinars, practitioner fact sheets, and NDCI's scholarly journal, the *Drug Court Review*. Volumes I and II of the Standards are simply the first documents to compile and distill that research into concrete and measurable practice recommendations.

Future Volumes

The standards contained in Volumes I and II do not come close to addressing every practice performed in a Drug Court. Unless reliable and convincing evidence demonstrated that a practice significantly improves outcomes, it was not incorporated (yet) into a best practice standard. This should in no way be interpreted to suggest that omitted practices are unimportant or less important than the practices that were included. Practices were omitted simply because the current state of research is insufficient at this time to provide dependable guidance to the field or to impose an obligation on Drug Courts to alter their operations. Additional practices will be added to the Standards in future volumes as new studies are completed. Future standards are expected to address topics including best practices for community-supervision officers in Drug Courts; restorative-justice interventions such as community service or victim restitution; payment of fines, fees, and costs; peer and vocational mentoring; and recovery-oriented systems of care. NADCP is working actively with researchers and funders to fill these gaps in the literature and is committed to publishing related practice guidance as soon as a sufficient body of evidence is compiled.

To date, best practice standards have only been developed for Adult Drug Courts. This fact does not suggest that Adult Drug Courts are more effective or valued than other types of problem-solving courts such as Juvenile Drug Courts, DWI Courts, Family Drug Courts, or Veterans Treatment Courts. Adult Drug Courts simply have far more research on them than other types of problem-solving courts. When a sufficient body of research identifies best practices for other problem-solving court programs, NADCP will develop and release best practice standards for those programs as well.

Implementation

Putting science into practice is the greatest challenge facing the substance abuse treatment and criminal justice fields (Damschroder et al., 2009; Rudes et al., 2013; Taxman & Belenko, 2013). So far, Drug Courts are doing considerably better than most programs at following best practice standards; however, more work is needed. Programs that ignore best practices and fail to attend training conferences are the ones most likely to produce ineffective or harmful results (Carey et al., 2012; Shaffer, 2006; van Wormer, 2010) and thus to diminish the effects of Drug Courts and tarnish the reputation of the field. There is no escaping the need to redouble our efforts to disseminate best practice information widely, provide needed technical assistance to help Drug Courts bring themselves into compliance with the standards, and hold outlier programs accountable for refusing to align their practices with what works.

Responsibility for enforcing best practices is the province of state and local court and treatment systems; however, NADCP and other national organizations can and will play a critical role in

training, consulting, and evaluating program adherence to best practices. Coordinated efforts at the state, local, and national levels will teach Drug Courts what they should be doing, why they should be doing it, and how to do it. Programs that turn a blind eye to this assistance will be readily identifiable and will ultimately face the same consequences as any other program or professional that provides deficient services below the recognized standard of care for their field.

Drug Courts have always set the highest standards for themselves. Dissatisfied with what was being done in the past, Drug Courts pushed the envelope and redesigned the criminal justice system. They brushed aside old paradigms and changed the language of justice reform. The large majority of Drug Courts can be expected to follow best practices once those practices have been identified and to save innumerable lives in the process. With a critical mass of effective programs crowding out ineffective alternatives, Drug Courts will continue to lead the way toward improved public health, public safety, and higher financial benefits for taxpayers.

REFERENCES

Carey, S.M., Mackin, J.R., & Finigan, M.W. (2012). What works? The ten key components of Drug Court: Research-based best practices. *Drug Court Review, 8*(1), 6–42.

Damschroder, L.J., Aron, D.C., Keith, R.E., Kirsh, S.R., Alexander, J.A., & Lowery, J.C. (2009). Fostering implementation of health services research findings into practice: A consolidated framework for advancing implementation science. *Implementation Science, 4*(50). doi:10.1186/1748-5908-4-50

National Association of Drug Court Professionals. (2013). *Adult Drug Court Best Practice Standards* (Vol. 1). Alexandria, VA: Author. *Available at* http://www.nadcp.org/sites/default/files/nadcp/AdultDrugCourtBestPracticeStandards.pdf

Rudes, D.S., Viglione, J., & Porter, C.M. (2013). Using quality improvement models in correctional organizations. *Federal Probation, 77*(2), 69–75.

Shaffer, D.K. (2006). *Reconsidering Drug Court Effectiveness: A Meta-Analytic Review* (Doctoral dissertation, University of Cincinnati). Retrieved from https://etd.ohiolink.edu/ap:10:0::NO:10:P10_ACCESSION_NUM:ucin1152549096

Taxman, F.S., & Belenko, S. (2013). *Implementing evidence-based practices in community corrections and addiction treatment.* New York: Springer.

Van Wormer, J. (2010). *Understanding operational dynamics of Drug Courts* (Doctoral dissertation, University of Washington). Retrieved from http://research.wsulibs.wsu.edu:8080/xmlui/bitstream/handle/2376/2810/vanWormer_wsu_0251E_10046.pdf?sequence=1

VI. COMPLEMENTARY TREATMENT AND SOCIAL SERVICES

Participants receive complementary treatment and social services[1] for conditions that co-occur with substance abuse and are likely to interfere with their compliance in Drug Court, increase criminal recidivism, or diminish treatment gains.

A. Scope of Complementary Services
B. Sequence and Timing of Services
C. Clinical Case Management
D. Housing Assistance
E. Mental Health Treatment
F. Trauma-Informed Services
G. Criminal Thinking Interventions
H. Family and Interpersonal Counseling
I. Vocational and Educational Services
J. Medical and Dental Treatment
K. Prevention of Health-Risk Behaviors
L. Overdose Prevention and Reversal

A. Scope of Complementary Services

The Drug Court provides or refers participants for treatment and social services to address conditions that are likely to interfere with their response to substance abuse treatment or other Drug Court services (*responsivity needs*), to increase criminal recidivism (*criminogenic needs*), or to diminish long-term treatment gains (*maintenance needs*). Depending on participant needs, complementary services may include housing assistance, mental health treatment, trauma-informed services, criminal-thinking interventions, family or interpersonal counseling, vocational or educational services, and medical or dental treatment. Participants receive only those services for which they have an assessed need.

B. Sequence and Timing of Services

In the first phase of Drug Court, participants receive services designed primarily to address responsivity needs such as deficient housing, mental health symptoms, and substance-related cravings, withdrawal, or anhedonia (diminished ability to experience pleasure). In the interim phases of Drug Court, participants receive services designed to resolve criminogenic needs that co-occur frequently with substance abuse, such as

[1] The term *complementary treatment and social services* refers to interventions other than substance abuse treatment that ameliorate symptoms of distress, provide for participants' basic living needs, or improve participants' long-term adaptive functioning. The term does not include restorative-justice interventions such as victim restitution, supervisory interventions such as probation home visits, or recovery-oriented services such as peer mentoring.

criminal-thinking patterns, delinquent peer interactions, and family conflict. In the later phases of Drug Court, participants receive services designed to maintain treatment gains by enhancing their long-term adaptive functioning, such as vocational or educational counseling.

C. Clinical Case Management

Participants meet individually with a clinical case manager or comparable treatment professional at least weekly during the first phase of Drug Court. The clinical case manager administers a validated assessment instrument to determine whether participants require complementary treatment or social services, provides or refers participants for indicated services, and keeps the Drug Court team apprised of participants' progress.

D. Housing Assistance

Where indicated, participants receive assistance finding safe, stable, and drug-free housing beginning in the first phase of Drug Court and continuing as necessary throughout their enrollment in the program. If professional housing services are not available to the Drug Court, clinical case managers or other staff members help participants find safe and sober housing with prosocial and drug-free relatives, friends, or other suitable persons. Participants are not excluded from participation in Drug Court because they lack a stable place of residence.

E. Mental Health Treatment

Participants are assessed using a validated instrument for major mental health disorders that co-occur frequently in Drug Courts, including major depression, bipolar disorder (manic depression), posttraumatic stress disorder (PTSD), and other major anxiety disorders. Participants suffering from mental illness receive mental health services beginning in the first phase of Drug Court and continuing as needed throughout their enrollment in the program. Mental illness and addiction are treated concurrently using an evidence-based curriculum that focuses on the mutually aggravating effects of the two conditions. Participants receive psychiatric medication based on a determination of medical necessity or medical indication by a qualified medical provider. Applicants are not denied entry to Drug Court because they are receiving a lawfully prescribed psychiatric medication [see Standard I, Target Population], and participants are not required to discontinue lawfully prescribed psychiatric medication as a condition of graduating from Drug Court [see Standard V, Substance Abuse Treatment].

F. Trauma-Informed Services

Participants are assessed using a validated instrument for trauma history, trauma-related symptoms, and posttraumatic stress disorder (PTSD). Participants with PTSD receive an evidence-based intervention that teaches them how to manage distress without resorting to substance abuse or other avoidance behaviors, desensitizes them gradually to symptoms of panic and anxiety, and encourages them to engage in productive actions that reduce the risk of retraumatization. Participants with PTSD or severe trauma-related symptoms are evaluated for their suitability for group interventions and are treated on an individual basis or in small groups when necessary to manage panic, dissociation, or

severe anxiety. Female participants receive trauma-related services in gender-specific groups. All Drug Court team members, including court personnel and other criminal justice professionals, receive formal training on delivering trauma-informed services.

G. Criminal Thinking Interventions

Participants receive an evidence-based criminal-thinking intervention after they are stabilized clinically and are no longer experiencing acute symptoms of distress such as cravings, withdrawal, or depression. Staff members are trained to administer a standardized and validated cognitive-behavioral criminal-thinking intervention such as Moral Reconation Therapy, the Thinking for a Change program, or the Reasoning & Rehabilitation program.

H. Family and Interpersonal Counseling

When feasible, at least one reliable and prosocial family member, friend, or daily acquaintance is enlisted to provide firsthand observations to staff about participants' conduct outside of the program, to help participants arrive on time for appointments, and to help participants satisfy other reporting obligations in the program. After participants are stabilized clinically, they receive an evidence-based cognitive-behavioral intervention that focuses on improving their interpersonal communication and problem-solving skills, reducing family conflicts, and eliminating associations with substance-abusing and antisocial peers and relatives.

I. Vocational and Educational Services

Participants with deficient employment or academic histories receive vocational or educational services beginning in a late phase of Drug Court. Vocational or educational services are delivered after participants have found safe and stable housing, their substance abuse and mental health symptoms have resolved substantially, they have completed a criminal-thinking intervention, and they are spending most or all of their time interacting with prosocial and sober peers. Vocational interventions are standardized and cognitive-behavioral in orientation and teach participants to find a job, keep a job, and earn a better or higher-paying job in the future though continuous self-improvement. Participants are required to have a stable job, be enrolled in a vocational or educational program, or be engaged in comparable prosocial activity as a condition of graduating from Drug Court. Continued involvement in work, education, or comparable prosocial activity is a component of each participant's continuing-care plan.

J. Medical and Dental Treatment

Participants receive immediate medical or dental treatment for conditions that are life-threatening, cause serious pain or discomfort, or may lead to long-term disability or impairment. Treatment for nonessential or nonacute conditions that are exacerbated by substance abuse may be provided in a late phase of Drug Court or included in the participant's continuing-care plan.

K. Prevention of Health-Risk Behaviors

Participants complete a brief evidence-based educational curriculum describing concrete measures they can take to reduce their exposure to sexually transmitted and other communicable diseases.

L. Overdose Prevention and Reversal

Participants complete a brief evidence-based educational curriculum describing concrete measures they can take to prevent or reverse drug overdose.

COMMENTARY

A. Scope of Complementary Services

Drug Court participants frequently have needs for treatment and social services that extend well beyond substance abuse treatment. National and statewide studies have found that substantial proportions of Drug Court participants suffered from a serious co-occurring mental health or medical disorder, were chronically unemployed, had low educational achievement, were homeless, or had experienced physical or sexual abuse or other trauma (see Table 1).

TABLE 1 COMPLEMENTARY NEEDS IDENTIFIED IN NATIONAL AND STATEWIDE STUDIES OF DRUG COURTS

Complementary Need	Percentage of Participants
Any mental health problem/disorder	63%
Major depression	16%–39%
Posttraumatic stress disorder (PTSD)	10%
Anxiety disorder other than PTSD	9%
Bipolar disorder	8%
Chronic medical condition	26%
Unemployed	54%–72%
Less than a high school diploma or GED	32%–38%
Homeless	11%–47%
Abuse or trauma history	27%–29%

Sources: Cissner et al. (2013); Green & Rempel (2012); Peters et al. (2012).

Drug Courts are more effective and cost-effective when they offer complementary treatment and social services to address these co-occurring needs. A multisite study of approximately seventy Drug Courts found that programs were significantly more effective at reducing crime when they offered mental health treatment, family counseling, and parenting classes and were marginally more effective when they offered medical and dental services (Carey et al., 2012). The same study determined that Drug Courts were more cost-effective when they helped participants find a job, enroll in an educational program, or obtain sober and supportive housing. Similarly, a statewide study of eighty-six Drug Courts in New York found that programs were significantly more effective at reducing crime when they assessed participants for trauma and other mental health treatment needs, and delivered mental health, medical, vocational, or educational services where indicated (Cissner et al., 2013).

Studies do not, however, support a practice of delivering the same complementary services to all participants. Drug Courts that required all participants to receive educational or employment services were

determined in one meta-analysis to be less effective at reducing crime than Drug Courts that matched these services to the assessed needs of the participants (Shaffer, 2006). Requiring participants to receive unnecessary services wastes time and resources and can make outcomes worse by placing excessive demands on participants and interfering with the time they have available to engage in productive activities (Gutierrez & Bourgon, 2012; Lowenkamp et al., 2006; Prendergast et al., 2013; Smith et al., 2009; Vieira et al., 2009; Viglione et al., 2015). Evidence also suggests participants may become resentful, despondent, or anxious if they are sanctioned for failing to meet excessive or unwarranted demands, a phenomenon referred to as learned helplessness or ratio burden (Seligman, 1975). Under such circumstances, behavior fails to improve, and participants may leave treatment prematurely (Marlowe & Wong, 2008). If a Drug Court team cannot articulate a sound rationale for requiring a participant to receive a given service, then the team should reconsider requiring that service.

B. Sequence and Timing of Services

Timing is critical to the successful delivery of complementary treatment and social services. Outcomes are significantly better when rehabilitation programs address complementary needs in a specific sequence. This finding has important implications for designing the phase structure in a Drug Court. The first phase of Drug Court should focus primarily on resolving conditions that are likely to interfere with retention or compliance in treatment (responsivity needs). This process may include meeting participants' basic housing needs, stabilizing mental health symptoms if present, and ameliorating acute psychological or physiological symptoms of addiction, such as cravings, anhedonia, or withdrawal. Subsequently, the interim phases of Drug Court should focus on resolving needs that increase the likelihood of criminal recidivism and substance abuse (criminogenic needs). This process includes initiating sustained abstinence from drugs and alcohol, addressing dysfunctional or antisocial thought patterns, eliminating delinquent peer associations, and reducing family conflict. Finally, later phases of Drug Court should address remaining needs that are likely to undermine the maintenance of treatment gains (maintenance needs). This process may include providing vocational or educational assistance, parent training, or other interventions designed to enhance participants' activities of daily living (ADL) skills.[2]

Responsivity Needs. When participants first enter Drug Court, one of the most pressing goals is to ensure that they remain in treatment and comply with other reporting obligations. This objective requires Drug Courts to resolve symptoms or conditions that are likely to interfere with attendance or engagement in treatment. Such conditions are commonly referred to as responsivity needs because they interfere with a person's response to rehabilitation efforts (Andrews & Bonta, 2010; Smith et al., 2009). Although responsivity needs do not necessarily cause or exacerbate crime, they nevertheless must be addressed early in treatment to prevent participants from failing or dropping out of treatment prematurely (Hubbard & Pealer, 2009; Karno & Longabaugh, 2007).

Responsivity needs that are commonly encountered in Drug Courts include severe mental illness and homelessness or unstable housing (Cissner et al., 2013; Green & Rempel, 2012; Peters et al., 2012). Although these conditions usually do not cause crime (Andrews & Bonta, 2010; Bonta et al., 1998; Gendreau et al., 1996), they have a marked tendency to undermine the effectiveness of Drug Courts and other correctional rehabilitation programs (Gray & Saum, 2005; Hickert et al., 2009; Johnson et al., 2011; Mendoza et al., 2013; Young & Belenko, 2002). To avoid premature termination from Drug Court, these responsivity needs must be addressed, when present, beginning in the first phase of treatment and continuing as needed throughout participants' enrollment in the program.

Criminogenic Needs. Criminogenic needs refer to disorders or conditions that cause or exacerbate crime (Andrews & Bonta, 2010). Drug and alcohol dependence are highly criminogenic needs (Bennett et al., 2008; Walters, 2015), which explains why they are the primary focus of most interventions in Drug Courts. Other criminogenic needs that are encountered frequently in Drug Courts include criminal-thinking

[2] This phase structure assumes a Drug Court is serving high-risk and high-need participants [see Standard I]. If a Drug Court serves individuals who are not addicted to drugs or alcohol or suffering from a serious mental illness, it may be advisable to deliver vocational, educational or other maintenance interventions beginning in an early phase of the program (Cresswell & Deschenes, 2001; Gallagher, 2013a; Vito & Tewksbury, 1998).

patterns, impulsivity, family conflict, and delinquent peer affiliations (Green & Rempel, 2012; Hickert et al., 2009; Jones et al., 2015).

Studies have reported improved outcomes when Drug Courts provided services to address these criminogenic needs. For example, superior outcomes have been reported when Drug Court participants learned to apply effective and prosocial decision-making skills, such as learning to think before they act, to consider the potential consequences of their actions, and to recognize their own role in interpersonal conflicts (Cheesman & Kunkel, 2012; Heck, 2008; Kirchner & Goodman, 2007; Lowenkamp et al., 2009; Vito & Tewksbury, 1998). Similarly, studies found that crime and substance abuse declined significantly when Drug Court participants spent less time interacting with delinquent peers, spent more time interacting with prosocial peers and relatives, and reported fewer conflicts with family members (Green & Rempel, 2012; Hickert et al., 2009; Shaeffer et al., 2010; Wooditch et al., 2013).

Maintenance Needs. Some needs, such as poor job skills, illiteracy, or low self-esteem, are often the result of living a nonproductive or antisocial lifestyle rather than the cause of that lifestyle (Hickert et al., 2009; Wooditch et al., 2013). Treating such noncriminogenic needs before one treats criminogenic needs is associated with increased criminal recidivism, treatment failure, and other undesirable outcomes (Andrews & Bonta, 2010; Andrews et al., 1990; Smith et al., 2009; Vieira et al., 2009). Nevertheless, if these needs are ignored over the long term, they are likely to interfere with the maintenance of treatment gains. Improvements in certain maintenance needs, such as improved educational achievement or job skills, predict better long-term persistence of treatment effects (Leukefeld et al., 2007).

The important point is that improvements in maintenance needs rarely occur until after the more pressing responsivity and criminogenic needs have been resolved. Participants are unlikely, for example, to improve their job performance until after they have stopped experiencing debilitating symptoms of addiction or mental illness, stopped associating with delinquent peers, and relinquished self-centered attitudes and impulsive behaviors (Guastaferro, 2012; Samenow, 2014). After participants are stabilized clinically and have achieved a reasonable period of sobriety, maintenance services designed to enhance their adaptive functioning and ADL skills help to ensure the gains are sustained. Outcomes are also significantly better when continued involvement in maintenance activities after discharge is a requirement for graduation and a component of each participant's continuing-care plan (Carey et al., 2012).

C. Clinical Case Management

Studies consistently find that Drug Courts are more effective and cost-effective when participants meet individually with a clinical case manager or comparable treatment professional at least weekly during the first phase of the program (Carey et al., 2012; Cissner et al., 2013; Zweig et al., 2012). As described previously, Drug Courts must identify a range of complementary needs among participants, refer participants for indicated services, and ensure the services are delivered in an effective sequence. To do otherwise risks wasting resources and making outcomes worse for some participants. These complicated tasks require input from a professionally trained clinical case manager or clinician who is competent to perform clinical and social service assessments, understands how services should be sequenced and matched to participant needs, and is skilled at monitoring and reporting on participant progress (Monchick et al., 2006; Rodriguez, 2011).

Typically, clinical case managers are addiction counselors, social workers, or psychologists who have received specialized training to assess participant needs, broker referrals for indicated services, coordinate care between partner agencies, and report progress information to other interested professionals (Monchick et al., 2006; Rodriguez, 2011). In some Drug Courts, probation officers or other criminal justice professionals may serve as court case managers, to be distinguished from clinical case managers. Typically, court case managers administer brief screening instruments designed to identify participants requiring more in-depth clinical assessments. Participants scoring above established thresholds on the screening instruments are referred for further evaluation by a clinically trained treatment professional.

Broadly speaking, there are four basic models of clinical case management (Hesse et al., 2007; Rapp et al., 2014):

- *Brokerage Model*—The least intensive form of case management, the brokerage model involves assessing participants and linking them to indicated services.
- *Generalist or Clinician Model*—In the most common form of case management, the Generalist case manager assesses participant needs and delivers some or all of the indicated services.
- *Assertive Community Treatment (ACT) Model*—The most intensive form of case management, the ACT Model provides around-the-clock access to a multidisciplinary team of professionals that delivers wrap-around services in the community designed to meet an array of treatment and social-service needs.
- *Strengths-Based Model*—A strengths-based philosophy may be applied in the context of any of the above models. It focuses on leveraging participants' natural resources and encouraging participants to take an active role in setting treatment goals and selecting treatment options.

Meta-analyses reveal that all four case management models significantly increase referrals for indicated services and retain participants longer in treatment; however, they have relatively small effects on substance abuse, crime, and other long-term outcomes (Hesse et al., 2007; Rapp et al., 2014). Whether a program produces long-term improvements depends ultimately on the quality and quantity of treatment and social services that are delivered. No evidence suggests any one case management model is superior to another; however, the models were developed for different types of programs serving individuals with different clinical and social service profiles. The generalist model was developed primarily for use in outpatient treatment settings where a primary therapist commonly delivers or coordinates the delivery of various components of a participant's care. Although few Drug Court studies have provided a clear description of the case management services that were provided, the generalist model appears to be used most frequently in adult Drug Courts (Carey et al., 2012; Cissner et al., 2013; Zweig et al., 2012).

The brokerage model was developed for participants who are served by more than one agency or system. For example, some substance abuse treatment programs may lack the required expertise to deliver mental health treatment or vocational rehabilitation. As a result, participants must be referred to another agency for a portion of their care. A clinical case manager is required to broker the referral, reconcile conflicting demands that may be placed on participants by different agencies, and report on participant progress to the Drug Court team.

A specific model of case management, called Treatment Accountability for Safer Communities or Treatment Alternatives to Street Crime (TASC), was designed to bridge gaps between the substance abuse, mental health, and criminal justice systems. TASC programs typically apply a brokerage or generalist model depending on whether treatment is available within the criminal justice system or must be brokered through another system or agency. Evidence is convincing that TASC programs increase participants' access to services and retention in treatment; however, impacts on substance abuse and crime have been mixed (Anglin et al., 1999; Ventura & Lambert, 2004). As was already noted, the key to successful outcomes depends on the quality and quantity of treatment and social services that are delivered (Clark et al., 2013; Cook, 2002; Rodriguez, 2011). Outcomes are more consistently favorable when TASC case management is delivered in conjunction with intensive evidence-based treatment as in Drug Courts (Monchick et al., 2006). Therefore, training on the TASC model or a comparable case management model is important for staff members providing clinical case management services in Drug Courts.

Finally, the ACT model was developed for use with seriously impaired individuals who have a wide range of mental health and social service needs (McLellan et al., 1998, 1999). This intensive model of case management has been applied successfully in the context of a mental health court (Braude, 2005) and a community court serving persons with serious and persistent mental illness or social service needs (Somers et al., 2014). Training on the ACT model of case management is advisable for Drug Courts serving seriously impaired individuals suffering from co-occurring mental illness, chronic homelessness, or other severe functional impairments.

Regardless of which model of case management is applied, outcomes are superior when case managers administer reliable and valid needs-assessment instruments (Andrews & Bonta, 2010; Andrews et al., 2006). [Appendix C provides examples of validated instruments designed to assess clinical and

criminogenic needs among persons in substance abuse treatment and the criminal justice system.] Whether needs assessments should be administered repeatedly during the course of treatment is an open question. Although evidence suggests changes in need scores correlate with progress in treatment (Greiner et al., 2015; Serin et al., 2013; Vose et al, 2013; Wooditch et al., 2013), little guidance is available to determine when or how to alter treatment conditions in light of changing scores (Serin et al., 2013). Until such guidance is available, Drug Courts are advised to rely on objective indices of participant progress, such as drug test results and treatment attendance rates, to make decisions about adjusting treatment and social services.

On a final note, a critical function of case management is linking participants to public benefits and other subsidies to which they are legally entitled. For example, under the Affordable Care Act (ACA), Drug Court participants may be eligible for medical or mental health care benefits pursuant to Medicaid expansion or newly created health-insurance exchanges (Frescoln, 2014). Court case managers or clinical case managers must leverage these financial resources and enroll participants for eligible benefits to meet participants' needs for substance abuse treatment and other complementary services.

D. Housing Assistance

Participants are unlikely to succeed in treatment if they do not have a safe, stable, and drug-free place to live (Morse et al., 2015; Quirouette et al., 2015). No study was identified that has examined the impact of housing assistance on Drug Court outcomes. However, studies in similar contexts have reported improved outcomes when housing assistance was provided for parolees reentering the community after prison (Clark, 2014; Lutze et al., 2014), in community courts for persons suffering from serious and persistent mental illness (Kilmer & Sussell, 2014; Lee et al., 2013), and in programs serving homeless military veterans (Elbogen et al., 2013; Winn et al., 2014).

Some Drug Courts may have a policy of denying entry to persons who do not have a stable place of residence. Such a policy is likely to have the unintended effect of excluding the highest-risk and highest-need individuals—those who need Drug Court the most—from participation in Drug Court (Morse et al., 2015; Quirouette et al., 2015). The preferable course of action is to provide housing assistance, where indicated, beginning in the first phase of Drug Court and continuing as needed throughout participants' enrollment in the program. If professional housing services are not available to a Drug Court, then clinical case managers or other staff members should make every effort to help participants find safe and stable housing with prosocial and drug-free relatives, friends, or other suitable individuals.

E. Mental Health Treatment

Approximately two-thirds of Drug Court participants report serious mental health symptoms and roughly one-quarter have a diagnosed Axis I psychiatric disorder, most commonly major depression, bipolar disorder, PTSD, or other anxiety disorder (Cissner et al., 2013; Green & Rempel, 2012; Peters et al., 2012). Mental illness, by itself, is ordinarily not a criminogenic need (Bonta et al., 1998; Elbogen & Johnson, 2009; Gendreau et al., 1996; Peterson et al., 2014; Phillips et al., 2005; Prins et al., 2014); however, it is a responsivity need that can interfere significantly with the effectiveness of Drug Courts and other rehabilitation programs (Gray & Saum, 2005; Hickert et al., 2009; Johnson et al., 2011; Manchak et al., 2014; Mendoza et al., 2013; Ritsher et al., 2002; Young & Belenko, 2002). Moreover, when mental illness is combined with substance abuse, the odds of recidivism increase significantly—although the magnitude of this effect is smaller than for most other criminogenic risk factors, such as a participant's criminal history or association with delinquent peers (Andrews & Bonta, 2010; Peters et al., 2015; Rezansoff et al., 2013).

Mental illness and substance abuse may co-occur in a given case for several reasons. Substance abuse may trigger or exacerbate mental illness, mentally ill individuals may abuse substances in a misguided effort to self-medicate psychiatric symptoms, or the two disorders may emerge independently in a person who has a generalized vulnerability to stress-related illness (Ross, 2008). Causality aside, treating either disorder alone without treating both disorders simultaneously is rarely, if ever, successful. Addiction and mental illness are reciprocally aggravating conditions, meaning that continued symptoms of one disorder are likely to precipitate relapse in the other disorder (Chandler et al., 2004; Drake et al., 2008). For example, a

formerly depressed person who continues to abuse drugs is likely to experience a resurgence of depressive symptoms. Conversely, a person recovering from addiction who continues to suffer from depression is at risk for relapsing to drug abuse. For this reason, best practice standards for Drug Courts and other treatment programs require mental illness and addiction to be treated concurrently as opposed to consecutively (Drake et al., 2004; Kushner et al., 2014; Mueser et al., 2003; Osher et al., 2012; Peters, 2008; Steadman et al., 2013). Whenever possible, both disorders should be treated in the same facility by the same professional(s) using an integrated treatment model that focuses on the mutually aggravating effects of the two conditions. The Substance Abuse and Mental Health Services Administration (SAMHSA, 2010) has published therapist toolkits to assist in delivering evidence-based integrated treatments for co-occurring substance-use and mental health disorders.

Participants should also have unhindered access to medical providers qualified to prescribe and monitor response to psychiatric medications (Kushner et al, 2014; Steadman et al., 2013). In one study, Drug Court participants who were prescribed psychiatric medications were seven times more likely to graduate successfully from the program than participants with psychiatric symptoms who did not receive psychiatric medications (Gray & Saum, 2005). Thus, for Drug Courts to deny participants access to psychiatric medication or require them to discontinue legally prescribed psychiatric medication as a condition of entering or graduating from Drug Court is not appropriate [see also Standard I, Target Population, and Standard V, Substance Abuse Treatment]. A participant should only be denied psychiatric medication if the decision is based on expert medical evidence from a qualified physician who has examined the participant and is adequately informed about the facts of the case (Peters & Osher, 2004; Steadman et al., 2013).

F. Trauma-Informed Services

More than one-quarter of Drug Court participants report having been physically or sexually abused in their lifetime or having experienced another serious traumatic event, such as a life-threatening car accident or work-related injury (Cissner et al., 2013; Green & Rempel, 2012). Among female Drug Court participants, studies have found that more than 80% experienced a serious traumatic event in their lifetime, more than half were in need of trauma-related services, and over a third met diagnostic criteria for PTSD (Messina et al., 2012; Powell et al., 2012; Sartor et al., 2012).

Unlike most types of mental illness which are typically noncriminogenic, individuals in the criminal justice system who have PTSD are approximately one and a half times more likely to reoffend than those without PTSD (Sadeh & McNiel, 2015). Moreover, as is true for many forms of mental illness, individuals with PTSD are significantly more likely to drop out or to be discharged prematurely from substance abuse treatment than individuals without PTSD (Mills et al., 2012; Read et al., 2004; Saladin et al., 2014). For these reasons, addressing trauma-related symptoms beginning in the first phase of Drug Court and continuing as necessary throughout participants' enrollment in the program is essential.

Most research on treatment of PTSD and other trauma-related syndromes has been conducted with military veterans or women in gender-specific treatment programs. For persons suffering from a diagnosed PTSD, evidence-based treatments are manualized, standardized, and cognitive-behavioral in orientation (Benish et al., 2008). Effective interventions focus on the following objectives (Benish et al., 2008; Bisson et al., 2007; Bradley et al., 2005; Mills et al., 2012):

- Creating a safe and dependable therapeutic relationship between the participant and therapist
- Helping participants deal with anger, anxiety, and other negative emotions without lashing out or engaging in avoidance behaviors such as substance abuse
- Assisting participants to construct a coherent "narrative" or understanding of the traumatic events that points toward productive actions (For example, many trauma victims believe they were to blame for past traumas or are helpless to prevent future traumas. Helping participants absolve themselves of guilt for past events and learn effective behavioral strategies to avoid future retraumatization is far more productive.)
- Exposing participants, in tolerable dosages, to memories or images of the event in a manner that gradually desensitizes them to associated feelings of panic and anxiety

Web sites providing additional information about evidence-based treatments for PTSD are listed in Appendix D.

In a randomized controlled experiment, female Drug Court participants with trauma histories who received manualized cognitive-behavioral PTSD treatments—Helping Women Recover (Covington, 2008) or Beyond Trauma (Covington, 2003)—in gender-specific groups were more likely to graduate from Drug Court, were less likely to receive a jail sanction in the program, and reported more than twice the reduction in PTSD symptoms than participants with trauma histories who did not receive PTSD treatment (Messina et al., 2012). In another study, female Drug Court participants who received similar interventions—trauma-focused cognitive-behavioral therapy or abuse-focused cognitive-behavioral therapy—reported substantial reductions in substance use and mental health symptoms as well as improvements in housing and employment (Powell et al., 2012). Given the design of these studies, separating the effects of the PTSD treatments from the effects of the gender-specific groups is not possible. Studies have reported superior outcomes when women in the criminal justice system received various types of substance abuse treatment in female-only groups (Grella, 2008; Kissin et al., 2013; Liang & Long, 2013; Morse et al., 2013). Given the current state of knowledge, the best practice is to deliver trauma-related services for women in female-only groups because this combination of services clearly enhances outcomes for these participants.

Not all individuals who experience trauma will develop PTSD or require PTSD treatment, nor can Drug Courts assume that past trauma was the cause of a participant's substance abuse problem or criminal history (Saladin et al., 2014). In some cases, trauma is the result rather than the cause of a participant's substance abuse problem or criminal involvement. Persons who engage in substance abuse or crime often expose themselves repeatedly to the potential for trauma; therefore, treating trauma symptoms without paying equivalent attention to substance abuse and other criminogenic needs is unlikely to produce sustainable improvements.

Although some participants with trauma histories do not require formal PTSD treatment, all staff members, including court personnel and other criminal justice professionals, need to be *trauma-informed* for all participants (Bath, 2008). Staff members should remain cognizant of how their actions may be perceived by persons who have serious problems with trust, are paranoid or unduly suspicious of others' motives, or have been betrayed, sometimes repeatedly, by important persons in their lives. Safety, predictability and reliability are critical for treating such individuals. Several practice recommendations should be borne in mind (Bath, 2008; Covington, 2003; Elliott et al., 2005; Liang & Long, 2013):

- Staff members should strive continually to avoid inadvertently retraumatizing participants. For example, responding angrily to participant infractions, ignoring participants' fears or concerns, maintaining a chaotic or noisy group-counseling environment, or performing urine drug testing in a public or disrespectful manner may reawaken feelings of shame, fear, guilt, or panic in formerly traumatized individuals.
- Staff should remain true to their word, including following policies and procedures as described in the program manual and applying incentives and sanctions as agreed. Too much flexibility, no matter how well-intentioned, may seem unfair and unpredictable to persons who have fallen victim to unexpected dangers in the past.
- Staff should provide clear instructions in advance to participants concerning behaviors that are expected and prohibited in the program. Individuals with trauma histories need to understand the rules and to be prepared for what will occur in the event of an accomplishment or infraction.
- Staff should start and end counseling sessions, court hearings, and other appointments on time, at the agreed-upon location, and according to an agreed-upon structure and format. If participants cannot rely on staff to follow a basic itinerary, relying on those same staff persons for trustworthy support, feedback, and counseling may prove difficult for participants.
- Participants with PTSD or severe trauma-related symptoms, such as panic or dissociation (feeling detached from one's surroundings), may not be suitable candidates for group interventions, especially in the early stages of treatment (Yalom & Leszcz, 2005). Such individuals may need to be treated on an individual basis or in small groups with carefully selected group members who are nonthreatening

and nonpredatory. As was noted earlier, female participants with trauma histories are especially well suited for gender-specific groups (Liang & Long, 2013; Messina et al., 2012).

- Participants with histories of childhood-onset abuse or neglect may be at risk for developing a severe personality disorder such as borderline personality disorder. These individuals may have considerable difficulty trusting others, controlling overwhelming feelings of anger or depression, and containing their impulses. Manualized cognitive-behavioral treatments, such as dialectical behavior therapy (Linehan, 1996), have been shown to improve outcomes in these difficult cases (Dimeff & Koerner, 2007; Linehan et al., 1999). These complicated treatments require specialized training and continuous supervision to help staff deal with uncomfortable and confusing reactions that are commonly engendered in these challenging cases.

G. Criminal Thinking Interventions

As stated earlier, criminal-thinking patterns are observed frequently among Drug Court participants (Jones et al., 2015) and may contribute to program failure (responsivity need) and criminal recidivism (criminogenic need) (Gendreau et al., 1996; Helmond et al., 2015; Knight et al., 2006; Walters, 2003). Some Drug Court participants have considerable difficulty seeing other people's perspectives, recognizing their role in interpersonal conflicts, or anticipating consequences before they act. Moreover, they may hold counterproductive attitudes or values, such as assuming that all people are untrustworthy and motivated to manipulate or dominant others. Given such antisocial sentiments, these participants are often viewed as suspicious or manipulative in character, get into repeated conflicts with others, and fail to learn from negative social interactions.

Several manualized cognitive-behavioral interventions address criminal-thinking patterns among individuals addicted to drugs or charged with crimes. Evidence-based curricula demonstrating improved outcomes in Drug Courts and similar programs include but are not limited to Moral Reconation Therapy (Cheesman & Kunkel, 2012; Heck, 2008; Kirchner & Goodman, 2007), Thinking for a Change (Lowenkamp et al., 2009), and Reasoning & Rehabilitation (Cullen et al., 2012; Tong & Farrington, 2006). Other curricula focused specifically on the needs of men in the criminal justice system, such as Habilitation, Empowerment and Accountability Therapy (Turpin & Wheeler, 2012; Vito & Tewksbury, 1998) and Helping Men Recover (Covington et al., 2011), are undergoing development and effectiveness testing in Drug Courts. Additional information about evidence-based criminal-thinking interventions is provided in Appendix D.

Studies have not determined when delivering criminal-thinking interventions is most beneficial. Clinical experience suggests the most beneficial time to introduce these interventions is after participants are stabilized in treatment and no longer experiencing acutely debilitating symptoms such as cravings, withdrawal, or anhedonia (Milkman & Wanberg, 2007). Until participants are no longer in acute distress, expecting them to benefit from a cognitive-behavioral intervention that requires them to maintain consistent attention and cognitive endurance is unrealistic. Participants should be stabilized clinically before a Drug Court can reasonably expect them to think flexibly about the motivations for their behaviors and the potential ramifications of continuing in their current behavioral patterns.

H. Family and Interpersonal Counseling

Reductions in substance abuse and crime go hand in hand with reduced family conflict, fewer interactions with delinquent relatives and peers, and increased interactions with sober and prosocial individuals (Berg & Huebner, 2011; Fergusson et al., 2002; Knight & Simpson, 1996; Wooditch et al., 2013; Wright & Cullen, 2004). These findings hold true in Drug Courts as they do in most correctional rehabilitation programs (Green & Rempel, 2012; Hickert et al., 2009).

Most studies of family treatments in Drug Courts have been conducted in the context of Family Drug Courts or Juvenile Drug Courts. Results have demonstrated consistently superior outcomes when manualized, cognitive-behavioral family interventions were added to the Drug Court curriculum, including Strengthening Families and Celebrating Families! (Brook et al., 2015) and modified versions of multidimensional family therapy (Dakof et al., 2009, 2010, 2015), multisystemic therapy (Henggeler et al., 2006), and functional family therapy (Datchi & Sexton, 2013). [Further information about these and other

evidence-based family treatments is provided in Appendix D.] Each of these treatments focuses on lessening familial conflict, reducing interactions with drug-using and antisocial peers and relatives, improving communication skills, and enhancing problem-solving skills. In the beginning of treatment, prosocial and drug-free family members, friends, or daily acquaintances are trained by staff to monitor participant behavior reliably, reinforce prosocial activities, respond appropriately and helpfully to problematic behaviors, reduce tension and conflict, and deescalate confrontations. As therapy progresses, treatment focuses on teaching all parties effective communication and problem-solving skills.

Studies have not determined when delivering family or interpersonal counseling in Drug Courts is most beneficial. Given the powerful association between family functioning and criminal justice outcomes, these services should be delivered as soon as practicable. Outcomes in substance abuse treatment are significantly better when at least one reliable and prosocial family member, friend, or close acquaintance is enlisted early in treatment to help the participant arrive on time for appointments and comply with other obligations in the program, such as following a curfew, adhering to prescribed medications, and avoiding forbidden locations like bars (Meyers et al., 1998; Roozen et al., 2010). The same individual may be enlisted to provide helpful observations to staff about the participant's conduct outside of treatment (Kirby et al., 1999). After participants are stabilized clinically, family interventions should focus on improving communication skills, altering maladaptive interactions, reinforcing prosocial behaviors, and reducing interpersonal conflicts.

I. Vocational and Educational Services

Approximately one-half to three-quarters of Drug Court participants have poor work histories or low educational achievement (Cissner et al., 2013; Deschenes et al., 2009; Green & Rempel, 2012; Hickert et al, 2009; Leukefeld et al., 2007). Being unemployed or having less than a high school diploma or general educational development (GED) certificate predicts poor outcomes in Drug Courts (DeVall & Lanier, 2012; Gallagher, 2013b; Gallagher et al., 2015; Mateyoke-Scrivener et al., 2004; Peters et al., 1999; Roll et al., 2005; Shannon et al., 2015) as it does in most other substance abuse treatment (Keefer, 2013) and correctional rehabilitation programs (Berg & Huebner, 2011; Wright & Cullen, 2004).

Unfortunately, few vocational or educational interventions have been successful at reducing crime (Aos et al., 2006; Cook et al., 2014; Farabee et al., 2014; Wilson et al., 2000) or substance abuse (Lidz et al., 2004; Magura et al., 2004; Platt, 1995). Disappointing results have commonly been attributable to poor quality and timing of the interventions. Many vocational programs amount to little more than job-placement services, which alert participants to job openings, place them in a job, or help them conduct a job search. Placing high-risk and high-need individuals in a job is unlikely to be successful if they continue to crave drugs or alcohol, experience serious mental health symptoms, associate with delinquent peers, or respond angrily or impulsively when they are criticized or receive negative feedback from others (Coviello et al., 2004; Lidz et al., 2004; Magura et al., 2004; Platt, 1995; Samenow, 2014). Improvements in education and employment rarely occur until after participants are stabilized clinically, cease interacting with delinquent peers, and learn to deal with frustration in a reasonably effective and mature manner.

At least two studies in Drug Courts have reported improved outcomes when unemployed or underemployed participants received a manualized, cognitive-behavioral vocational intervention. The effective interventions taught participants not only how to find a job, but also how to keep the job by behaving responsibly and dependably and how to land a better or higher-paying job in the future by continually honing their skills and productivity (Deschenes et al., 2009; Leukefeld et al., 2007). Comparable studies in drug abuse treatment reported improved outcomes when participants learned to interact effectively with coworkers and employers and resolve interpersonal conflicts on the job (Platt et al., 1993; Platt, 1995).

Studies have not determined when administering vocational or educational interventions is most beneficial. For high-risk and high-need individuals, these services are best introduced late in the course of Drug Court after participants have secured safe and stable housing, their addiction and mental health symptoms have resolved substantially, they have completed a criminal-thinking intervention, and they are spending most or all of their time interacting with prosocial, sober, and supportive peers (Magura et al., 2004; Platt, 1995). For many high-risk and high-need participants, this preparatory process may require at least six months of

treatment, and twelve months may be needed for individuals with serious substance use disorders or mental illness (Gottfredson et al., 2007; Peters et al., 2002).

J. Medical and Dental Treatment

Approximately one-quarter of Drug Court participants suffer from chronic medical or dental conditions that cause them serious discomfort, require ongoing medical attention, or interfere with their daily functioning (Green & Rempel, 2012). Medical and dental problems are typically maintenance needs, meaning they are most often a result rather than the cause of substance abuse and crime but can interfere with the maintenance of treatment gains. (An obvious exception is participants who become addicted to prescription medications during the course of medical or dental treatment.) Evidence suggests providing medical or dental treatment can improve outcomes for some Drug Court participants (Carey et al., 2012). Moreover, for humanitarian reasons, treating pain or discomfort regardless of the impact on criminal justice outcomes is always important.

No study has determined when addressing medical or dental concerns in Drug Courts is most appropriate. Needless to say, conditions that are life-threatening or may cause long-term disability should be treated immediately. However, waiting until later phases of Drug Court to treat nonessential or nonacute conditions that are exacerbated or maintained by substance abuse may be prudent. Outcomes may be better if medical or dental services are delivered after participants have achieved sobriety and relinquished other antisocial behaviors. For example, participants who abuse methamphetamine often have serious dental problems (American Dental Association, n.d.). If these dental problems are not causing acute distress, it might be appropriate to wait until the participant has stopped using methamphetamine before attempting dental repairs. Continued substance abuse risks undoing dental efforts and may cause a participant to discontinue dental treatment prematurely. A more efficient use of resources may be to address nonessential dental or medical treatment in a late phase of Drug Court or as part of a participant's continuing-care plan so as to maintain and extend the Drug Court's beneficial effects. A logical first step is to refer participants for routine medical and dental checkups to establish relationships with health care providers and begin a long-term process of preventive and routine medical and dental care.

K. Prevention of Health-Risk Behaviors

Alarmingly high percentages of Drug Court participants engage in behaviors which put them at serious risk for contracting human immunodeficiency virus (HIV) and other sexually transmitted diseases (STDs). In some studies, approximately 50% to 85% of Drug Court participants reported engaging in frequent unprotected sex with multiple sex partners (Festinger et al., 2012; Robertson et al., 2012; Tolou-Shams et al., 2012). Drug Court participants were found in one study to lack basic knowledge about simple self-protective measures they can take to reduce their health-risk exposure, such as using condoms and cleaning injection needles (Robertson et al., 2012).

A recent systematic review identified several brief educational interventions that are proven to reduce HIV risk behaviors among drug-addicted persons in the criminal justice system (Underhill et al., 2014). [Additional resources for identifying effective health-risk prevention programs are provided in Appendix D.] Most effective interventions are brief and inexpensive to administer, and some can be delivered via computer or videotape with minimal burden on staff. The criminal justice system is a major vector for the spread of HIV, STDs, and other serious communicable diseases (Belenko et al., 2004; Spaulding et al., 2009). Impacts on crime and substance abuse aside, Drug Courts have a responsibility to reduce the chances that participants will contract a life-threatening or incurable illness, especially in light of the fact that effective interventions can be delivered at minimal cost and burden to the program.

L. Overdose Prevention and Reversal

Unintentional overdose deaths from illicit and prescribed opiates have more than tripled in the past fifteen years (Meyer et al., 2014). Individuals addicted to opiates are at especially high risk for overdose death following release from jail or prison because tolerance to opiates decreases substantially during periods of incarceration (Dolan et al., 2005; Strang, 2015; Strang et al., 2014).

Drug Courts should educate participants, their family members, and close acquaintances about simple precautions they can take to avoid or reverse a life-threatening drug overdose. At a minimum, this should include providing emergency phone numbers and other contact information to use in the event of an overdose or similar medical emergency.

As permitted by law, Drug Courts should also support local efforts to train Drug Court personnel, probation officers, law enforcement, and other persons likely to be first responders to an overdose on the safe and effective administration of overdose-reversal medications such as naloxone hydrochloride (naloxone or Narcan). Naloxone is nonaddictive, nonintoxicating, poses a minimal risk of medical side effects, and can be administered intranasally by nonmedically trained laypersons (Barton et al., 2002; Kim et al., 2009). The Centers for Disease Control and Prevention (2012) estimates that more than 10,000 potentially fatal opiate overdoses have been reversed by naloxone administered by nonmedical laypersons. Studies in the U.S. and Scotland confirm that educating at-risk persons and their significant others about ways to prevent or reverse overdose, including the use of naloxone, significantly reduces overdose deaths (National Institute on Drug Abuse, 2014; Strang, 2015).

State laws vary in terms of who may administer naloxone. Some states shield professional first responders and nonprofessional Good Samaritans from criminal or civil liability if they administer naloxone or render comparable medical aid in the event of a drug overdose (Strang et al., 2006). Other states restrict administration of naloxone to licensed medical providers, trained law enforcement personnel, or other professional first responders.

Some Drug Court professionals may fear this practice could give the unintended message to participants that continued drug use is acceptable or anticipated. On the contrary, educating participants about drug overdose delivers a clear message about the potentially fatal consequences of continued drug abuse. Moreover, drug-abstinent participants may find themselves in the position of needing to save the life of a nonsober family member or acquaintance. Preparing participants to respond effectively in such circumstances delivers the prosocial message that they have a responsibility to help their fellow citizens.

REFERENCES

American Dental Association. (n.d.). Oral health topics: Meth mouth. *Retrieved from* http://www.ada.org/en/member-center/oral-health-topics/meth-mouth

Andrews, D.A., & Bonta, J. (2010). *The psychology of criminal conduct* (5th ed.). New Providence, NJ: Anderson.

Andrews, D.A., Bonta, J., & Wormith, J.S. (2006). The recent past and near future of risk and/or need assessment. *Crime and Delinquency, 52*(1), 7–27.

Andrews, D.A., Zinger, I., Hoge, R.D., Bonta, J., Gendreau, P., & Cullen, F.T. (1990). Does correctional treatment work? A clinically relevant and psychologically informed meta-analysis. *Criminology, 28*(3), 369–404.

Anglin, D.M., Longshore, D., & Turner, S. (1999). Treatment alternatives to street crime: An evaluation of five programs. *Criminal Justice and Behavior, 26*(2), 168–195.

Aos, S., Miller, M., & Drake, E. (2006). *Evidence-based public policy options to reduce future prison construction, criminal justice costs, and crime rates*. Olympia: Washington State Institute for Public Policy.

Barton, E.D., Ramos, J., Colwell, C., Benson, J., Baily, J., & Dunn, W. (2002). Intranasal administration of naloxone by paramedics. *Prehospital Emergency Care, 6*(1), 54–58.

Bath, H. (2008). The three pillars of trauma-informed care. *Reclaiming Children and Youth, 17*(3), 17–21.

Belenko, S., Langley, S., Crimmins, S., & Chaple, M. (2004). HIV risk behaviors, knowledge, and prevention education among offenders under community supervision: A hidden risk group. *AIDS Education and Prevention, 16*(4), 367–385.

Benish, S.G., Imel, Z.E., & Wampold, B.E. (2008). The relative efficacy of bona fide psychotherapies for treating post-traumatic stress disorder: A meta-analysis of direct comparisons. *Clinical Psychology Review, 28*(5), 746–758.

Bennett, T., Holloway, K., & Farrington, D. (2008). The statistical association between drug misuse and crime: A meta-analysis. *Aggression & Violent Behavior, 13*(2), 107–118.

Berg, M.T., & Huebner, B.M. (2011). Reentry and the ties that bind: An examination of social ties, employment, and recidivism. *Justice Quarterly, 28*(2), 382–410.

Bisson, J.I., Ehlers, A., Matthews, R., Pilling, S., Richards, D., & Turner, S. (2007). Psychological treatments for chronic post-traumatic stress disorder: Systematic review and meta-analysis. *British Journal of Psychiatry, 190*, 97–104. doi:10.1192/bjp.bp.106.021402

Bonta, J., Law, M., & Hanson, R.K. (1998). The prediction of criminal and violent recidivism among mentally disordered offenders: A meta-analysis. *Psychological Bulletin, 123*(2), 123–142.

Bradley, R., Greene, J., Russ, E., Dutra, L., & Westen, D. (2005). A multidimensional meta-analysis of psychotherapy for PTSD. *American Journal of Psychiatry, 162*(2), 214–227.

Braude, L. (2005). The Cook County Mental Health Court: Development, implementation, and initial implications. *Offender Substance Abuse Report, 5*(5), 67–76.

Brook, J., Akin, B.A., Lloyd, M.H., & Yan, Y. (2015). Family drug court, targeted parent training and family reunification: Did this enhanced service strategy make a difference? *Juvenile and Family Court Journal, 66*(2), 35–52.

Carey, S.M., Mackin, J.R., & Finigan, M.W. (2012). What works? The ten key components of drug court: Research-based best practices. *Drug Court Review*, *8*(1), 6–42.

Centers for Disease Control and Prevention. (2012). Community-based opioid overdose prevention programs providing naloxone—United States, 2010. *Morbidity and Mortality Weekly Report, 61*(6), 101–105.

Chandler, R.K., Peters, R.H., Field, G., & Juliano-Bult, D. (2004). Challenges in implementing evidence-based treatment practices for co-occurring disorders in the criminal justice system. *Behavioral Sciences & the Law, 22*(4), 431–448.

Cheesman, F.L., & Kunkel, T.L. (2012). *Virginia Adult Drug Treatment Courts: Cost benefit analysis*. Williamsburg, VA: National Center for State Courts.

Cissner, A.B., Rempel, M., Franklin, A.W., Roman, J.K., Bieler, S., Cohen, R., & Cadoret, C.R. (2013). *A statewide evaluation of New York's adult drug courts: Identifying which policies work best*. New York: Center for Court Innovation.

Clark, C.B., McCullumsmith, C.B., Redmond, N., Hardy, S., Waesche, M.C., Osula, G., & Cropsey, K.L. (2013). Factors associated with rapid failure in a Treatment Alternatives for Safer Communities (TASC) program. *Journal of Substance Abuse Treatment, 45*(4), 376–380.

Clark, V.A. (2014, November 12). Predicting two types of recidivism among newly released prisoners: First addresses as "launch pads" for recidivism or reentry success. *Crime & Delinquency: Online.* doi:10.1177/0011128714555760

Cook, F. (2002). Treatment accountability for safer communities: Linking the criminal justice and treatment systems. In C.G. Leukefeld, F. Tims, and D. Farabee (Eds.), *Treatment of drug offenders: Policies and issues* (pp. 105–110). New York: Springer.

Cook, P.J., Kang, S., Braga, A.A., Ludwig, J., & O'Brien, M.E. (2014, December 20). An experimental evaluation of a comprehensive employment-oriented prisoner re-entry program. *Journal of Quantitative Criminology: Online*. doi:10.1007/s10940-014-9242-5

Coviello, D.M., Zanis, D.A., & Lynch., K. (2004). Effectiveness of vocational problem-solving skills on motivation and job-seeking action steps. *Substance Use and Misuse, 39*(13-14), 2309–2324.

Covington, S. (2003). *Beyond trauma: A healing journey for women. Facilitator's guide*. Center City, MN: Hazelden.

Covington, S.S. (2008). *Helping women recover: A program for treating substance abuse—Special edition for use in the criminal justice system* (Facilitator's guide, Rev. ed.). San Francisco: Jossey-Bass.

Covington, S.S., Griffin, D., & Dauer, R. (2011). *A man's workbook: Helping men recover: A program for treating addiction—Special edition for use in the criminal justice system.* San Francisco: Jossey-Bass.

Cresswell, L.S, & Deschenes, E.P. (2001). Minority and non-minority perceptions of drug court program severity and effectiveness. *Journal of Drug Issues, 31*(1), 259–291.

Cullen, A.E., Clarke, A.Y., Kuipers, E., Hodgins, S., Dean, K., & Fahy, T. (2012). A multisite randomized trial of a cognitive skills program for male mentally disordered offenders: Violence and antisocial behavior outcomes. *Journal of Consulting and Clinical Psychology, 80*(6), 1114–1120.

Dakof, G.A., Cohen, J.B., & Duarte, E. (2009). Increasing family reunification for substance-abusing mothers and their children: Comparing two drug court interventions in Miami. *Juvenile and Family Court Journal, 60*(4), 11–23.

Dakof, G.A., Cohen, J.B., Henderson, C.E., Duarte, E., Boustani, M., Blackburn, A.,…Hawes, S. (2010). A randomized pilot study of the Engaging Moms program for family drug court. *Journal of Substance Abuse Treatment, 38*(3), 263–274.

Dakof, G.A., Henderson, C.E., Rowe, C.L., Boustani, M., Greenbaum, P.E., Wang, W.,…Liddle, H.A. (2015). A randomized clinical trial of family therapy in juvenile drug court. *Journal of Family Psychology, 29*(2), 232–241.

Datchi, C.C., & Sexton, T.L. (2013). Can family therapy have an effect on adult criminal conduct? Initial evaluation of functional family therapy. *Couple and Family Psychology: Research and Practice, 2*(4), 278–293.

Deschenes, E.P., Ireland, C., & Kleinpeter, C.B. (2009). Enhancing drug court success. *Journal of Offender Rehabilitation, 48*(1), 19–36.

DeVall, K.E., & Lanier, C.L. (2012). Successful completion: An examination of factors influencing drug court completion for white and non-white male participants. *Substance Use and Misuse, 47*(10), 1106–1116.

Dimeff, L.A., & Koerner, K. (Eds.) (2007). *Dialectical behavior therapy in clinical practice: Applications across disorders and settings*. New York: Guilford Press.

Dolan, K.A., Shearer, J., White, B., Zhou, J., Kaldor, J., & Wodak, A.D. (2005). Four-year follow-up of imprisoned male heroin users and methadone treatment: Mortality, reincarceration and hepatitis C infection. *Addiction, 100*(6), 820–828.

Drake, R.E., Mueser, K.T., Brunette, M.F., & McHugo, G.J. (2004). A review of treatments for people with severe mental illnesses and co-occurring substance use disorders. *Psychiatric Rehabilitation Journal, 27*(4), 360–374.

Drake, R.E., O'Neal, E.L., & Wallach, M.A. (2008). A systematic review of psychosocial research on psychosocial interventions for people with co-occurring severe mental and substance use disorders. *Journal of Substance Abuse Treatment, 34*(1), 123–138.

Elbogen, E.B., & Johnson, S.C. (2009). The intricate link between violence and mental disorder: Results from the National Epidemiologic Survey on Alcohol and Related Conditions. *Archives of General Psychiatry, 66*(2), 152–161.

Elbogen, E.B., Sullivan, C.P., Wolfe, J., Wagner, H.R., & Beckham, J.C. (2013). Homelessness and money mismanagement in Iraq and Afghanistan veterans. *American Journal of Public Health, 103*(S2), S248–S254.

Elliott, D.E., Bjelajac, P., Fallot, R.D., Markoff, L.S., & Reed, B.G. (2005). Trauma-informed or trauma-denied: Principles and implementation of trauma-informed services for women. *Journal of Community Psychology, 33*(4), 461–477.

Farabee, D., Zhang, S.X., & Wright, B. (2014). An experimental evaluation of a nationally recognized employment-focused offender reentry program. *Journal of Experimental Criminology, 10*(3), 309–322.

Fergusson, D.M., Swain-Campbell, N.R., & Horwood, L.J. (2002). Deviant peer affiliations, crime and substance abuse: A fixed effects regression analysis. *Journal of Abnormal Child Psychology, 30*(4), 419–430.

Festinger, D.S., Dugosh, K.L., Metzger, D.S., & Marlowe, D.B. (2012). The prevalence of HIV risk behaviors among felony drug court participants. *Drug Court Review, 8*(1), 131–146.

Frescoln, K.P. (2014). *Engaging with the Affordable Care Act: Implications and recommendations for adult drug court professionals*. Alexandria, VA: National Association of Drug Court Professionals.

Gallagher, J.R. (2013a). African American participants' views on racial disparities in drug court outcomes. *Journal of Social Work Practice in the Addictions, 13*(2), 143–162.

Gallagher, J.R. (2013b). Drug court graduation rates: Implications for policy advocacy and future research. *Alcoholism Treatment Quarterly, 31*(2), 241–253.

Gallagher, J.R., Nordberg, A., Deranek, M.S., Ivory, E., Carlton, J., & Miller, J.W. (2015). Predicting termination from drug court and comparing recidivism patterns: Treating substance use disorders in criminal justice settings. *Alcoholism Treatment Quarterly, 33*(1), 28–43.

Gendreau, P., Little, T., & Goggin, C. (1996). A meta-analysis of the predictors of adult offender recidivism: What works! *Criminology, 34*(4), 575–608.

Gottfredson, D.C., Kearley, B.W., Najaka, S.S., & Rocha, C.M. (2007). How Drug Treatment Courts work: An analysis of mediators. *Journal of Research on Crime & Delinquency, 44*(1), 3–35.

Gray, A.R., & Saum, C.A. (2005). Mental health, gender and drug court completion. *American Journal of Criminal Justice, 30*(1), 55–69.

Green, M., & Rempel, M. (2012). Beyond crime and drug use: Do adult drug courts produce other psychosocial benefits? *Journal of Drug Issues, 42*(2), 156–177.

Greiner, L.E., Law, M.A., & Brown, S.L. (2015). Using dynamic factors to predict recidivism among women: A four-wave prospective study. *Criminal Justice and Behavior, 42*(5), 457–480.

Grella, C. (2008). Gender-responsive drug treatment services for women: A summary of current research and recommendations for drug court programs. In C. Hardin & J.N. Kushner (Eds.), *Quality improvement for drug courts: Evidence-based practices* (Monograph Series no. 9, pp. 63–74). Alexandria, VA: National Drug Court Institute.

Guastaferro, W.P. (2012). Using the Level of Service Inventory-Revised to improve assessment and treatment in drug court. *International Journal of Offender Therapy and Comparative Criminology, 56*(5), 769–789.

Gutierrez, L., & Bourgon, G. (2012). Drug treatment courts: A quantitative review of study and treatment quality. *Justice Research and Policy, 14*(2), 47–77.

Heck, C. (2008). MRT: Critical component of a local drug court program. *Cognitive Behavioral Treatment Review, 17(1)*, 1–2.

Helmond, P., Overbeek, G., Brugman, D., & Gibbs, J.C. (2015). A meta-analysis on cognitive distortions and externalizing problem behavior: Associations, moderators, and treatment effectiveness. *Criminal Justice and Behavior, 42*(3), 245–262.

Henggeler, S.W., Halliday-Boykins, C.A., Cunningham, P.B., Randall, J., Shapiro, S.B., & Chapman, J.E. (2006). Juvenile drug court: Enhancing outcomes by integrating evidence-based treatments. *Journal of Consulting and Clinical Psychology, 74*(1), 42–54.

Hesse, M., Vanderplasschen, W., Rapp, R., Broekaert, E., & Fridell, M. (2007). Case management for persons with substance use disorders. *Cochrane Database of Systematic Reviews, 4*, CD006265.

Hickert, A.O., Boyle, S.W., & Tollefson, D.R. (2009). Factors that predict drug court completion and drop out: Findings from an evaluation of Salt Lake County's adult felony drug court. *Journal of Social Service Research, 35*(2), 149–162.

Hubbard, D.J., & Pealer, J. (2009). The importance of responsivity factors in predicting reductions in antisocial attitudes and cognitive distortions among adult male offenders. *Prison Journal, 89*(1), 79–98.

Johnson, J.E., O'Leary, C.C., Striley, C.W., Abdallah, A.B., Bradford, S., & Cottler, L.B. (2011). Effects of major depression on crack use and arrests among women in drug court. *Addiction, 106*(7), 1279–1286.

Jones, C.G., Fearnley, H., Panagiotopoulos, B., & Kemp, R.I. (2015, June 18). Delay discounting, self-control, and substance use among adult drug court participants. *Behavioural Pharmacology: Online.*

Karno, M.P., & Longabaugh, R. (2007). Does matching matter? Examining matches and mismatches between patient attributes and therapy techniques in alcoholism treatment. *Addiction, 102*(4), 587–596.

Keefer, Q.A.W. (2013). Employment type and length of stay in substance abuse treatment: Economic factors and gender specific effects. *International Journal of Social Science Studies, 1*(2), 219–229.

Kilmer, B., & Sussell, J. (2014). *Does San Francisco's Community Justice Center reduce criminal recidivism?* Santa Monica, CA: RAND Corp. & Superior Court of California, County of San Francisco.

Kim, D., Irwin, K.S., & Khoshnood, K. (2009). Expanded access to naloxone: Options for critical response to the epidemic of opioid overdose mortality. *American Journal of Public Health, 99*(3), 402–407.

Kirby, K.C., Marlowe, D.B., Festinger, D.S., & LaMonaca, V. (1999). Community reinforcement training for family and significant others of drug abusers: A unilateral intervention to increase treatment entry of drug users. *Drug and Alcohol Dependence, 56*(1), 85–96.

Kirchner, R.A., & Goodman, E. (2007). Effectiveness and impact of Thurston County, Washington drug court program. *Cognitive Behavioral Treatment Review, 16(2)*, 1–4.

Kissin, W.B., Tang, Z., Campbell, K.M., Claus, R.E., & Orwin, R.G. (2014). Gender-sensitive substance abuse treatment and arrest outcomes for women. *Journal of Substance Abuse Treatment, 46*(3), 332–339.

Knight, D.K., & Simpson, D.D. (1996). Influences of family and friends on client progress during drug abuse treatment. *Journal of Substance Abuse, 8*(4), 417–429.

Knight, K., Garner, B.R., Simpson, D.D., Morey, J.T., & Flynn, P.M. (2006). An assessment for criminal thinking. *Crime and Delinquency, 52*(1), 159–177.

Kushner, J.N., Peters, R.H., & Cooper, C.S. (2014). *A technical assistance guide for drug court judges on drug court treatment services*. Washington, DC: American University.

Lee, C.G., Cheesman, F.L., Rottman, D.B., Swaner, R., Lambson, S., Rempel, M., & Curtis, R. (2013). *A community court grows in Brooklyn: A comprehensive evaluation of the Red Hook Community Justice Center, Final Report*. Williamsburg, VA: National Center for State Courts.

Leukefeld, C., Webster, J.M., Staton-Tindall, M., & Duvall, J. (2007). Employment and work among drug court clients: 12-month outcomes. *Substance Use & Misuse, 42*(7), 1109–1126.

Liang, B., & Long, M.A. (2013). Testing the gender effect in drug and alcohol treatment: Women's participation in Tulsa County drug and DUI programs. *Journal of Drug Issues, 43*(3), 270–288.

Lidz, V., Sorrentino, D.M., Robison, L., & Bunce, S. (2004). Learning from disappointing outcomes: An evaluation of prevocational interventions for methadone maintenance patients. *Substance Abuse & Misuse, 39*(13–14), 2287–2308.

Linehan, M.M. (1996). Dialectical behavior therapy for borderline personality disorder. In B. Schmitz (Ed.), *Treatment of personality disorders* (pp. 179–199). Munich, Germany: Psychologie Verlags Union.

Linehan, M.M., Schmidt, H., Dimeff, L.A., Craft, J.C., Kanter, J., & Comtois, K.A. (1999). Dialectical behavior therapy for clients with borderline personality disorder and drug-dependence. *American Journal of Addiction, 8*(4), 279–292.

Lowenkamp, C.T., Hubbard, D., Makarios, M.D., & Latessa, E.J. (2009). A quasi-experimental evaluation of Thinking for a Change: A "real-world" application. *Criminal Justice & Behavior, 36*(2), 137–146.

Lowenkamp, C.T., Pealer, J., Smith, P., & Latessa, E.J. (2006). Adhering to the risk and need principles: Does it matter for supervision-based programs*? Federal Probation, 70*(3), 3–8.

Lutze, F.E., Rosky, J.W., & Hamilton, Z.K. (2014). Homelessness and reentry: A multisite outcome evaluation of Washington State's Reentry Housing Program for high risk offenders. *Criminal Justice and Behavior, 41*(4), 471–491.

Magura, S., Staines, G.L., Blankertz, L., & Madison, E.M. (2004). The effectiveness of vocational services for substance users in treatment. *Substance Use & Misuse, 39*(13-14), 2165–2213.

Manchak, S.M., Sullivan, C.C., Schweitzer, M., & Sullivan, C.J. (2014). The influence of co-occurring mental health and substance use problems on the effectiveness of juvenile drug courts. *Criminal Justice Policy Review*.

Marlowe, D.B., & Wong, C.J. (2008). Contingency management in adult criminal drug courts. In S.T. Higgins, K. Silverman, & S.H. Heil (Eds.), *Contingency management in substance abuse treatment* (pp. 334–354). New York: Guilford Press.

Mateyoke-Scrivner, A., Webster, J.M., Staton, M., & Leukefeld, C. (2004). Treatment retention predictors of drug court participants in a rural state. *American Journal of Drug and Alcohol Abuse, 30*(3), 605–625.

McLellan, A.T., Hagan, T.A., Levine, M., Gould, F., Meyers, K., Bencivengo, M., & Durell, J. (1998). Supplemental social services improve outcomes in public addiction treatment. *Addiction, 93*(10), 1489–1499.

McLellan, A.T., Hagan, T.A., Levine, M., Meyers, K., Gould, F., Bencivengo, M.,…Jaffe, J. (1999). Does clinical case management improve outpatient addiction treatment. *Drug and Alcohol Dependence, 55*(1–2), 91–103.

Mendoza, N.S., Trinidad, J.R., Nochajski, T.H., & Farrell, M.C. (2013). Symptoms of depression and successful drug court completion. *Community Mental Health Journal, 49*(6), 787–792.

Messina, N., Calhoun, S., & Warda, U. (2012). Gender-responsive drug court treatment: A randomized controlled trial. *Criminal Justice and Behavior, 39*(12), 1539–1558.

Meyer, R., Patel, A.M., Rattana, S.K., Quock, T.P., & Mody, S.H. (2014). Prescription opioid abuse: A literature review of the clinical and economic burden in the United States. *Population Health Management, 17*(6), 372–387.

Meyers, R.J., Miller, W.R., Hill, D.E., & Tonigan, J.S. (1998). Community reinforcement and family training (CRAFT): Engaging unmotivated drug users in treatment. *Journal of Substance Abuse, 10*(3), 291–308.

Milkman, H., & Wanberg, K. (2007). Cognitive-behavioral treatment: A review and discussion for corrections professionals. Washington, DC: National Institute of Corrections.

Mills, K.L., Teesson, M., Back, S.E., Brady, K.T., Baker, A.L., Hopwood, S.,…Ewer, P.L. (2012). Integrated exposure-based therapy for co-occurring posttraumatic stress disorder and substance dependence: A randomized controlled trial. *Journal of the American Medical Association, 308*(7), 690–699.

Monchick, R., Scheyett, A., & Pfeiffer, J. (2006). *Drug court case management: Role, function, and utility* (Monograph Series no. 7). Alexandria, VA: National Drug Court Institute.

Morse, D.S., Cerulli, C., Bedell, P., Wilson, J.L., Thomas, K., Mittal, M.,…Chin, N. (2014). Meeting health and psychological needs of women in drug treatment court. *Journal of Substance Abuse Treatment, 46*(2), 150–157.

Morse, D.S., Silverstein, J., Thomas, K., Bedell, P., & Cerulli, C. (2015). Finding the loopholes: A cross-sectional qualitative study of systemic barriers to treatment access for women drug court participants. *Health and Justice, 3*(12). doi:10.1186/s40352-015-0026-2

Mueser, K.T., Noordsy, D.L., Drake, R.E., & Fox, L. (2003). *Integrated treatment for dual disorders: A guide to effective practice*. New York: Guilford Press.

National Institute on Drug Abuse (2014). Nora's Blog: Naloxone—A potential lifesaver. *Retrieved from* http://www.drugabuse.gov/about-nida/noras-blog/2014/02/naloxone-potential-lifesaver

Osher, F., D'Amora, D.A., Plotkin, M., Jarrett, N., & Eggleston, A. (2012). *Adults with behavioral health needs under correctional supervision: A shared framework for reducing recidivism and promoting recovery*. New York: Council of State Governments Justice Center.

Peters, R.H., Haas, A.L., & Hunt, W.M. (2002). Treatment "dosage" effects in drug court programs. *Journal of Offender Rehabilitation, 33*(4), 63–72.

Peters, R.H. (2008). Co-occurring disorders. In C. Hardin & J.N. Kushner (Eds.), *Quality improvement for drug courts: Evidence-based practices* (Monograph Series no. 9, pp. 51–61). Alexandria, VA: National Drug Court Institute.

Peters, R.H., Haas, A.L., & Murrin, M.R. (1999). Predictors of retention and arrest in drug courts. *National Drug Court Institute Review, 2*(1), 33–60.

Peters, R.H., Kremling, J., Bekman, N.M., & Caudy, M.S. (2012). Co-occurring disorders in treatment-based courts: Results of a national survey. *Behavioral Sciences and the Law, 30*(6), 800–820.

Peters, R.H., & Osher, F.C. (2004). *Co-occurring disorders and specialty courts* (2nd ed.). Delmar, NY: National GAINS Center.

Peters, R.H., Wexler, H.K., & Lurigio, A.J. (2015). Co-occurring substance use and mental disorders in the criminal justice system: A new frontier of clinical practice and research. *Psychiatric Rehabilitation Journal, 38*(1), 1–6.

Peterson, J.K., Skeem, J., Kennealy, P., Bray, B. & Zvonkovic, A. (2014). How often and how consistently do symptoms directly precede criminal behavior among offenders with mental illness? *Law and Human Behavior, 38*(5), 439–449.

Phillips, H.K., Gray, N.S., MacCulloch, S.I., Taylor, J., Moore, S.C., Huckle, P., & MacCulloch, M.J. (2005). Risk assessment in offenders with mental disorders: Relative efficacy of personal demographic, criminal history, and clinical variables. *Journal of Interpersonal Violence, 20*(7), 833–847.

Platt, J.J. (1995). Vocational rehabilitation of drug abusers. *Psychological Bulletin, 117*(3), 416–433.

Platt, J.J., Husband, S.D., Hermalin, J., Cater, J., & Metzger, D. (1993). A cognitive problem-solving employment readiness intervention for methadone clients. *Journal of Cognitive Psychotherapy, 7*(1), 21–33.

Powell, C., Stevens, S., Dolce, B.L., Sinclair, K.O., & Swenson-Smith, C. (2012). Outcomes of a trauma-informed Arizona family drug court. *Journal of Social Work Practice in the Addictions, 12*(3), 219–241.

Prendergast, M.L., Pearson, F.S., Podus, D., Hamilton, Z.K., & Greenwell, L. (2013). The Andrews' principles of risk, needs, and responsivity as applied in drug treatment programs: Meta-analysis of crime and drug use outcomes. *Journal of Experimental Criminology, 9*(3), 275–300.

Prins, S.J., Skeem, J.L., Mauro, C., & Link, B.G. (2015). Criminogenic factors, psychotic symptoms, and incident arrests among people with serious mental illnesses under intensive outpatient treatment. *Law and Human Behavior, 39*(2), 177–188.

Quirouette, M., Hannah-Moffat, K., & Maurutto, P. (2015). 'A precarious place': Housing and clients of specialized courts. *British Journal of Criminology.* doi:10.1093/bjc/azv050

Rapp, R.C., Van Den Noortgate, W., Broekaert, E., & Vanderplasschen, W. (2014). The efficacy of case management with persons who have substance abuse problems: A three-level meta-analysis of outcomes. *Journal of Consulting and Clinical Psychology, 82*(4), 605–618.

Read, J.P., Brown, P.J., & Kahler, C.W. (2004). Substance use and posttraumatic stress disorders: Symptom interplay and effects on outcome. *Addictive Behaviors, 29*(8), 1665–1672.

Rezansoff, S.N., Moniruzzaman, A., Gress, C., & Somers, J.M. (2013). Psychiatric diagnoses and multiyear criminal recidivism in a Canadian provincial offender population. *Psychology, Public Policy, and Law, 19*(4), 443–453.

Ritsher, J.B., McKellar, J.D., Finney, J.W., Otilingam, P.G., & Moos, R.H. (2002). Psychiatric comorbidity, continuing care, and mutual help as predictors of five-year remission from substance use disorders. *Journal of Studies on Alcohol and Drugs, 63*(6), 709–715.

Robertson, A.A., St. Lawrence, J.S., & McCluskey, D.L. (2012). HIV/STI risk behavior of drug court participants. *Journal of Offender Rehabilitation, 51*(7), 453–473.

Rodriguez, P.F. (2011). Case management for substance abusing offenders. In C. Leukefeld, T.P. Gullotta & J. Gregrich (Eds.), *Handbook of evidence-based substance abuse treatment in criminal justice settings* (pp. 173–181). New York: Springer.

Roll, J.M., Prendergast, M., Richardson, K., Burdon, W., & Ramirez, A. (2005). Identifying predictors of treatment outcome in a drug court program. *American Journal of Drug and Alcohol Abuse, 31*(4), 641–656.

Roozen, H.G., De Waart, R., Van Der Kroft, P. (2010). Community reinforcement and family training: An effective option to engage treatment-resistant substance-abusing individuals in treatment. *Addiction, 105*(10), 1729–1738.

Ross, S. (2008). The mentally ill substance abuser. In M. Galanter & H.D. Kleber (Eds.), *Textbook of substance abuse treatment* (4th ed.) (pp. 537–554). Arlington, VA: American Psychiatric Publishing.

Sadeh, N., & McNiel, D.E. (2015). Posttraumatic stress disorder increases risk of criminal recidivism among justice-involved persons with mental disorders. *Criminal Justice and Behavior, 42*(6), 573–586.

Saladin, M.E., Back, S.E., Payne, R.A., Schumm, J., Goldsmith, R.J., & Chard, K.M. (2014). Posttraumatic stress disorder and substance use disorder comorbidity. In R.K. Ries, D.A. Fiellin, S.C. Miller & R. Saitz, *The ASAM principles of addiction medicine* (5th ed., pp. 1403–1417). Philadelphia: Wolters Kluwer.

Samenow, S. (2014). *Inside the criminal mind* (Rev. & upd. ed.). New York: Broadway Books.

Sartor, C.E., McCutcheon, V.V., O'Leary, C.C., Van Buren, D.J., Allsworth, J.E., Jeffe, D.B., & Cottler, L.B. (2012). Lifetime trauma exposure and posttraumatic stress disorder in women sentenced to drug court. *Psychiatry Research, 200*(2), 602–608.

Schaeffer, C.M., Henggeler, S.W., Chapman, J.E., Halliday-Boykins, C.A., Cunningham, P.B., Randall, J., & Shapiro, S.B. (2010). Mechanisms of effectiveness in juvenile drug court: Altering risk processes associated with delinquency and substance abuse. *Drug Court Review, 7*(1), 57–94.

Seligman, M.E.P. (1975). *Helplessness: On depression, development, and death*. New York: W.H. Freeman.

Serin, R.C., Lloyd, C.D., Helmus, L., Derkzen, D.M., & Luong, D. (2013). Does intra-individual change predict offender recidivism? Searching for the Holy Grail in assessing offender change. *Aggression and Violent Behavior, 18*(1), 32–53.

Shaffer, D.K. (2006). Reconsidering drug court effectiveness: A meta-analytic review (Doctoral dissertation, University of Cincinnati). Retrieved from https://etd.ohiolink.edu/ap:10:0::NO:10:P10_ACCESSION_NUM:ucin1152549096

Shannon, L.M., Jackson, A., Newell, J., Perkins, E., & Neal, C. (2015). Examining factors associated with treatment completion in a community-based program for individuals with criminal justice involvement. *Addiction Science and Clinical Practice, 10*(Supp. 1), A60.

Smith, P., Gendreau, P., & Swartz, K. (2009). Validating the principles of effective intervention: A systematic review of the contributions of meta-analysis in the field of corrections. *Victims & Offenders, 4*(2), 148–169.

Somers, J.M., Moniruzzaman, A., Rezansoff, S.N., & Patterson, M. (2014). Examining the impact of case management in Vancouver's Downtown Community Court: A quasi-experimental design. *PLoS One, 9*(3), e90708. doi:10.1371/journal.pone.0090708

Spaulding, A.C., Seals, R.M., Page, M.J., Brzozowski, A.K., Rhodes, W., & Hammet, T.M. (2009). HIV/AIDS among inmates of and releasees from US correctional facilities, 2006: Declining share of epidemic but persistent public health opportunity. *PLoS One, 4*(11), e7558. doi:10.1371/journal.pone.0007558

Steadman, H.J., Peters, R.H., Carpenter, C., Mueser, K.T., Jaeger, N.D., Gordon, R.B.,…Hardin, C. (2013). Six steps to improve your drug court outcomes for adults with co-occurring disorders. *NDCI Drug Court Practitioner Fact Sheet, 8*(1), 1–27.

Strang, J. (2015). Death matters: Understanding heroin/opiate overdose risk and testing potential to prevent deaths. *Addiction, 110*(S2), 27–35.

Strang, J., Bird, S.M., Dietze, P., Gerra, G., & McLellan, A.T. (2014). Take-home emergency naloxone to prevent deaths from heroin overdose. *British Medical Journal, 349*, g6580. doi:10.1136/bmj.g6580

Strang, J., Kelleher, M., Best, D., Mayet, S., & Manning, V. (2006). Emergency naloxone for heroin overdose: Should it be available over the counter? *British Medical Journal, 333*(7569), 614–615.

Substance Abuse and Mental Health Services Administration. (2010). *Integrated treatment for co-occurring disorders: Evidence-based practices (EBT) KIT*. Rockville, MD: Author. *Available at* http://store.samhsa.gov/product/SMA08-4367

Tolou-Shams, M., Houck, C.D., Nugent, N., Conrad, S.M., Reyes, A., & Brown, L.K. (2012). Alcohol use and HIV risk among juvenile drug court offenders. *Journal of Social Work Practice in the Addictions, 12*(2), 178–188.

Tong, L.S.J., & Farrington, D.P. (2006). How effective is the "Reasoning and Rehabilitation" programme in reducing reoffending? A meta-analysis of evaluations in four countries. *Psychology, Crime & Law, 12*(1), 3–24.

Turpin, D., & Wheeler, G. (2012). *HEAT: Habilitation, Empowerment, Accountability Therapy*. Louisville, KY: Pinwheel Group.

Underhill, K., Dumont, D., & Operario, D. (2014). HIV prevention for adults with criminal justice involvement: A systematic review of HIV risk-reduction interventions in incarceration and community settings. *American Journal of Public Health,* 104(11), e27–e53. doi:10.2105/AJPH.2014.302152

Ventura, A.L., & Lambert, E.G. (2004). Recidivism 12 months after TASC. *Journal of Offender Rehabilitation, 39*(1), 63–82.

Vieira, T.A., Skilling, T.A., & Peterson-Badali, M. (2009). Matching court-ordered services with treatment needs: Predicting treatment success with young offenders. *Criminal Justice and Behavior, 36*(4), 385–401.

Viglione, J., Rudes, D.S, & Taxman, F.S. (2015). Misalignment in supervision: Implementing risk/needs assessment instruments in probation. *Criminal Justice and Behavior, 42*(3), 263–285.

Vito, G.F., & Tewksbury, R.A. (1998). The impact of treatment: The Jefferson County (Kentucky) drug court program. *Federal Probation, 62*(2), 46–51.

Vose, B., Smith, P., & Cullen, F.T. (2013). Predictive validity and the impact of change in total LSI-R score on recidivism. *Criminal Justice and Behavior, 40*(12), 1383–1396.

Walters G.D. (2003). Predicting institutional adjustment and recidivism with the Psychopathy Checklist factor scores: A meta-analysis. *Law and Human Behavior, 27*(5), 541–558.

Walters, G.D. (2015). Recidivism and the "worst of both worlds" hypothesis: Do substance misuse and crime interact or accumulate? *Criminal Justice and Behavior, 42*(4), 435–451.

Wilson, D.B., Gallagher, C.A., & MacKenzie, D.L. (2000). A meta-analysis of corrections-based education, vocation, and work programs for adult offenders. *Journal of Research in Crime and Delinquency, 37*(4), 347–368.

Winn, J.L., Shealy, S.E., Kropp, G.J., Felkins-Dohm, D., Gonzales-Nolas, C., & Francis, E. (2013). Housing assistance and case management: Improving access to substance use disorder treatment for homeless veterans. *Psychological Services, 10*(2), 233–240.

Wooditch, A., Tang, L.L., & Taxman, F.S. (2014). Which criminogenic need changes are most important in promoting desistance from crime and substance use? *Criminal Justice and Behavior, 41*(3), 276–299.

Wright, J.P., & Cullen, F.T. (2004). Employment, peers, and life-course transitions. *Justice Quarterly, 21*(1), 183–205.

Yalom, I.D., & Leszcz, M. (2005). *The theory and practice of group psychotherapy* (5th ed.). New York: Basic Books.

Young, D., & Belenko, S. (2002). Program retention and perceived coercion in three models of mandatory drug treatment. *Journal of Drug Issues, 32*(1), 297–328.

Zweig, J.M., Lindquist, C., Downey, P.M., Roman, J.K., & Rossman, S.B. (2012). Drug Court policies and practices: How program implementation affects offender substance use and criminal behavior outcomes. *Drug Court Review, 8*(1), 43–79

VII. DRUG AND ALCOHOL TESTING

Drug and alcohol testing provides an accurate, timely, and comprehensive assessment of unauthorized[3] substance use throughout participants' enrollment in the Drug Court.

A. Frequent Testing
B. Random Testing
C. Duration of Testing
D. Breadth of Testing
E. Witnessed Collection
F. Valid Specimens
G. Accurate and Reliable Testing Procedures
H. Rapid Results
I. Participant Contract

A. Frequent Testing

Drug and alcohol testing is performed frequently enough to ensure substance use is detected quickly and reliably. Urine testing is performed at least twice per week until participants are in the last phase of the program and preparing for graduation. Tests that measure substance use over extended periods of time, such as ankle monitors, are applied for at least ninety consecutive days followed by urine or other intermittent testing methods. Tests that have short detection windows, such as breathalyzers or oral fluid tests, are administered when recent substance use is suspected or when substance use is more likely to occur, such as during weekends or holidays.

B. Random Testing

The schedule of drug and alcohol testing is random and unpredictable. The probability of being tested on weekends and holidays is the same as on other days. Participants are required to deliver a test specimen as soon as practicable after being notified that a test has been scheduled. Urine specimens are delivered no more than eight hours after being notified that a urine test has been scheduled. For tests with short detection windows, such as oral fluid tests, specimens are delivered no more than four hours after being notified that a test was scheduled.

C. Duration of Testing

Drug and alcohol testing continues uninterrupted to determine whether relapse occurs as other treatment and supervision services are adjusted.

[3] Unauthorized substances include alcohol, illicit drugs, and addictive or intoxicating prescription medications that are taken without prior approval from the Drug Court and not during a medical emergency.

D. Breadth of Testing

Test specimens are examined for all unauthorized substances of abuse that are suspected to be used by Drug Court participants. Randomly selected specimens are tested periodically for a broader range of substances to detect new substances of abuse that might be emerging in the Drug Court population.

E. Witnessed Collection

Collection of test specimens is witnessed directly by a staff person who has been trained to prevent tampering and substitution of fraudulent specimens. Barring exigent circumstances, participants are not permitted to undergo independent drug or alcohol testing in lieu of being tested by trained personnel assigned to or authorized by the Drug Court.

F. Valid Specimens

Test specimens are examined routinely for evidence of dilution and adulteration.

G. Accurate and Reliable Testing Procedures

The Drug Court uses scientifically valid and reliable testing procedures and establishes a chain of custody for each specimen. If a participant denies substance use in response to a positive screening test, a portion of the same specimen is subjected to confirmatory analysis using an instrumented test, such as gas chromatography/mass spectrometry (GC/MS) or liquid chromatography/mass spectrometry (LC/MS). Barring staff expertise in toxicology, pharmacology, or a related discipline, drug or metabolite concentrations falling below industry- or manufacturer-recommended cutoff levels are not interpreted as evidence of new substance use or changes in participants' substance use patterns.

H. Rapid Results

Test results, including the results of confirmation testing, are available to the Drug Court within forty-eight hours of sample collection.

I. Participant Contract

Upon entering the Drug Court, participants receive a clear and comprehensive explanation of their rights and responsibilities related to drug and alcohol testing. This information is described in a participant contract or handbook and reviewed periodically with participants to ensure they remain cognizant of their obligations.

COMMENTARY

Certainty is one of the most influential factors for success in a behavior modification program (Harrell & Roman, 2001; Marlowe & Kirby, 1999). Outcomes improve significantly when detection of substance use is likely (Kilmer et al., 2012; Marques et al., 2014; Schuler et al., 2014), and participants receive incentives for abstinence and sanctions or treatment adjustments for positive test results (Hawken & Kleiman, 2009; Marlowe et al., 2005). Therefore, the success of any Drug Court will depend, in part, on the reliable monitoring of substance use. If a Drug

Court does not have accurate and timely information about whether participants are maintaining abstinence from alcohol and other drugs, the team has no way to apply incentives or sanctions correctly or to adjust treatment and supervision services accordingly. Drug and alcohol testing also serves other important therapeutic aims, such as helping to confirm clinicians' diagnostic impressions, providing objective feedback to participants about their progress or lack thereof in treatment, and assisting clinicians to challenge and resolve participant denial about the severity of their problems (American Society of Addiction Medicine (ASAM), 2010, 2013; DuPont & Selavka, 2008; DuPont et al., 2014; Srebnik et al., 2014).

Participants cannot be relied upon to self-disclose substance use accurately (Hunt et al., 2015). Studies consistently find that between 25% and 75% of participants in substance abuse treatment deny recent substance use when biological testing reveals a positive result (Auerbach, 2007; Harris et al., 2008; Hindin et al., 1994; Magura & Kang, 1997; Morral et al., 2000; Peters et al., 2015; Tassiopoulos et al., 2004). The accuracy of self-reporting is particularly low among individuals involved in the criminal justice system, presumably because they are likely to receive sanctions for substance use (Harrison, 1997; Peters et al., 2015). Although some clinicians may assume that the accuracy of self-report increases during the course of treatment, contrary evidence suggests participants may be *less* likely to acknowledge substance use after they have been enrolled in treatment for a period of time or have completed treatment (Wish et al., 1997). The longer participants are in treatment, the more staff come to expect and insist upon abstinence. For this reason, participants find it increasingly difficult to admit to substance abuse after they have been enrolled in treatment for several months (Davis et al., 2014; Nirenberg et al., 2013).

Best practices for conducting drug and alcohol testing vary considerably depending on whether a test is administered intermittently as opposed to continually, the length of the test's detection window, and the range of substances the test is capable of detecting. Some tests, such as urine or oral fluid tests, must be administered repeatedly, whereas others, such as sweat patches or ankle monitors, can measure substance use over extended periods of time. Most drug metabolites are detectable in urine for approximately two to four days, but are detectable in oral fluid for an average of twenty-four hours and in breath or blood for less than twelve hours (Auerbach, 2007; Cary, 2011; DuPont et al., 2014). Some tests, such as breathalyzers, can only assess for alcohol use, whereas urine tests can assess for a wide range of substances. These factors influence how the tests must be used to obtain useful results.

Urine testing is, by far, the most common methodology used in Drug Courts and probation programs. This is because urine is typically available in copious amounts, is relatively simple to collect, does not require elaborate sample preparation procedures, is inexpensive to analyze, and can be examined for many substances (Cary, 2011). Most studies, to date, have examined best practices for conducting urine testing with offenders; however, recent studies have begun to examine other testing methods in Drug Courts, including sweat patches and ankle monitors.

A. Frequent Testing

The more frequently Drug Courts and probation programs perform urine drug testing, the better their outcomes in terms of higher graduation rates and lower drug use and criminal recidivism (Banks & Gottfredson, 2003; Gottfredson et al., 2007; Griffith et al., 2000; Harrell et al., 1998; Hawken & Kleiman, 2009; Kinlock et al., 2013; National Institute on Drug Abuse, 2006). In focus groups, Drug Court participants consistently identified frequent drug and alcohol testing as being among the most influential factors for success in the program (Gallagher et al., 2015; Goldkamp et al., 2002; Saum et al., 2002; Turner et al., 1999; Wolfer, 2006).

The most effective Drug Courts perform urine drug testing at least twice per week for the first several months of the program (Carey et al., 2008). In a multisite study of approximately seventy Drug Courts, programs performing urine testing at least twice per week in the first phase produced 38% greater reductions in crime and were 61% more cost-effective than programs performing urine testing less frequently (Carey et al., 2012). Because the metabolites of most drugs of abuse are detectable in urine for approximately two to four days, testing less frequently leaves an unacceptable time gap during which participants can abuse substances and evade detection, thus leading to significantly poorer outcomes (Stitzer & Kellogg, 2008).

Recent studies have examined the impact of other testing methods in Drug Courts. The Secure Continuous Remote Alcohol Monitor (SCRAM) is an ankle device that can detect alcohol in sweat and transmits a wireless signal to a remote monitoring station. Preliminary evidence suggests the use of a SCRAM may

deter alcohol consumption and alcohol-impaired driving among recidivist driving-while-impaired (DWI) offenders if it is worn for at least ninety consecutive days (Flango & Cheesman, 2009; Tison et al., 2015). Another study found that adding sweat patches to urine testing did not improve outcomes in a Drug Court (Kleinpeter et al., 2010). However, that study did not examine the influence of sweat patches alone or as compared against urine testing. The study merely found that the addition of sweat patches did not improve outcomes beyond what was already being achieved from frequent urine drug testing.

Ethyl glucuronide (EtG) and ethyl sulfate (EtS) are metabolites of alcohol that can be detected in urine for longer periods of time than ethanol. The use of EtG or EtS can extend the time window for detecting alcohol consumption from several hours to several days (Cary, 2011). A recent randomized, controlled trial reported that participants completed the first two phases of a Drug Court significantly sooner when they were subjected to weekly EtG and EtS testing (Gibbs & Wakefield, 2014). The EtG and EtS testing enabled the Drug Court to respond more rapidly and reliably to instances of alcohol use, thus producing more efficient results. Importantly, EtG and EtS testing was determined in the same study to be superior to standard ethanol testing for detecting alcohol use occurring over weekends. Because some Drug Courts may not perform drug or alcohol testing on weekends, weekday tests capable of detecting weekend substance use are crucial.

As was noted previously, some drug or alcohol tests have short detection windows of twelve to twenty-four hours. This makes them generally unsuitable for use as the primary testing method in Drug Courts. Such tests can be used effectively, however, for spot-testing when recent use is suspected or during high-risk times, such as weekends or holidays. Evidence also suggests these tests can deter substance use effectively if they are administered on a daily basis. A statewide study in South Dakota found that daily breathalyzer testing significantly reduced failures to appear and rearrest rates among DWI offenders released on bail (Kilmer et al., 2012). In that study, daily breathalyzer testing appears to have been sufficient to deter alcohol consumption in the majority of cases without the need for additional services.

B. Random Testing

Drug and alcohol testing is most effective when performed on a random basis (ASAM, 2013; ASAM, 2010; Auerbach, 2007; Carver, 2004; Cary, 2011; Harrell & Kleiman, 2002; McIntire et al., 2007). If participants know in advance when they will be tested, they can adjust the timing of their usage or take other countermeasures, such as excessive fluid consumption, to defraud the tests (McIntire & Lessenger, 2007). Random drug testing elicits significantly higher percentages of positive tests than prescheduled testing, suggesting that many participants can evade detection if they have advance notice about when testing will occur (Harrison, 1997).

Random testing means the odds of being tested are the same on any given day of the week, including weekends and holidays. For example, if a participant is scheduled to be drug tested two times per week, then the odds of being tested should be two in seven (28%) on every day of the week. For this reason, Drug Courts should not schedule their testing regimens in seven-day or weekly blocks, which is a common practice. Assume, for example, that a participant is randomly selected for drug testing on Monday and Wednesday of a given week. If testing is scheduled in weekly blocks, then the odds of that same participant being selected again for testing on Thursday will be zero. In behavioral terms, this is referred to as a *respite* from detection, which can lead to increased drug or alcohol use owing to the absence of negative consequences (Marlowe & Wong, 2008).

The odds of being tested for drugs and alcohol should be the same on weekends and holidays as on any other day of the week (Marlowe, 2012). Weekends and holidays are high-risk times for drug and alcohol use (Kirby et al., 1995; Marlatt & Gordon, 1985). Providing a respite from detection during high-risk times reduces the randomness of testing and undermines the central aims of a drug-testing program (ASAM, 2013).

Limiting the time delay between notification of an impending drug or alcohol test and collection of the test specimen is essential (ASAM, 2013). If participants can delay provision of a specimen for even a day or two, they can rely on natural elimination processes to reduce drug and metabolite concentrations below cutoff levels. For participants who live in close proximity to the testing facility and do not have confirmed

scheduling conflicts, Drug Courts can reasonably expect samples to be delivered within a few hours of notification that a test has been scheduled (Cary, 2011). Barring exigent circumstances, participants should be required to deliver a urine specimen no more than eight hours after being notified that a urine test has been scheduled (Auerbach, 2007). This practice should give most participants ample time to meet their daily obligations and travel to the sample collection site, while also reducing the likelihood that metabolite concentrations will fall below cutoff levels. For tests with short detection windows of less than twenty-four hours, such as oral fluid tests, participants should be required to deliver a specimen no more than four hours after being notified that a test has been scheduled.

C. Duration of Testing

A basic tenet of behavior modification provides that the effects of any intervention should be assessed continually until all components of the intervention are completed (Rusch & Kazdin, 1981). This is the only way to know whether a participant is likely to relapse or regress after the program ends.

Drug Courts commonly decrease the intensity of treatment and supervision as participants make progress in the program. For example, the frequency of court hearings or case management sessions is commonly reduced as participants advance through successive phases. With a reduction of services comes the ever-present risk of relapse or other behavioral setback; therefore, drug and alcohol testing should continue uninterrupted to reveal any relapse as other components of the participants' treatment regimens are adjusted (Cary, 2011; Marlowe, 2011, 2012). Although research has not addressed the issue, logic dictates maintaining the frequency of drug and alcohol testing until participants are engaged in what will ultimately be their continuing-care or aftercare plan. This practice provides the greatest assurance that participants are likely to remain abstinent after program graduation.

D. Breadth of Testing

Drug Courts must test for the full range of substances that are likely to be used by participants in the program. Participants can easily evade detection of their substance use on many standard test panels—such as the National Institute on Drug Abuse five-panel test (NIDA-5) or a standard eight-panel test—simply by switching to other drugs of abuse that have similar psychoactive effects but are not detected by the test (ASAM, 2013). For example, heroin users can avoid detection by many standard test panels if they switch to pharmaceutical opioids, such as oxycodone or buprenorphine (Wish et al., 2012). Similarly, marijuana users can avoid detection by using synthetic cannabinoids, such as K2 or Spice, which were developed for the specific purpose of avoiding detection (Cary, 2014; Castaneto et al., 2014). Studies confirm that some marijuana users do switch to synthetic cannabinoids to evade detection by drug tests and then return to marijuana use after the testing regimen has been discontinued (Perrone et al., 2013). Because new substances of abuse are constantly being sought out by offenders to cheat drug tests, Drug Courts should select test specimens randomly and frequently and examine them for a wide range of potential drugs of abuse that might be emerging in their population (ASAM, 2013).

E. Witnessed Collection

Drug Court participants and probationers acknowledge engaging in widespread efforts to defraud drug and alcohol tests. These efforts include, but are not limited to, consuming excessive water to dilute the sample (dilution), adulterating the sample with chemicals intended to mask a positive result (adulteration), and substituting another person's urine or a look-alike sample that is not urine, such as apple juice (substitution) (Cary, 2011; McIntire & Lessenger, 2007). Collectively, these efforts are referred to as tampering. In focus groups, Drug Court participants reported being aware of several individuals in their program who tampered with drug tests on more than one occasion without being detected by staff (Goldkamp et al., 2002).

The most effective way to avoid tampering is to ensure that sample collection is witnessed directly by a trained and experienced staff person (ASAM, 2013; Cary, 2011). If substitution or adulteration is suspected, a new sample should be collected immediately under closely monitored conditions (McIntire et al., 2007). Staff members should be trained in how to implement countermeasures to avoid tampered test specimens. Examples of such countermeasures include searching participants' clothing for chemical adulterants or fraudulent samples, requiring participants to leave outerwear outside of the test-collection

room, and putting colored dye in the sink and toilet to prevent water from being used to dilute test specimens (McIntire & Lessenger, 2007).

If substitution or other efforts at tampering are suspected for a urine specimen, it may be useful to obtain an oral fluid specimen immediately as a secondary measure of substance use. Generally speaking, observing the collection of oral fluid closely is easier than for the collection of urine, and oral fluid tests are less susceptible to dilution than urine tests (Heltsley et al., 2012; Sample et al., 2010). However, because oral fluid testing has a shorter detection window than urine testing, a negative oral fluid test would not necessarily rule out recent drug use or the possibility of a tampered urine test.

Because specialized training is required to minimize tampering of test specimens, under most circumstances participants should be precluded from undergoing drug and alcohol testing by independent sources. In exigent circumstances, such as when participants live a long distance from the test collection site, the Drug Court might designate independent professionals or laboratories to perform drug and alcohol testing. As a condition of approval, these professionals should be required to complete formal training on the proper collection, handling, and analyses of drug and alcohol test samples among Drug Court participants or comparable criminal justice populations. Drug Courts are also required to follow generally accepted chain-of-custody procedures when handling test specimens (ASAM, 2013; Cary, 2011; Meyer, 2011). Therefore, if independent professionals or laboratories perform drug and alcohol testing, they must be trained carefully to follow proper chain-of-custody procedures.

F. Valid Specimens

Several low-cost analyses can be performed to detect adulterated or diluted test specimens (McIntire et al., 2007). The temperature of each urine specimen should be examined immediately upon collection to ensure it is consistent with an expected human body temperature. An unusual temperature might suggest the sample cooled down because it was collected at an earlier point in time, or was mixed with water that was too cold or too hot to be consistent with body temperature. Under normal conditions, urine specimens should be between 90^0 and 100^0 F within four minutes of collection, and a lower or higher temperature likely indicates a deliberate effort at deception (ASAM, 2013; Tsai et al., 1998).

Urine specimens should also be tested for creatinine and specific gravity. Creatinine is a metabolic product of muscle contraction that is excreted in urine at a relatively constant rate. A creatinine level below 20 mg/dL is rare and is a reliable indicator of an intentional effort at dilution or excessive fluid consumption barring unusual medical or metabolic conditions (ASAM, 2013; Cary, 2011; Jones & Karlsson, 2005; Katz et al., 2007). Specific gravity reflects the amount of solid substances that are dissolved in urine. The greater the specific gravity, the more concentrated the urine; and the lower the specific gravity, the closer its consistency to water. The normal range of specific gravity for urine is 1.003 to 1.030, and a specific gravity of 1.000 is essentially water. Some experts believe a specific gravity below 1.003 reflects a diluted sample (Katz et al., 2007). Although this analysis, by itself, may not be sufficient to prove excessive fluid consumption, dilution is likely to have occurred if the specific gravity is low and accompanies other evidence of tampering or invalidity, such as a low creatinine level or temperature. Several commercially available test strips, such as Adultacheck and Intect, have also been shown to reliably detect dilution or adulteration of urine test samples (Dasgupta et al., 2004; Mikkelsen & Ash, 1988).

G. Accurate and Reliable Testing Procedures

To be admissible as evidence in a legal proceeding, drug and alcohol test results must be derived from scientifically valid and reliable methods (Meyer, 2011). Appellate courts have recognized the scientific validity of several commonly used methods for analyzing urine, including gas chromatography/mass spectrometry (GC/MS), liquid chromatography/tandem mass spectrometry (LC/MS/MS), the enzyme multiple immunoassay technique (EMIT), and some sweat, oral fluid, hair, and ankle-monitor tests (Meyer, 2011).

Tests such as GC/MS and LC/MS/MS are referred to as instrumented tests, laboratory-based tests, or confirmation tests. These tests have a higher degree of scientific precision than immunoassay tests, point of collection tests (POCT), or screening tests, such as on-site test cups or instant test strips. If a participant

denies substance use in the face of a positive screening test, courts will typically require, and toxicology experts recommend, performing confirmation testing using GC/MS or a similar instrumented technique (ASAM, 2013; Cary, 2011). Confirmation with an instrumented test virtually eliminates the odds of a false-positive result, assuming the sample was collected and stored properly (Auerbach, 2007; Peat, 1988). Drug Courts commonly require participants to pay the cost of confirmation tests if the initial screening result is confirmed (Cary, 2011; Meyer, 2011). Confirmation testing should be performed on a portion of the original test specimen. If confirmation testing is performed on a different specimen that was collected at a later point in time, a conflicting result might not reflect a failure to confirm but rather differences in the detection windows for the tests or the metabolic processes of the participant.

Drug Courts must follow generally accepted chain-of-custody procedures when handling test specimens (ASAM, 2013; Cary, 2011; Meyer, 2011). They need to establish a reliable paper trail identifying each professional who handled the specimen from collection through laboratory analysis to reporting of the results. Establishing a proper chain of custody requires sufficient labeling and security measures to provide confidence the specimen belongs to the individual identified on the record and the specimen was transported and stored according to generally accepted laboratory procedures and manufacturer recommendations.

Some Drug Courts interpret changes in quantitative levels of drug metabolites as evidence that new substance use has occurred or a participant's substance use pattern has changed. Unless a Drug Court has access to an expert trained in toxicology, pharmacology, or a related discipline, such practices should be avoided. Quantitative metabolite levels can vary considerably based on a number of factors, including the total fluid content in urine or blood (Cary, 2004; Schwilke et al., 2010). Moderate changes in participants' fluid intake or fluid retention could lead Drug Courts to miscalculate substance use patterns. Most drug and alcohol tests used in Drug Courts were designed to be *qualitative*, meaning they were designed to determine whether a drug or drug metabolite is present at levels above a prespecified concentration level. The cutoff concentration level is calculated empirically to maximize the true-positive rate, true-negative rate, or classification rate. When Drug Courts engage in quantitative analyses, they are effectively altering the cut-off score and making the results less accurate.

Some Drug Courts have difficulty interpreting positive cannabinoid (marijuana) test results. Because cannabinoids are lipid-soluble (i.e., bind to fat molecules), they may be excreted more slowly than other substances of abuse. This has caused confusion about when a positive cannabinoid result may be interpreted as evidence of new use as opposed to residual use from an earlier episode. A participant is highly unlikely to produce a cannabinoid-positive urine result above 50 ng/mL after more than ten days following cessation of chronic usage or for more than three to four days following a single-use event (Cary, 2005). Therefore, a Drug Court would be justified in considering the first two weeks of enrollment to be a grace period during which there would be no sanctions for positive cannabinoid test results. However, subsequent positive tests may be interpreted as evidence of new cannabis use and dealt with accordingly. Moreover, once a participant has produced two consecutive cannabinoid-negative urine specimens (called an *abstinence baseline*), a subsequent cannabinoid-positive test may be interpreted as new use (Cary, 2005). Some Drug Courts or laboratories may employ a lower cutoff level of 20 ng/mL for cannabis metabolites. Using this lower cutoff, thirty days is sufficient to establish a presumptive abstinence baseline even for chronic users (Cary, 2005); in the majority of cases, twenty-one days should be sufficient.

Some participants may attempt to attribute a positive cannabinoid test to passive inhalation or second-hand smoke. This excuse should not be credited. The likelihood of passive inhalation triggering a positive cannabinoid test is negligible (Cone et al., 2014; Law et al., 1984; Katz et al., 2007; Niedbala et al., 2005). Moreover, because Drug Court participants are usually prohibited from associating with people who are engaged in substance use, passive inhalation may be viewed as a violation of this central prohibition, thus meriting an additional sanction (Marlowe, 2011).

H. Rapid Results

In addition to certainty, timing is one of the most influential factors for success in a behavior modification program (Harrell & Roman, 2001; Marlowe & Kirby, 1999). The sooner sanctions are delivered after an infraction and incentives delivered after an achievement, the better the results. Because sanctions and

incentives are imposed routinely on the basis of drug and alcohol test results, the Drug Court team needs test results before participants appear for status hearings.

A study of approximately seventy Drug Courts reported significantly greater reductions in criminal recidivism and significantly greater cost benefits when the teams received drug and alcohol test results within forty-eight hours of sample collection (Carey et al., 2012). Drug Courts that received test results within forty-eight hours were 73% more effective at reducing crime and 68% more cost-effective than Drug Courts receiving test results after longer delays. Ordinarily, negative test results should take no longer than one business day to produce, and positive results should require no more than two days if confirmation testing is requested (Cary, 2011; Robinson & Jones, 2000).

I. Participant Contract

Outcomes are significantly better when Drug Courts specify their policies and procedures clearly in a participant manual or handbook (Carey et al., 2012). Criminal defendants are significantly more likely to react favorably to an adverse judgment if they were given advance notice about how such judgments would be made (Burke & Leben, 2007; Frazer, 2006; Tyler, 2007). Drug Courts can enhance participants' perceptions of fairness substantially and reduce avoidable delays from contested drug and alcohol tests by describing their testing procedures and requirements in a participant contract or handbook.

Below are examples of provisions that should be included in a participant contract to address many of the best practices discussed above. For participants with limited educational histories, the language may need to be simplified and the requirements explained orally. Repeat the information periodically to ensure participants understand their rights and obligations.

- Drug and alcohol testing will be performed frequently and on a random basis throughout your enrollment in the Drug Court.
- Drug and alcohol testing will be performed on weekends and holidays.
- Drug and alcohol testing will be performed by a laboratory or program approved by the Drug Court.
- Because cannabinoids (a byproduct of marijuana) may persist in the body for several days, marijuana users have a two-week grace period following enrollment during which no sanctions will be given for positive cannabinoid test results. However, after two weeks positive cannabinoid tests will be presumed to reflect new marijuana use. Participants bear the burden of establishing a convincing alternative explanation for such results. After you have had two consecutive cannabinoid-negative urine specimens, the Drug Court will presume that subsequent positive cannabinoid results reflect new use.
- You must arrive at the testing facility as soon as possible after being notified that a test has been scheduled. You will be sanctioned for an unexcused failure to arrive within eight hours of being notified that a urine test has been scheduled or within four hours for tests that have short detection windows, such as breath or oral fluid tests.
- A staff person will directly observe the collection of test specimens. The staff person will be the same gender as you unless you, your defense attorney or your therapist request otherwise.
- Failure to provide a test specimen or providing an insufficient volume of fluid for analysis is an infraction of the rules of the program and will be sanctioned accordingly. You will be given a sufficient time (up to one hour) to deliver a urine specimen and allowed to drink up to one cup of water in the presence of staff.
- You may not drink any fluid excessively before testing and must avoid environmental contaminants, over-the-counter medications, or foods that can reduce the accuracy of the tests. Potential contaminants that you need to avoid are [provide list of contaminants].
- You may be subjected to immediate spot testing if the Drug Court has reason to suspect recent use or during high-risk times such as weekends or holidays.

- You have the right to challenge the results of a screening test and to request proof that an adequate chain of custody was established for your specimen. The Drug Court will rely on the results of an instrumented or laboratory-based test in confirming whether substance use has occurred. You may be charged the cost of the confirmation test if a screening test is confirmed.
- You will be sanctioned for providing diluted, adulterated, or substituted test specimens. Urine specimens below 90° F, above 100° F, or that have a creatinine level below 20 mg/dL will be presumed to be diluted or fraudulent. Participants bear the burden of establishing a convincing alternative explanation for such results. Under such circumstances, you may receive two sanctions, one for the substance use and one for the effort at deception.
- You will be sanctioned for using synthetic substances such as K2 or Spice that are designed to avoid detection by standard drug tests. Switching to a new substance of abuse (for example, switching from heroin to an unauthorized prescription opioid) will be presumed to be an effort to defraud the drug test. You may receive two sanctions in such circumstances, one for the substance use and one for the effort at deception.
- You will be sanctioned for associating with other people who are engaged in substance use or for exposing yourself to passive inhalation or secondhand smoke.

REFERENCES

American Society of Addiction Medicine. (2010). *Public policy statement on drug testing as a component of addiction treatment and monitoring programs and in other clinical settings.* Chevy Chase, MD: Author. *Available at* http://www.asam.org/advocacy/find-a-policy-statement/view-policy-statement/public-policy-statements/2011/12/15/drug-testing-as-a-component-of-addiction-treatment-and-monitoring-programs-and-in-other-clinical-settings

American Society of Addiction Medicine. (2013). *Drug testing: A white paper of the American Society of Addiction Medicine (ASAM).* Chevy Chase, MD: Author. *Available at* http://www.asam.org/docs/default-source/publicy-policy-statements/drug-testing-a-white-paper-by-asam.pdf?sfvrsn=2

Auerbach, K. (2007). Drug testing methods. In J.E. Lessenger & G.F. Roper (Eds.), *Drug courts: A new approach to treatment and rehabilitation* (pp. 215–233). New York: Springer.

Banks, D., & Gottfredson, D.C. (2003). The effects of drug treatment and supervision on time to rearrest among drug treatment court participants. *Journal of Drug Issues*, *33*(2), 385–412.

Burke, K., & Leben, S. (2007). Procedural fairness: A key ingredient in public satisfaction. *Court Review, 44*(1-2), 4–25.

Carey, S.M., Finigan, M.W., & Pukstas, K. (2008). *Exploring the key components of drug courts: A comparative study of 18 adult drug courts on practices, outcomes and costs*. Portland, OR: NPC Research. *Available at* http://www.npcresearch.com/Files/NIJ_Cross-site_Final_Report_0308.pdf

Carey, S.M., Mackin, J.R., & Finigan, M.W. (2012). What works? The ten key components of drug court: Research-based best practices. *Drug Court Review*, *8*(1), 6–42.

Carver, C. (2004). Drug testing: A necessary prerequisite for treatment and for crime control. In P. Bean & T. Nemitz (Eds.), *Drug treatment: What works?* (pp. 142–177). New York: Routledge.

Cary, P. (2004). Urine drug concentrations: The scientific rationale for eliminating the use of drug test levels in drug court proceedings. *NDCI Drug Court Practitioner Fact Sheet, 4*(1).

Cary, P. (2005). The marijuana detection window: Determining the length of time cannabinoids will remain detectable in urine following smoking: A critical review of relevant research and cannabinoid detection guidance for drug courts. *Drug Court Review, 5*(1), 23–58.

Cary, P. (2011). The fundamentals of drug testing. In D.B. Marlowe & W.G. Meyer (Eds.), *The drug court judicial benchbook* (pp. 113–138). Alexandria, VA: National Drug Court Institute. *Available at* http://www.ndci.org/sites/default/files/nadcp/14146_NDCI_Benchbook_v6.pdf

Cary, P. (2014). Designer drugs: What drug court practitioners need to know. *NDCI Drug Court Practitioner Fact Sheet, 9*(2).

Castaneto, M.S., Gorelick, D.A., Desrosiers, N.A., Hartman, R.L., Pirard, S., & Huestis, M.A. (2014). Synthetic cannabinoids: Epidemiology, pharmacodynamics, and clinical implications. *Drug and Alcohol Dependence: Online, 144*, 12–41. doi:http://dx.doi.org/10.1016/j.drugalcdep.2014.08.005

Cone, E.J., Bigelow, G.E., Herrmann, E.S., Mitchell, J.M., LoDico, C., Flegel, R., & Vandrey, R. (2014).Nonsmoker exposure to secondhand cannabis smoke. I. Urine screening and confirmation results. *Journal of Analytic Toxicology: Online, 39*(1), 1–12. doi:10.1093/jat/bku116

Dasgupta, A., Chughtai, O., Hannah, C., David, B., & Wells, A. (2004). Comparison of spot tests with Adultacheck 6 and Intect 7 urine test strips for detecting the presence of adulterants in urine specimens. *Clinica Chimica Acta, 348 (1-2),* 19–25.

Davis, C.G., Doherty, S., & Moser, A.E. (2014). Social desirability and change following substance abuse treatment in male offenders. *Psychology of Addictive Behaviors, 28*(3), 872–879.

DuPont, R.L., Goldberger, B.A., & Gold, M.S. (2014). The science and clinical uses of drug testing. In R.K. Ries, D.A. Fiellin, S.C. Miller, & R. Saitz (Eds.), *The ASAM principles of addiction medicine* (5th ed., pp. 1717–1729). Philadelphia: Wolters Kluwer Health.

DuPont, R.L., & Selavka, C. (2008). Testing to identify recent drug use. In M. Galanter & H.D. Kleber (Eds.), *Textbook of substance abuse treatment* (4th ed., pp. 655–664). Arlington, VA: American Psychiatric Publishing.

Flango, V.E., & Cheesman, F.L. (2009). The effectiveness of the SCRAM alcohol monitoring device: A preliminary test. *Drug Court Review, 6*(2), 109–134.

Frazer, M.S. (2006). *The impact of the community court model on defendant perceptions of fairness.* New York: Center for Court Innovation. *Available at* http://www.courtinnovation.org/sites/default/files/Procedural_Fairness.pdf

Gallagher, J.R., Nordberg, A., & Kennard, T. (2015). A qualitative study assessing the effectiveness of the key components of a Drug Court. *Alcoholism Treatment Quarterly, 33*(1), 64–81.

Gibbs, B.R., & Wakefield, W. (2014). The efficacy of enhanced alcohol use monitoring: An examination of the effects of EtG/EtS screening on participant performance in Drug Court. *Drug Court Review, 9*(1), 1–22.

Goldkamp, J.S., White, M.D., & Robinson, J.B. (2002). An honest chance: Perspectives on drug courts. *Federal Sentencing Reporter, 14*(6), 369–372.

Gottfredson, D.C., Kearley, B.W., Najaka, S.S., & Rocha, C.M. (2007). How drug treatment courts work: An analysis of mediators. *Journal of Research on Crime & Delinquency, 44*(1), 3–35.

Griffith, J.D., Rowan-Szal, G.A., Roark, R.R., & Simpson, D.D. (2000). Contingency management in outpatient methadone maintenance treatment: A meta-analysis. *Drug & Alcohol Dependence, 58*(1), 55–66.

Harrell, A., Cavanagh, S., & Roman, J. (1998). *Findings from the evaluation of the D.C. Superior Court Drug Intervention Program* (Final report). Washington, DC: The Urban Institute.

Harrell, A., & Kleiman, M. (2002). Drug testing in criminal justice settings. In C.G. Leukefeld, F.M. Tims & D. Farabee (Eds.), *Treatment of drug offenders: Policies and issues* (pp. 149–171). New York: Springer.

Harrell, A., & Roman, J. (2001). Reducing drug use and crime among offenders: The impact of graduated sanctions. *Journal of Drug Issues, 31*(1), 207–231.

Harris, K.M., Griffin, B.A., McCaffrey, D.F., & Morral, A.R. (2008). Inconsistencies in self-reported drug use by adolescents in substance abuse treatment: Implications for outcome and performance measurements. *Journal of Substance Abuse Treatment, 34*(3), 347–355.

Harrison, L. (1997). The validity of self-reported drug use in survey research: An overview and critique of research methods. In L. Harrison & A. Hughes (Eds.), *The validity of self-reported drug use: Improving the accuracy of survey estimates* [Research Monograph No. 167] (pp. 17–36). Rockville, MD; National Institute on Drug Abuse.

Hawken, A., & Kleiman, M. (2009). *Managing drug involved probationers with swift and certain sanctions: Evaluating Hawaii's HOPE* (NCJRS No. 229023). Washington, DC: National Institute of Justice. *Available at* http://www.ncjrs.gov/pdffiles1/nij /grants /229023.pdf

Heltsley, R., DePriest, A., Black, D.L., Crouch, D.J., Robert, T., Marshall, L.,…Cone, E.J. (2012). Oral fluid drug testing of chronic pain patients. II. Comparison of paired oral fluid and urine specimens. *Journal of the Annals of Toxicology, 36*(2), 75–80. doi:10.1093/jat/bkr019

Hindin, R., McCusker, J., Vickers-Lahti, M., Bigelow, C., Garfield, F., & Lewis, B. (1994). Radioimmunoassay of hair for determination of cocaine, heroin and marijuana exposure: Comparison with self-report. *Addiction, 29*(6), 771–789.

Hunt, D.E., Kling, R., Almozlino, Y., Jalbert, S., Chapman, M.T., & Rhodes, W. (2015). Telling the truth about drug use: How much does it matter? *Journal of Drug Issues, 45*(3), 31–329.

Jones, A.W., & Karlsson, L. (2005). Relation between blood- and urine-amphetamine concentrations in impaired drivers as influenced by urinary pH and creatinine. *Human Experimental Toxicology, 24*(12), 615–622.

Katz, O.A., Katz, N.B., Mandel, S., & Lessenger, J.E. (2007). Analysis of drug testing results. In J.E. Lessenger & G.F. Roper (Eds.), *Drug Courts: A new approach to treatment and rehabilitation* (pp. 255–262). New York: Springer.

Kilmer, B., Nicosia, N., Heaton, P., & Midgette, G. (2012). Efficacy of frequent monitoring with swift, certain, and modest sanctions for violations: Insights from South Dakota's 24/7 Sobriety Project. *American Journal of Public Health: Online, 103*(1), e37–e43. doi:10.2105/AJPH.2012.300989

Kinlock, T.M., Gordon, M.S., Schwartz, R.P., & O'Grady, K.E. (2013). Individual patient and program factors related to prison and community treatment completion in prison-initiated methadone maintenance treatment. *Journal of Offender Rehabilitation, 52*(8), 509–528.

Kirby, K.C., Lamb, R.J., Iguchi, M.Y., Husband, S.D., & Platt, J.J. (1995). Situations occasioning cocaine use and cocaine abstinence strategies. *Addiction, 90*(9), 1241–1252.

Kleinpeter, C.B., Brocato, J., & Koob, J.J. (2010). Does drug testing deter drug court participants from using drugs or alcohol? *Journal of Offender Rehabilitation, 49*(6), 434–444.

Law, B., Mason, P.A., Moffat, A.C., King, L.J., & Marks, V. (1984). Passive inhalation of cannabis smoke. *Journal of Pharmacy & Pharmacology, 36*(9), 578–581.

Magura, S., & Kang, S. (1997). The validity of self-reported cocaine use in two high-risk populations. In L. Harrison & A. Hughes (Eds.), *The validity of self-reported drug use: Improving the accuracy of survey estimates* [Research Monograph No. 167] (pp. 227–246). Rockville, MD; National Institute on Drug Abuse.

Marlatt, G.A., & Gordon, J.R. (1985). *Relapse prevention: Maintenance strategies in the treatment of addictive behaviors*. New York: Guilford Press.

Marlowe, D.B. (2011). Applying incentives and sanctions. In D.B. Marlowe & W.B. Meyer (Eds.), *The drug court judicial benchbook* (pp.139–157). Alexandria, VA: National Drug Court Institute. *Available at* http://www.ndci.org/sites/default/files/nadcp/14146_NDCI_Benchbook_v6.pdf

Marlowe, D.B. (2012). Behavior modification 101 for drug courts: Making the most of incentives and sanctions. *NDCI Drug Court Practitioner Fact Sheet, 7*(3), 1–11.

Marlowe, D.B., Festinger, D.S., Foltz, C., Lee, P.A., & Patapis, N.S. (2005). Perceived deterrence and outcomes in drug court. *Behavioral Sciences & the Law, 23*(2), 183–198.

Marlowe, D.B., & Kirby, K.C. (1999). Effective use of sanctions in drug courts: Lessons from behavioral research. *National Drug Court Institute Review, 2*(1), 1–31.

Marlowe, D.B., & Wong, C.J. (2008). Contingency management in adult criminal drug courts. In S.T. Higgins, K. Silverman, & S.H. Heil (Eds.), *Contingency management in substance abuse treatment* (pp. 334–354). New York: Guilford Press.

Marques, P.H., Jesus, V., Olea, S.A., Vairinhos, V., & Jacinto, C. (2014). The effect of alcohol and drug testing at the workplace on individual's occupational accident risk. *Safety Science, 68,* 108–120. doi:10.1016/j.ssci.2014.03.007

McIntire, R.L., & Lessenger, J.E. (2007). Drug testing scams. In J.E. Lessenger & G.F. Roper (Eds.), *Drug Courts: A new approach to treatment and rehabilitation* (pp. 247–254). New York: Springer.

McIntire, R.L., Lessenger, J.E., & Roper, G.F. (2007). The drug and alcohol testing process. In J.E. Lessenger & G.F. Roper (Eds.), *Drug Courts: A new approach to treatment and rehabilitation* (pp. 234–246). New York: Springer.

Meyer, W. (2011). Constitutional and legal issues in drug courts. In D.B. Marlowe & W.G. Meyer (Eds.), *The drug court judicial benchbook* (pp. 159–180). Alexandria, VA: National Drug Court Institute. *Available at* http://www.ndci.org/sites/default/files/nadcp/14146_NDCI_Benchbook_v6.pdf

Mikkelsen, A.L., & Ash, K.O. (1988). Adulterants causing false negatives in illicit drug testing. *Clinical Chemistry, 34*(11), 2333–2336.

Morral, A.R., McCaffrey, D.F., & Iguchi, M.Y. (2000). Hardcore drug users claim to be occasional users: Drug use frequency underreporting. *Drug & Alcohol Dependence, 57*(3), 193–202.

National Institute on Drug Abuse. (2006). *Principles of drug abuse treatment for criminal justice populations* (NIH Pub. No. 06–5316). Bethesda, MD: Author.

Niedbala, R.S., Kardos, K.W., Fritch, D.F., Kunsman, K.P., Blum, K.A., Newland, G.A.,…Cone, E.J. (2005). Passive cannabis smoke exposure and oral fluid testing. II. Two studies of extreme cannabis smoke exposure in a motor vehicle. *Journal of Analytical Toxicology, 29*(7), 607–615.

Nirenberg, T., Longabaugh, R., Baird, J., & Mello, M.J. (2013). Treatment may influence self-report and jeopardize our understanding of outcome. *Journal of Studies on Alcohol and Drugs, 74*(5), 770–776.

Peat, M.A. (1988). Analytical and technical aspects of testing for drug abuse: Confirmatory procedures. *Clinical Chemistry, 34*(3), 471–473.

Perrone, D., Helgesen, R.D., & Fischer, R.G. (2013). United States drug prohibition and legal highs: How drug testing may lead cannabis users to Spice. *Drugs: Education, Prevention and Policy, 20*(3), 216–224.

Peters, R.H., Kremling, J., & Hunt, E. (2015). Accuracy of self-reported drug use among offenders: Findings from the Arrestee Drug Abuse Monitoring-II Program. *Criminal Justice and Behavior, 42*(6), 623–643.

Robinson, J.J., & Jones, J.W. (2000). *Drug testing in a drug court environment: Common issues to address* (NCJ Pub. No. 181103). Washington, DC: Office of Justice Programs, Drug Court Clearinghouse and Technical Assistance Project at American University.

Rusch, F.R., & Kazdin, A.E. (1981). Toward a methodology of withdrawal designs for the assessment of response maintenance. *Journal of Applied Behavior Analysis, 14*(2), 131–140.

Sample, R.H.B., Abbott, L.B., Brunelli, B.A., Clouette, R.E., Johnson, T.D., Predescu, R.D., & Rowland, B.J. (2010). *Positive prevalence rates in drug tests for drugs of abuse in oral-fluid and urine*. Paper presented at the Society of Forensic Toxicologists Annual Meeting, Richmond, VA.

Saum, C.A., Scarpitti, F.R., Butzin, C.A., Perez, V.W., Jennings, D., & Gray, A.R. (2002). Drug court participants' satisfaction with treatment and the court experience. *Drug Court Review, 4*(1), 39–81.

Schuler, M.S., Griffin, B.A., Ramchand, R., Almirall, D., & McCaffrey, D.F. (2014). Effectiveness of treatment for adolescent substance use: Is biological drug testing sufficient? *Journal of Studies on Alcohol, 75*(2), 358–370.

Schwilke, E.W., Gullberg, R.G., Darwin, W.D., Chiang, C.N., Cadet, J.L., Gorelick, D.A.,…Huestis, M.A. (2010). Differentiating new cannabis use from residual urinary cannabinoid excretion in chronic, daily cannabis users. *Addiction, 106*(3), 499–506.

Srebnik, D.S., McDonell, M.G., Ries, R.K., & Andrus, G. (2014). Conflicts among CMHC clinicians over the role of urine drug testing. *Psychiatric Services, 65*(5), 700–701.

Stitzer, M.L., & Kellogg, S. (2008). Large-scale dissemination efforts in drug abuse treatment clinics. In S.T. Higgins, K. Silverman, & S.H. Heil (Eds.), *Contingency management in substance abuse treatment* (pp. 241–260). New York: Guilford Press.

Tassiopoulos, K., Bernstein, J., Heeren, T., Levenson, S., Hingson, R., & Bernstein, E. (2004). Hair testing and self-report of cocaine use by heroin users. *Addiction, 99*(4), 590–597.

Tison, J., Nichols, J.L., Casanova-Powell, T., & Chaudhary, N.K. (2015). *Comparative study and evaluation of SCRAM use, recidivism rates, and characteristics* (Report No. DOT HS 812 143). Washington, DC: National Highway Traffic Safety Administration.

Tsai, S.C., ElSohly, M A., Dubrovsky, T., Twarowski, B., Towt, J., & Salamonde, S.J. (1998). Determination of five abused drugs in nitrite-adulterated urine by immunoassay and gas chromatography-mass spectrometry. *Journal of the Annals of Toxicology, 22*(6), 474–480.

Turner, S., Greenwood, P. Fain, T., & Deschenes, E. (1999). Perceptions of drug court: How offenders view ease of program completion, strengths and weaknesses, and the impact on their lives. *National Drug Court Institute Review, 2*(1), 61–85.

Tyler, T.R. (2007). Procedural justice and the courts. *Court Review, 44*(1-2), 26.

Wish, E.D., Artigiani, E., Billing, A., Hauser, A., Hemberg. J., Shiplet, M., & DuPont, R.L. (2012). The emerging buprenorphine epidemic in the United States. *Journal of Addictive Diseases, 31*(1), 3–7.

Wish, E.D., Hoffman, J.A., & Nemes, S. (1997). The validity of self-reports of drug use at treatment admission and at follow-up: Comparisons with urinalysis and hair assays. In L. Harrison & A. Hughes (Eds.), *The validity of self-reported drug use: Improving the accuracy of survey estimates* [Research Monograph No. 167] (pp. 200–226). Rockville, MD; National Institute on Drug Abuse.

Wolfer, L. (2006). Graduates speak: A qualitative exploration of drug court graduates' views of the strengths and weaknesses of the program. *Contemporary Drug Problems, 33*(2), 303–320.

VIII. MULTIDISCIPLINARY TEAM

A dedicated multidisciplinary team of professionals manages the day-to-day operations of the Drug Court, including reviewing participant progress during pre-court staff meetings and status hearings, contributing observations and recommendations within team members' respective areas of expertise, and delivering or overseeing the delivery of legal, treatment and supervision services.

A. Team Composition

B. Pre-Court Staff Meetings

C. Sharing Information

D. Team Communication and Decision Making

E. Status Hearings

F. Team Training

A. Team Composition

The Drug Court team comprises representatives from all partner agencies involved in the creation of the program, including but not limited to a judge or judicial officer, program coordinator, prosecutor, defense counsel representative, treatment representative, community supervision officer, and law enforcement officer.

B. Pre-Court Staff Meetings

Team members consistently attend pre-court staff meetings to review participant progress, determine appropriate actions to improve outcomes, and prepare for status hearings in court. Pre-court staff meetings are presumptively closed to participants and the public unless the court has a good reason for a participant to attend discussions related to that participant's case.

C. Sharing Information

Team members share information as necessary to appraise participants' progress in treatment and compliance with the conditions of the Drug Court. Partner agencies execute memoranda of understanding (MOUs) specifying what information will be shared among team members. Participants provide voluntary and informed consent permitting team members to share specified data elements relating to participants' progress in treatment and compliance with program requirements. Defense attorneys make it clear to participants and other team members whether they will share communications from participants with the Drug Court team.

D. Team Communication and Decision Making

Team members contribute relevant insights, observations, and recommendations based on their professional knowledge, training, and experience. The judge considers the perspectives of all team members before making decisions that affect participants'

welfare or liberty interests and explains the rationale for such decisions to team members and participants [see Standard III, Roles and Responsibilities of the Judge].

E. Status Hearings

Team members attend status hearings on a consistent basis. During the status hearings, team members contribute relevant information or recommendations when requested by the judge or as necessary to improve outcomes or protect participants' legal interests.

F. Team Training

Before starting a Drug Court, team members attend a formal preimplementation training to learn from expert faculty about best practices in Drug Courts and develop fair and effective policies and procedures for the program. Subsequently, team members attend continuing education workshops on at least an annual basis to gain up-to-date knowledge about best practices on topics including substance abuse and mental health treatment, complementary treatment and social services, behavior modification, community supervision, drug and alcohol testing, team decision making, and constitutional and legal issues in Drug Courts. New staff hires receive a formal orientation training on the Drug Court model and best practices in Drug Courts as soon as practicable after assuming their position and attend annual continuing education workshops thereafter.

COMMENTARY

The Drug Court team is a multidisciplinary group of professionals responsible for administering the day-to-day operations of a Drug Court, including reviewing participant progress during pre-court staff meetings and status hearings, contributing observations and recommendations within team members' respective areas of expertise, and delivering or overseeing the delivery of legal, treatment, and supervision services (Hardin & Fox, 2011). Some Drug Courts may have additional governing bodies such as Steering Committees that are not involved in the daily operations of the program, but provide oversight on policies and procedures, negotiate MOUs between partner agencies, garner political and community support for the Drug Court, or engage in fundraising. Researchers have examined the influence of the multidisciplinary Drug Court team on participant outcomes but have not addressed the influence of other governing bodies.

A. Team Composition

Studies reveal the composition of the Drug Court team has a substantial influence on outcomes. Drug Courts produce significantly greater reductions in criminal recidivism and are significantly more cost-effective when the following professionals are dedicated members of the Drug Court team and participate regularly in pre-court staff meetings and status hearings (Carey et al., 2008, 2012; Cissner et al., 2013; Rossman et al., 2011; Shaffer, 2010):

- *Judge*—Typically a trial court judge leads the Drug Court team; however, in some jurisdictions a nonjudicial officer such as a magistrate or commissioner may preside over the Drug Court. Nonjudicial officers usually report directly to a judge and require judicial authorization for actions that affect participants' liberty interests such as jail sanctions or discharge from the program. No study has compared outcomes between judges and nonjudicial officers.
- *Program Coordinator*—Typically a court administrator or clerk serves as the coordinator for the Drug Court program; however, some Drug Courts may employ a senior probation officer, case manager, or clinician as the coordinator. Among many other duties, the coordinator is responsible for maintaining

accurate and timely records and documentation for the program, overseeing fiscal and contractual obligations, facilitating communication between team members and partner agencies, ensuring policies and procedures are followed, overseeing collection of performance and outcome data, scheduling court sessions and staff meetings, and orienting new hires.

- *Prosecutor*—Typically an assistant district attorney serves on the team. Among other duties, the prosecutor advocates on behalf of public safety, victim interests, and holding participants accountable for meeting their obligations in the program. The prosecutor may also help to resolve other pending legal cases that impact participants' legal status or eligibility for Drug Court.

- *Defense Attorney*—Typically an assistant public defender or private defense attorney specializing in Drug Court cases serves on the team. Among other duties, the defense attorney ensures participants' constitutional rights are protected and advocates for participants' stated legal interests. Defendants are usually represented by a public defender or private defense attorney in proceedings leading up to their entry into Drug Court. After entry, participants may retain their previous defense counsel, provide informed consent to be represented by a defense representative serving on the Drug Court team, or consent to be represented jointly by private defense counsel and the defense representative. In cases of joint representation, the defense representative typically handles most day-to-day issues relating to Drug Court participation, but private counsel may step in if the participant faces a potential jail sanction or discharge from the program (Freeman-Wilson et al., 2003; Tobin, 2012).

  In postconviction Drug Courts, participation in the program is a condition of probation or part of a criminal sentence. Ordinarily, participants are not entitled to defense representation at the postconviction stage unless they face a potential jail sanction or revocation of probation (Meyer, 2011a). Nevertheless, postconviction Drug Courts should include a defense representative on their team because studies indicate defense involvement improves outcomes significantly (Carey et al., 2012; Cissner et al., 2013; National Association of Drug Court Professionals [NADCP], 2009). Evidence suggests participants may be more likely to perceive Drug Court procedures as fair when a dedicated defense attorney represents their interests in team meetings and status hearings (Frazer, 2006), and greater perceptions of fairness are consistently associated with better outcomes in Drug Courts and other problem-solving courts (Berman & Gold, 2012; Burke, 2010; Gottfredson et al., 2007; Rossman et al., 2011).

  Some Drug Courts require participants to waive defense representation as a condition of entry. Although no case has addressed this issue squarely in the context of Drug Court, the weight of legal authority suggests defendants and probationers are entitled to withdraw such waivers and reassert their right to counsel at critical stages in the proceedings such as when they face a potential jail sanction or probation revocation (McKaskle v. Wiggins, 1984; Menefield v. Borg, 1989; Robinson v. Ignacio, 2004; State v. Pitts, 2014). Regardless of the legality of such waivers, defense representation should be encouraged rather than discouraged in Drug Courts because doing so is associated with significantly better outcomes and ensures participants' due process rights are protected (Hora & Stalcup, 2008; NADCP, 2009).

- *Community Supervision Officer*—Typically a probation officer or pretrial services officer serves on the team; however, some Drug Courts may rely on law enforcement or specially trained case managers or social service professionals to provide community supervision. Duties of the community supervision officer may include performing drug and alcohol testing, conducting home or employment visits, enforcing curfews and travel restrictions, and delivering cognitive-behavioral interventions designed to improve participants' problem-solving skills and alter dysfunctional criminal-thinking patterns (Harberts, 2011).

- *Treatment Representative*—Typically an addiction counselor, social worker, psychologist, or clinical case manager serves on the team. In many Drug Courts, participants can be referred to multiple treatment agencies or providers for substance abuse treatment and other complementary services such as mental health counseling or vocational rehabilitation. Because it is unwieldy to have multiple providers attend pre-court staff meetings and status hearings, many Drug Courts will designate one or two treatment professionals to serve as treatment representatives on the Drug Court team (Carey et al., 2012). The treatment representatives receive clinical information from programs treating Drug Court

participants, report that information to the Drug Court team, and contribute clinical knowledge and expertise during team deliberations.

- *Law Enforcement Officer*—Typically a police officer, deputy sheriff, highway patrol officer, or jail official serves on the team. Law enforcement is often the eyes and ears of Drug Court on the street, observing participant behavior and interacting with participants in the community. Law enforcement may also assist with home and employment visits, and serves as a liaison between the Drug Court and the police department, sheriff's office, jail, and correctional system.

Drug Courts may include other community representatives on their team as well, such as peer mentors, vocational advisors, or sponsors from the self-help recovery community. Studies have not examined the impact of including such persons on the Drug Court team; however, anecdotal reports suggest this practice can enhance team decision making and effectiveness (Taylor, 2014). As a condition of federal grant funding and funding from many states, Drug Courts may also be required to include an evaluator on their team beginning in the planning stages for the program and continuing during implementation. This practice helps to ensure Drug Courts collect reliable performance data to report to grant-making authorities and is generally advisable for all Drug Courts to ensure good-quality program monitoring and evaluation [see Standard X, Monitoring and Evaluation]. Finally, Drug Courts may be advised to include a nurse or physician on their team if they treat substantial numbers of participants requiring medication-assisted treatment or suffering from co-occurring medical or mental health disorders.

B. Pre-Court Staff Meetings

The Drug Court model requires Drug Courts to hold pre-court staff meetings—commonly referred to as *staffings* or *case reviews*—to review participant progress, develop a plan to improve outcomes, and prepare for status hearings in court (Hardin & Fox, 2011; NADCP, 1997; Roper & Lessenger, 2007). Not every participant is discussed in every meeting; however, staffings are held frequently enough (typically weekly or at the same frequency as status hearings) to ensure the team has an opportunity to consider the needs of each case.

Consistent attendance by all team members at staffings is associated with significantly better outcomes (Carey et al., 2012; Cissner et al., 2013; Rossman et al., 2011; Shaffer, 2010). A multisite study of approximately seventy Drug Courts found that programs were 50% more effective at reducing recidivism when all team members—the judge, prosecutor, defense representative, program coordinator, treatment representative, law-enforcement representative, and community supervision officer—attended staffings on a consistent basis (Carey et al., 2008, 2012). Drug Courts were nearly twice as cost-effective when defense counsel attended staffings consistently, and were more than twice as effective at reducing recidivism when the program coordinator, treatment representative, and law enforcement representative attended staffings consistently (Carey et al., 2012).

In most Drug Courts, staffings are presumptively closed. Discussions are not transcribed or recorded and the meeting is not open to the public or to participants unless the court has a good reason to allow a participant to attend discussions related to his or her case. Few appellate opinions have addressed the constitutionality or legality of closing staffings. In a recent opinion, the Washington State Supreme Court—which traditionally holds a very dim view of off-the-record proceedings—ruled that staffings may be presumptively closed at the discretion of the Drug Court judge (State of Washington v. Sykes, 2014). The Court analogized staffings to *pre-court conferences* in which attorneys commonly meet with the judge in chambers to clarify what legal issues are under contention, determine which facts are in dispute, and address other practical or collateral matters necessary to achieve a fair and efficient resolution of the case, such as scheduling witnesses or issuing discovery orders. In line with this reasoning, staffings may be closed so long as no final decisions are reached concerning disputed facts or legal issues in the case, and the judge recites in open court what decisions, if any, were made during the staffing. A closed staffing may not result in a binding order or factual conclusion related to a contested matter (Meyer, 2011a). Contested matters must be addressed and resolved in open court during status hearings or related due process hearings such as termination hearings or probation violation hearings.

Studies have not determined whether closed staffings produce more favorable outcomes than open staffings. The rationale for closing staffings derives largely from empirical studies and ethical analyses conducted in the context of psychotherapy progress notes and case conferences. For example, the Health Insurance Portability and Accountability Act (HIPAA) of 1996 grants broad access for patients to their health records, yet provides a lone exception for psychotherapy progress notes (45 C.F.R §§ 164.508(a)(2) & 164.524; U.S. Dept. of Health & Human Services [U.S. DHHS], 2003; Wooten v. Duane Reade, 2009). Psychotherapy notes receive heightened protection against patient access, in part, because they often contain sensitive information provided by collateral sources, such as family members and friends (U.S. DHHS, 2003). If participants could gain access to this information, collateral sources might not be forthright in providing sensitive information about matters which are critical for delivering effective treatment, such as providing accurate histories of participants' substance abuse patterns, criminality, or related conduct (Stasiewicz et al., 2008). Studies have also reported that patients can be harmed psychologically by receiving unfettered access to their therapists' diagnostic impressions and conclusions (Lajeunesse & Lussier, 2010; Ross & Lin, 2003; Sergeant, 1986; Short, 1986; Westin, 1977). Sensitive clinical information must be communicated to patients in a cautious, empathic, and understandable manner to avoid causing psychological distress, embarrassment, confusion, or other untoward reactions (McFarlane et al., 1980; Miller et al., 1987).

Participant attendance at staffings might also inhibit free flow of information among staff, which is necessary to achieve productive aims. Treatment representatives, for example, may be reluctant to discuss their concerns about a participant's prognosis in front of the participant. Probation officers might similarly be reticent to recommend sanctions for participants in response to infractions. It is one thing for sanctions to be imposed by the team as a whole, but quite another for an individual staff member to be identified as the person who first proposed the sanction. Closed staffings allow team members to freely consider alternative courses of action that may or may not be adopted ultimately by the team.

Although staffings are presumptively closed, the judge and team may conclude they have a good reason for a participant to attend discussions related to that participant's case. For example, the team might wish to discuss highly sensitive matters with a participant in private, such as a history of childhood sexual abuse or positive HIV test result. Drug Courts are encouraged to include participants in staffings when clinically indicated or necessary to protect a participant from serious harm resulting from public disclosure of highly sensitive treatment information.

C. Sharing Information

Participants and staff rate communication among team members as one of the most important factors for success in Drug Courts (Frazer, 2006; Gallagher et al., 2015; Lloyd et al., 2014). Participants complain frequently that they are forced to repeat the same information to different professionals and to comply with excessive and inconsistent mandates stemming from different agencies (Goldkamp et al., 2002; Saum et al., 2002; Turner et al., 1999). Ongoing communication among staff ensures participants receive consistent messages, reduces unwarranted burdens on participants, and prevents participants from falling through the cracks or eluding responsibility for their actions by providing different information selectively to different team members.

Contrary to some misconceptions, the HIPAA and other applicable confidentiality statutes (e.g., Confidentiality of Substance Abuse Patient Records, 42 C.F.R. Part 2) do *not* prohibit treatment professionals or criminal justice professionals from sharing information related to substance abuse and mental health treatment (Matz, 2014; Meyer, 2011b). Rather, these statutes control how and under what circumstances such information may be disclosed (U.S. DHHS, 2003). Treatment professionals are generally permitted to share confidential treatment information with criminal justice professionals pursuant to a voluntary, informed, and competent waiver of a patient's confidentiality and privacy rights (45 C.F.R. §164.502(a)) or pursuant to a court order (45 C.F.R. §164.512(e)).

The scope of the disclosure must be limited to the minimum information necessary to achieve the intended aims of the disclosure (45 C.F.R. §§164.502(b) & 164.514(d)). In Drug Courts, team members may ordinarily share information pursuant to a valid waiver to the degree necessary to ensure that participants are progressing adequately in treatment and complying with other conditions of the program (Meyer,

2011b). At a minimum, the following data elements are required by all Drug Court team members to appraise participant progress and compliance or noncompliance with the conditions of Drug Court:

- Assessment results pertaining to a participant's eligibility for Drug Court and treatment and supervision needs
- Attendance at scheduled appointments
- Drug and alcohol test results, including efforts to defraud or invalidate said tests
- Attainment of treatment plan goals, such as completion of a required counseling regimen
- Evidence of symptom resolution, such as reductions in drug cravings or withdrawal symptoms
- Evidence of treatment-related attitudinal improvements, such as increased insight or motivation for change
- Attainment of Drug Court phase requirements, such as obtaining and maintaining employment or enrolling in an educational program
- Compliance with electronic monitoring, home curfews, travel limitations, and geographic or association restrictions
- Adherence to legally prescribed and authorized medically assisted treatments
- Procurement of unauthorized prescriptions for addictive or intoxicating medications
- Commission of or arrests for new offenses
- Menacing, threatening, or disruptive behavior directed at staff members, participants or other persons

To be legally valid, an informed consent document must specify what data elements may be shared, with whom, and for what authorized period of time (Meyer, 2011b). Therefore, the above data elements and any other information that may be shared among team members should be listed in releases of information or confidentiality waivers executed by Drug Court participants (Meyer, 2011b). If the scope of the disclosure is not enumerated clearly, then the waiver may not be knowing or informed—and thus may be legally invalid. Consent documents must also indicate which professionals are authorized to receive the information, what steps participants must take to revoke consent, and when the consent expires. Expiration of consent may be predicated upon a specific event, such as discharge from Drug Court, as opposed to a specific date or time frame (Meyer, 2011b). Finally, recipients of confidential information must be put on notice that they are only permitted to redisclose information to additional parties under carefully specified and approved conditions. MOUs between partner agencies—referred to as business associate contracts pursuant to HIPAA—must state clearly that confidential information may not be redisclosed to additional parties outside of the Drug Court without the express written permission of the participant and may not be used to prosecute new charges against the participant.

Assuming a participant has executed a valid waiver of his or her privacy and confidentiality rights, Drug Court team members are permitted, and indeed may be required, to share covered information in the course of performing their professional duties. Confidentiality and privacy rights belong to the participant, not to staff, and may be waived freely and voluntarily in exchange for receiving anticipated benefits, such as gaining access to effective treatment or avoiding a criminal record or jail sentence (Melton et al., 2007). Failing to abide by a valid confidentiality waiver could, under some circumstances, be a breach of a staff person's professional responsibilities to the participant.

Staff persons also have ethical obligations to other Drug Court team members. If a staff person knowingly withholds relevant information about a participant from other team members, this omission could inadvertently interfere with the participant's treatment goals, endanger public safety, or undermine the functioning of the Drug Court team. All agencies involved in the administration of a Drug Court should, therefore, execute MOUs specifying what data elements will be shared among team members (Harden & Fox, 2011). The data elements listed above might be included in such MOUs to clarify the obligations of each professional on the team.

If a staff person questions the validity or legality of a consent waiver, that staff person should raise this concern with the Drug Court team and make it clear that he or she may withhold relevant progress information until the matter is resolved. This course of action puts the Drug Court team on notice that important information may not be forthcoming and reduces the likelihood that mistaken actions will be taken based on erroneous or incomplete information.

Controversy surrounds the question of whether defense representatives should report infractions by participants to the Drug Court team. In most instances, infractions come to the attention of the team from sources other than defense counsel, such as positive drug tests or progress reports from treatment providers or probation officers. In some instances, however, participants may self-disclose infractions to defense representatives which would otherwise go undetected by the program.

Some defense experts advise against disclosing such communications because doing so may violate the attorney's ethical duty to advocate for the participant's stated legal interests, which are to be distinguished from the participant's *best* interests (Boldt, 1998; National Association of Criminal Defense Lawyers [NACDL], 2009). Other defense experts take the contrary position that withholding such information may undermine the defense representative's trustworthiness and credibility with the team. If team members know or suspect that defense counsel is shielding important information from them, they may discount recommendations from that defense expert as one-sided or nonobjective or may withhold information of their own (Tobin, 2012). In the absence of empirical evidence or legal precedent to guide the decision, defense representatives should make clear their position and the rationale for that position to participants and team members from the outset of each case (Freeman-Wilson et al., 2003). Participants have a right to know whether some confidences shared with defense representatives may be disclosed to other staff members, and team members have a right to know whether some information may not be available to them for decision making.

D. Team Communication and Decision Making

Before the advent of Drug Courts, studies of *courtroom workgroups* raised concerns about relying on multidisciplinary teams to manage criminal and civil cases. In response to overwhelming court dockets in the 1980s, some jurisdictions appointed teams of professionals—commonly including a judge, defense attorney, prosecutor, court clerk, probation officer, and bailiff—to process certain types of cases more efficiently, such as drug possession cases and child maltreatment cases. Observational studies revealed these workgroups tended to routinize their procedures to speed case processing, often at the expense of applying evidence-based practices or adapting dispositions to the needs and risk levels of litigants (Haynes et al., 2010; Knepper & Barton, 1997; Lipetz, 1980). Teaming up as a group did not necessarily improve outcomes and in some cases may have undermined litigants' due process rights. Drug Courts must not, in the interest of expediency, allow assembly-line procedures or groupthink mindsets to interfere with their adherence to due process and best practices.

Drug Courts are properly characterized as nonadversarial programs, meaning participants waive some, but not all, adversarial trial rights as a condition of entry, including the right to a speedy trial and to refuse to provide self-incriminating information (Hora & Stalcup, 2008; NADCP, 1997). Moreover, unlike traditional adversarial proceedings, the Drug Court judge speaks directly to participants rather than through legal counsel and takes an active role in supervising cases. The term nonadversarial does *not*, however, imply that team members relinquish their professional roles or responsibilities (Holland, 2010; Hora & Stalcup, 2008). Prosecutors continue to advocate on behalf of public safety, victim interests, and participant accountability; defense counsel continue to advocate for participants' legal rights; and treatment providers continue to advocate for effective and humane treatment (Freeman-Wilson et al., 2003; Holland, 2010; Tobin, 2012). In other words, the term *nonadversarial* does not have the same meaning as *nonadvocacy*. The principal distinction in Drug Courts is that advocacy occurs primarily in staffings as opposed to court hearings, reserving the greater share of court time for intervening with participants rather than arbitrating uncontested facts or legal issues (Christie, 2014; Portillo et al., 2013).

How Drug Court teams make decisions in this nonadversarial climate has constitutional implications. Due process and judicial ethics require Drug Court judges to exercise independent discretion when resolving factual controversies, ordering conditions of treatment and supervision, and administering sanctions and

incentives that affect participants' liberty interests (Hora & Stalcup, 2008; Meyer, 2011c; Meyer & Tauber, 2011). The judge may not delegate these decisions to the Drug Court team or acquiesce to majority rule [see Standard III, Roles and Responsibilities of the Judge]. The judge must, however, consider arguments from all sides of a controversy (typically from the defense and prosecution) before rendering a decision and must hear evidence from scientific experts if the subject matter of the controversy is beyond the common knowledge of laypersons (Hora & Stalcup, 2008; Meyer, 2011a). Information relating to addiction science and substance abuse treatment is typically beyond the knowledge of laypersons; therefore, this information must usually be introduced or explained by a qualified expert (e.g., Federal Rule of Evidence 702, 2015).

In Drug Courts, the multidisciplinary team serves essentially as a panel of "expert witnesses" providing legal and scientific expertise for the judge (Bean, 2002; Hora & Stalcup, 2008). Team members have an obligation to contribute relevant observations and insights and to offer suitable recommendations based on their professional knowledge, experience, and training. A team member who remains silent in staffings or defers habitually to group consensus is violating his or her professional obligations to participants and to the administration of justice (Freeman-Wilson et al., 2003; Holland, 2010; NACDL, 2009; Tobin, 2012). The judge may ultimately overrule a team member's assertions, but this fact does not absolve the team member from articulating and justifying an informed opinion.

Studies have identified effective communication strategies that can enhance team decision making in Drug Courts. For example, researchers have improved team decision-making skills in several Drug Courts using the NIATx (Network for the Improvement of Addiction Treatment) Organizational Improvement Model (Melnick et al., 2014a, 2014b; Wexler et al., 2012). The NIATx model seeks to create a climate of psychological safety by teaching team members to articulate divergent views in a manner that is likely to be heeded by fellow team members. Examples of NIATx techniques include the following (Melnick et al., 2014b):

- *Avoid Ego-Centered Communications*—Focus statements on the substantive issue at hand rather than attempting to be "right" or win an argument.
- *Avoid Downward Communication*—Ensure that all team members, regardless of status or authority, have an equal opportunity to speak.
- *Practice Attentive Listening*—Hear all aspects of a team member's statements before thinking about or forming a response.
- *Reinforce Others' Statements*—Express appreciation for a team member's input before making counterarguments or changing the subject.
- *Find Common Ground*—Acknowledge areas of agreement among team members before making counterarguments.
- *Reframe Statements Neutrally*—Restate a position in a manner that minimizes counterproductive affect such as anger or frustration.
- *Ensure Inclusiveness*—Ensure that all team members weigh in on subjects within their area of expertise or experience.
- *Show Understanding*—Restate others' positions to demonstrate accurate understanding.
- *Engage in Empathic Listening*—Imagine oneself in other team members' positions to understand issues from their perspective.
- *Sum Up*—The judge should recap the various arguments and positions, assure the team that all positions were considered carefully, and explain his or her rationale for reaching a conclusion or tabling the matter pending further information.

Preliminary studies in more than ten Drug Courts found that training Drug Court teams on the NIATx model enhanced team communication skills (Melnick et al., 2014b), increased staff job satisfaction (Melnick et al., 2014a), and improved program efficiency, leading to higher admission rates, shorter wait times for treatment, and reduced no-show rates at scheduled appointments (Wexler et al., 2012).

E. Status Hearings

Status hearings are critical components of Drug Courts (NADCP, 1997). In status hearings, participants interact with all team members in the same proceeding, the judge speaks personally with each participant, and incentives, sanctions and treatment adjustments are administered in accordance with participants' progress or lack thereof in treatment (Roper & Lessenger, 2007). A substantial body of research establishes convincingly that better outcomes are achieved when status hearings are held biweekly (every two weeks) or more frequently at least during the first phase of Drug Court (Carey et al., 2012; Cissner et al., 2013; Festinger et al., 2002; Jones, 2013; Marlowe et al., 2006, 2007; Mitchell et al., 2012; Rossman et al., 2011).[4]

Studies further reveal that consistent attendance by all team members at status hearings is associated with significantly better outcomes. A study of approximately seventy Drug Courts found that programs were 35% more cost-effective and 35% more effective at reducing crime when all team members—the judge, program coordinator, defense representative, prosecutor, probation officer, treatment representative, and law enforcement representative—attended status hearings regularly (Carey et al., 2012). When a treatment representative attended status hearings regularly, Drug Courts were nearly twice as effective at reducing crime and 80% more cost-effective, and when a representative from law enforcement attended hearings regularly, Drug Courts were over 80% more effective at reducing crime and 60% more cost-effective (Carey et al., 2008, 2012).

Although the judge typically controls most of the interactions during status hearings, observational studies reveal that other team members play an important role as well. Team members may report on participant progress, share their observations of participants, fill in missing information for the judge, offer praise and encouragement to participants, challenge inaccurate statements by participants, or make recommendations for suitable consequences to impose (Baker, 2013; Christie, 2014; Mackinem & Higgins, 2008; McPherson & Sauder, 2013; Portillo et al., 2013; Roper & Lessenger, 2007). Colloquially referred to as *courtroom as theater*, these interactions are often planned in advance during staffings to illustrate treatment-relevant concepts, prevent participants from fomenting disagreement among staff members, and demonstrate unity of purpose for the team as a whole (Satel, 1998; Tauber, 2011). In focus groups, participants rated interactions among staff during court sessions as informative and helpful to improving their performance (Goldkamp et al., 2002).

F. Team Training

Drug Courts represent a fundamentally new way of treating persons charged with drug-related offenses (Roper & Lessenger, 2007). Specialized knowledge and skills are required to implement these multifaceted programs effectively (Carey et al., 2012; Shaffer, 2010; Van Wormer, 2010). To be successful in their new roles, staff members require at least a journeyman's knowledge of best practices in a wide range of areas, including substance abuse and mental health treatment, complementary treatment and social services, behavior modification, community supervision, and drug and alcohol testing. Staff must also learn to perform their duties in a multidisciplinary environment, consistent with constitutional due process and the ethical mandates of their respective professions. These skills and knowledge sets are not taught in traditional law school, graduate school, or most continuing education programs (Berman & Feinblatt, 2005; Holland, 2010). Ongoing specialized training and supervision are needed for staff to achieve the goals of Drug Court and conduct themselves in an ethical, professional, and effective manner.

Preimplementation Trainings—In preimplementation trainings, staff meet for several days as a team to, among other things, develop a mission statement and goals and objectives for their program, learn from expert faculty about best practices in Drug Courts, and develop effective policies and procedures to govern their day-to-day operations (Hardin & Fox, 2011). A multisite study found that Drug Courts were nearly two and a half times more cost-effective and over 50% more effective at reducing recidivism when the teams participated in formal training prior to implementation (Carey et al., 2008, 2012). Drug Courts that

[4] This finding assumes the Drug Court is serving the appropriate target population of high-risk and high-need participants [see Standard I, Target Population].

did not receive preimplementation training produced outcomes that were negligibly different from traditional criminal justice approaches (Carey et al., 2008).

Continuing Education Workshops—Continuing education workshops are commonly delivered as part of national, regional, or state Drug Court training conferences or in stand-alone seminars. These workshops provide experienced Drug Court professionals with up-to-date knowledge about new research findings on best practices in Drug Courts. Studies consistently find that annual attendance by staff at training workshops is associated with significantly better outcomes. A multisite study involving more than sixty Drug Courts found that annual attendance at training conferences was the greatest predictor of program effectiveness (Shaffer, 2006, 2010). Another large-scale study found that regular participation in continuing education workshops was the greatest predictor of a program's adherence to the Drug Court model (Van Wormer, 2010). After taking continuing education into account, no other variable was independently or incrementally associated with adherence to the Drug Court model. This finding suggests that adherence to best practices may be mediated primarily through staff participation in continuing education workshops. The same study determined that regular attendance in continuing education workshops was also associated with better collaboration among Drug Court team members, increased job satisfaction by staff, greater perceived benefits of Drug Court, greater optimism about the effects of substance abuse treatment, and better perceived coordination between the criminal justice system and other social service and treatment systems (Van Wormer, 2010).

Tutorials for New Staff—Within five years, 30% to 60% of Drug Courts experience substantial turnover in key staff positions (Van Wormer, 2010). The highest turnover rates, commonly exceeding 50%, are among substance abuse and mental health treatment providers (Lutze & Van Wormer, 2007; McLellan et al., 2003; Taxman & Bouffard, 2003; Van Wormer, 2010). Evidence further reveals that staff turnover correlates significantly with downward drift in the quality of the services provided, meaning that services diverge increasingly from the Drug Court model as more staff positions turn over (Van Wormer, 2010).

Research has determined that Drug Courts are more effective when they provide introductory tutorials for new hires. A multisite study of approximately seventy Drug Courts found that programs were over 50% more effective at reducing recidivism when they routinely provided formal orientation training for new staff (Carey et al., 2012). Typically, the tutorials provide a *"Reader's Digest"* orientation to the Ten Key Components of Drug Courts (NADCP, 1997) and a synopsis of best practices associated with each component. The tutorials are not intended to take the place of formal continuing education workshops, but serve rather as a stopgap measure to prevent acute disruption in services and degradation of outcomes. To maintain effective outcomes over time, recent hires should attend formal training workshops as soon as practicable after assuming their new positions. Given the powerful influence of staff training on Drug Court outcomes (Carey et al., 2012; Shaffer, 2006, 2010; Van Wormer, 2010), a firm commitment to ongoing professional education is key to maintaining the success and integrity of Drug Courts.

REFERENCES

Baker, K.M. (2013). Decision making in a hybrid organization: A case study of a southwestern drug court treatment program. *Law and Social Inquiry*, *38*(1), 27–54.

Bean, P. (2002). Drug courts, the judge, and the rehabilitative ideal. In J.L. Nolan (Ed.), *Drug courts in theory and in practice* (pp. 235–245). New York: Aldine de Gruyter.

Berman, G., & Feinblatt, J. (2005). *Good courts: The case for problem-solving justice*. New York: New Press.

Berman, G., & Gold, E. (2012). Procedural justice from the bench: How judges can improve the effectiveness of criminal courts. *Judges' Journal, 51*(2), 20–22.

Boldt, R.C. (1998). Rehabilitative punishment and the Drug Treatment Court movement. *Washington University Law Review, 76*(4), 1205–1306.

Burke, K.S. (2010). Just what made drug courts successful? *New England Journal on Criminal & Civil Confinement, 36*(1), 39–58.

Carey, S.M., Finigan, M.W., & Pukstas, K. (2008). *Exploring the key components of drug courts: A comparative study of 18 adult drug courts on practices, outcomes and costs*. Portland, OR: NPC Research.

Carey, S.M., Mackin, J.R., & Finigan, M.W. (2012). What works? The ten key components of drug court: Research-based best practices. *Drug Court Review*, *8*(1), 6–42.

Christie, N.V. (2014, November 24). Understanding the role of cross-sector collaborations on the success of Florida's drug courts. *Criminal Justice Policy Review: Online*. doi:10.1177/0887403414559044

Cissner, A., Rempel, M., Franklin, A.W., Roman, J.K., Bieler, S., Cohen, R., & Cadoret, C.R. (2013). *A statewide evaluation of New York's adult drug courts: Identifying which policies work best*. New York: Center for Court Innovation.

FederalEvidence.com. (2015). Federal Rule of Evidence 2015. Arlington, VA: Author. *Available at* http://federalevidence.com /downloads/rules.of.evidence.pdf

Festinger, D.S., Marlowe, D.B., Lee, P.A., Kirby, K.C., Bovasso, G., & McLellan, A.T. (2002). Status hearings in drug court: When more is less and less is more. *Drug & Alcohol Dependence, 68*(2), 151–157.

Frazer, M.S. (2006). *The impact of the community court model on defendant perceptions of fairness: A case study at the Red Hook Community Justice Center*. New York: Center for Court Innovation.

Freeman-Wilson, K., Sullivan, R., & Weinstein, S.P. (2003). *Critical issues for defense attorneys in drug court* [Monograph Series No. 4]. Alexandria, VA: National Drug Court Institute.

Gallagher, J.R., Nordberg, A., & Kennard, T. (2015). A qualitative study assessing the effectiveness of the key components of a drug court. *Alcoholism Treatment Quarterly, 33*(1), 64–81.

Goldkamp, J.S., White, M.D., & Robinson, J.B. (2002). An honest chance: Perspectives on drug courts. *Federal Sentencing Reporter, 14*(6,) 369–372.

Gottfredson, D.C., Kearley, B.W., Najaka, S.S., & Rocha, C.M. (2007). How drug treatment courts work: An analysis of mediators. *Journal of Research on Crime & Delinquency, 44*(1), 3–35.

Harberts, H. (2011). Community supervision. In D.B. Marlowe & W.G. Meyer (Eds.), *The drug court judicial benchbook* (pp. 97–111). Alexandria, VA: National Drug Court Institute. *Available at* http://www.ndci.org/sites/default/files/nadcp /14146 _NDCI_Benchbook_v6.pdf

Hardin, C., & Fox, C. (2011). Getting started. In D.B. Marlowe & W.G. Meyer (Eds.), *The drug court judicial benchbook* (pp. 19–43). Alexandria, VA: National Drug Court Institute. *Available at* http://www.ndci.org/sites/default/files/nadcp/14146 _NDCI_Benchbook_v6.pdf

Haynes, S.H., Ruback, B., & Cusick, G.R. (2010). Courtroom workgroups and sentencing: The effects of similarity, proximity, and stability. *Crime & Delinquency, 56*(1), 126–161.

Holland, P. (2010). Lawyering and learning in problem-solving courts. *Washington University Journal of Law and Policy, 34*(1), 185–238.

Hora, P.F., & Stalcup, T. (2008). Drug Treatment Courts in the twenty-first century: The evolution of the revolution in problem-solving courts. *Georgia Law Review, 42*(3), 717–811.

Jones, C. (2013). Early-phase outcomes from a randomized trial of intensive judicial supervision in an Australian drug court. *Criminal Justice & Behavior, 40*(4), 453–468.

Knepper, P.E., & Barton, S.M. (1997). The effect of courtroom dynamics on child maltreatment proceedings. *Social Service Review, 71*(2), 288–308.

Lajeunesse, R.C., & Lussier, M.T. (2010). Therapeutic privilege: Between the ethics of lying and the practice of truth. *Journal of Medical Ethics, 36*(6), 353–357.

Lipetz, M.J. (1980). Routine and deviations: The strength of the courtroom workgroup in a misdemeanor court. *International Journal of the Sociology of Law, 8*(1), 47–60.

Lloyd, M.H., Johnson, T., & Brook, J. (2014). Illuminating the black box from within: Stakeholder perspectives on family drug court best practices. *Journal of Social Work Practice in the Addictions, 14*(4), 378–401.

Lutze, F.E., & Van Wormer, J.G. (2007). The nexus between drug and alcohol treatment program integrity and drug court effectiveness: Policy recommendations for pursuing success. *Criminal Justice Policy Review, 18*(3), 226–245.

Mackinem, M.B., & Higgins, P. (2008). *Drug courts: Constructing the moral identity of drug offenders*. Springfield, IL: Charles C. Thomas.

Marlowe, D.B., Festinger, D.S., Dugosh, K.L., Lee, P.A., & Benasutti, K.M. (2007). Adapting judicial supervision to the risk level of drug offenders: Discharge and six-month outcomes from a prospective matching study. *Drug & Alcohol Dependence, 88*(Suppl. 2) S4–S13.

Marlowe, D.B., Festinger, D.S., Lee, P.A., Dugosh, K.L., & Benasutti, K.M. (2006). Matching judicial supervision to clients' risk status in drug court. *Crime & Delinquency, 52*(1), 52–76.

Matz, A.K. (2014). *A note on HIPAA and 42 CFR Part 2: Dispelling the myths about justice-involved information sharing.* Washington, DC: Council of State Governments & American Probation and Parole Association.

McFarlane, W.J., Bowman, R.G., & MacInnes, M. (1980). Patient access to hospital records: A pilot project. *Canadian Journal of Psychiatry, 25*(6), 497.

McKaskle v. Wiggins, 465 U.S. 168, 104 S. Ct. 944, 79 L.Ed.2d 122 (1984).

McLellan, A.T., Carise, D., & Kleber, H.D. (2003). Can the national addiction treatment infrastructure support the public's demand for quality care? *Journal of Substance Abuse Treatment, 25*(2), 117–121.

McPherson, C.M., & Sauder, M. (2013). Logics in action: Managing institutional complexity in a drug court. *Administrative Science Quarterly, 58*(2), 165–198. doi:10.1177/0001839213486447

Melnick, G., Wexler, H.K., & Rajan, S. (2014a). Measuring team members' satisfaction in drug courts: An instrument to gauge the component disciplines in drug court. *Drug Court Review, 9*(1), 56–73.

Melnick, G., Wexler, H.K., & Zehner, M. (2014b). Communication in drug courts: The consensus-building enhancement. *Drug Court Review, 9*(1), 99–116.

Melton, G.B., Petrila, J., Poythress, N.G., & Slobogin, C. (2007). *Psychological evaluations for the courts: A handbook for mental health professionals and lawyers* (3rd ed.). New York: Guilford Press.

Menefield v. Borg, 881 F.2d 696 (9th Cir. 1989).

Meyer, W. (2011a). Constitutional and legal issues in drug courts. In D.B. Marlowe & W.G. Meyer (Eds.), *The drug court judicial benchbook* (pp. 159–180). Alexandria, VA: National Drug Court Institute. *Available at* http://www.ndci.org/sites/default/files/nadcp/14146_NDCI_Benchbook_v6.pdf

Meyer, W. (2011b). Confidentiality. In D.B. Marlowe & W.G. Meyer (Eds.), *The drug court judicial benchbook* (pp. 181–194). Alexandria, VA: National Drug Court Institute.

Meyer, W. (2011c). Ethical obligations of judges in drug courts. In D.B. Marlowe & W.G. Meyer (Eds.), *The drug court judicial benchbook* (pp. 195–212). Alexandria, VA: National Drug Court Institute. .

Meyer, W.G., & Tauber, J. (2011). The roles of the drug court judge. In D.B. Marlowe & W.G. Meyer (Eds.), *The drug court judicial benchbook* (pp. 45–61). Alexandria, VA: National Drug Court Institute.

Miller, R.D., Morrow, B., Kaye, M., & Maier, G. (1987). Patient access to medical records in a forensic center: A controlled study. *Hospital and Community Psychiatry, 38*(10), 1081–1085.

Mitchell, O., Wilson, D.B., Eggers, A., & MacKenzie, D.L. (2012). Assessing the effectiveness of drug courts on recidivism: A meta-analytic review of traditional and nontraditional Drug Courts. *Journal of Criminal Justice, 40*(1), 60–71.

National Association of Criminal Defense Lawyers. (2009). *America's problem-solving courts: The criminal costs of treatment and the case for reform*. Washington, DC: Author.

National Association of Drug Court Professionals. (1997). *Defining drug courts: The key components*. (NCJ No. 205621). Washington, DC: Author.

National Association of Drug Court Professionals. (2009). Position statement of the Board of Directors on defense counsel in drug courts. *Retrieved from* http://www.allrise.org/sites/default/files/nadcp/NADCP%20Board%20Position%20Statement%20-%20Defense%20Counsel%20in%20Drug%20Court%2006-10-09.pdf

Portillo, S., Rudes, D.S., Viglione, J., & Nelson, M. (2013). Front-stage stars and backstage producers: The role of judges in problem-solving courts. *Victims and Offenders, 8*(1), 1–22.

Robinson v. Ignacio, 360 F.3d 1044 (9th Cir. 2004).

Roper, G.F., & Lessenger, J.E. (2007). Drug court organization and operations. In J.E. Lessenger & G.F. Roper (Eds.), *Drug courts: A new approach to treatment and rehabilitation* (pp. 284–300). New York: Springer.

Ross, S.E., & Lin, C.T. (2003). The effects of promoting patient access to medical records: A review. *Journal of the American Medical Association, 10*(2), 129–138.

Rossman, S.B., Rempel, M., Roman, J.K., Zweig, J.M., Lindquist, C.H., Green, M.,…Farole, D.J. (2011). *The multi-site adult drug court evaluation: The impact of drug courts* (Vol.4). Washington, DC: Urban Institute Justice Policy Center. *Available at* https://www.ncjrs.gov/pdffiles1/nij/grants/237112.pdf

Satel, S. (1998). Observational study of courtroom dynamics in selected drug courts. *National Drug Court Institute Review, 1*(1), 43–72.

Saum, C.A., Scarpitti, F.R., Butzin, C.A., Perez, V.W., Jennings, D., & Gray, A.R. (2002). Drug court participants' satisfaction with treatment and the court experience. *Drug Court Review, 4*(1), 39–81.

Sergeant, H. (1986). Should psychiatric patients be granted access to their hospital records? *Lancet, 328*(8519), 1322–1325.

Shaffer, D.K. (2006). Reconsidering Drug Court Effectiveness: A Meta-Analytic Review (Doctoral dissertation, University of Cincinnati). *Retrieved from* https://etd.ohiolink.edu/ap:10:0::NO:10:P10_ACCESSION_NUM:ucin1152549096

Shaffer, D.K. (2010). Looking inside the black box of drug courts: A meta-analytic review. *Justice Quarterly, 28*(3), 493–521.

Short, D. (1986). Some consequences of granting patients access to consultants' records. *Lancet, 327*(8493), 1316–1318.

Stasiewicz, P.R., Vincent, P.C., Bradizza, C.M., Connors, G.J., Maisto, S.A., & Mercer, N.D. (2008). Factors affecting agreement between severely mentally ill alcohol abusers' and collaterals' reports of alcohol and other substance abuse. *Psychology of Addictive Behaviors, 22*(1), 78–87.

State v. Pitts, 131 Haw. 537 (2014).

State of Washington v. Sykes, slip op. no. 87946–0, consolidated with 87947–8 (S. Ct. Wash. en banc, 12/18/2014).

Tauber, J. (2011). Drug courts: Back to the future. In D.B. Marlowe & W.G. Meyer (Eds.), *The drug court judicial benchbook* (pp. 7–17). Alexandria, VA: National Drug Court Institute. *Available at* http://www.ndci.org/sites/default/files/nadcp/14146_NDCI_Benchbook_v6.pdf

Taxman, F.S., & Bouffard, J.A. (2003). Substance abuse counselors' treatment philosophy and the content of treatment services provided to offenders in drug court programs. *Journal of Substance Abuse Treatment, 25*(2), 75–84.

Taylor, P. (2014). Building recovery-oriented systems of care for drug court participants. *Drug Court Practitioner Fact Sheet, 9*(1), 1–8. Alexandria, VA: National Drug Court Institute.

Tobin, M. (2012). Participation of defense attorneys in drug courts. *Drug Court Review, 8*(1), 96–130.

Turner, S., Greenwood, P., Fain, T., & Deschenes, E. (1999). Perceptions of Drug Court: How offenders view ease of program completion, strengths and weaknesses, and the impact on their lives. *National Drug Court Institute Review, 2*(1), 61–85.

U.S. Department of Health & Human Services. (2003). *Summary of the HIPAA privacy rule* [Office for Civil Rights Policy Brief]. Washington, DC: Author.

Van Wormer, J. (2010). *Understanding operational dynamics of Drug Courts* (Doctoral dissertation, University of Washington). *Retrieved from* http://research.wsulibs.wsu.edu:8080/xmlui/bitstream/handle/2376/2810/vanWormer_wsu_0251E_10046.pdf?sequence=1

Westin, A.F. (1977). Medical records: Should patients have access? *Hastings Center Report, 7*(6), 23–28.

Wexler, H.K., Zehner, M., & Melnick, G. (2012). Improving Drug Court operations: NIATx organizational improvement model. *Drug Court Review, 8*(1), 80–95.

Wooten v. Duane Reade, 2009 U.S. Dist. LEXIS 14724 (E.D. N.Y., 2009).

IX. CENSUS AND CASELOADS

The Drug Court serves as many eligible individuals as practicable while maintaining continuous fidelity to best practice standards.

A. Drug Court Census

B. Supervision Caseloads

C. Clinician Caseloads

A. Drug Court Census

The Drug Court does not impose arbitrary restrictions on the number of participants it serves. The Drug Court census is predicated on local need, obtainable resources, and the program's ability to apply best practices. When the census reaches 125 active[5] participants, program operations are monitored carefully to ensure they remain consistent with best practice standards. If evidence suggests some operations are drifting away from best practices, the team develops a remedial action plan and timetable to rectify the deficiencies and evaluates the success of the remedial actions.

B. Supervision Caseloads

Caseloads for probation officers or other professionals responsible for community supervision of participants must permit sufficient opportunities to monitor participant performance, apply effective behavioral consequences, and report pertinent compliance information during pre-court staff meetings and status hearings. When supervision caseloads exceed thirty active participants per supervision officer, program operations are monitored carefully to ensure supervision officers can evaluate participant performance accurately, share significant observations with team members, and complete other supervisory duties as assigned. Supervision caseloads do not exceed fifty active participants per supervision officer.

C. Clinician Caseloads

Caseloads for clinicians must permit sufficient opportunities to assess participant needs and deliver adequate and effective dosages of substance abuse treatment and indicated complementary services. Program operations are monitored carefully to ensure adequate services are delivered when caseloads exceed the following thresholds:

- 50 active participants for clinicians providing clinical case management[6]

---

[5] Cases are considered to be active if participants are receiving treatment or supervision services from the Drug Court. Participants who have absconded from the program or are continuing on probation but no longer receiving Drug Court services are not considered active.

[6] Clinical case management includes assessing participant needs, brokering referrals for indicated services, coordinating care between partner agencies, and reporting progress information to the Drug Court team (Braude, 2005; Monchick et al., 2006; Rodriguez, 2011). Clinical case managers may also represent treatment concerns during pre-court staff meetings and status

- 40 active participants for clinicians providing individual therapy or counseling
- 30 active participants for clinicians providing both clinical case management and individual therapy or counseling

COMMENTARY

A. Drug Court Census

Drug Courts serve fewer than 10% of adults in the criminal justice system in need of their services (Bhati et al., 2008; Huddleston & Marlowe, 2011). An important goal for the Drug Court field is to take Drug Courts to scale and serve every drug-addicted person in the criminal justice system who meets evidence-based eligibility criteria for the programs (Fox & Berman, 2002). Putting arbitrary restrictions on the size of the Drug Court census unnecessarily reduces the program's impact on public health and public safety.

Not all Drug Courts, however, may have adequate resources to increase capacity while maintaining fidelity to best practices. Surveys of judges and other criminal justice professionals consistently identify insufficient personnel and other resources as the principal barrier preventing Drug Courts from expanding to serve more people (Center for Court Innovation, n.d.; Farole, 2006, 2009; Farole et al., 2005; Huddleston & Marlowe, 2011). Resource limitations may put some Drug Courts in the challenging position of needing to choose between diluting their services to treat more people or turning away deserving individuals.

Evidence suggests expanding Drug Court capacity without sufficient resources can interfere with adherence to best practices. A multisite study of approximately seventy Drug Courts found a significant inverse correlation between the size of the Drug Court census and effects on criminal recidivism (Carey et al., 2008, 2012a). On average, programs evidenced a steep decline in effectiveness when the census exceeded approximately 125 participants. Drug Courts with fewer than 125 participants were over five times more effective at reducing recidivism than Drug Courts with more than 125 participants (Carey et al., 2012a).

Further analyses uncovered a likely explanation for this finding: Drug Courts with more than 125 participants were less likely to follow best practices than Drug Courts with fewer participants. Specifically, when the census exceeded 125 participants, the following was observed (Carey et al., 2012b):[7]

- Judges spent approximately half as much time interacting with participants in court.
- Team members were less likely to attend pre-court staff meetings.
- Treatment and law enforcement representatives were less likely to attend status hearings.
- Drug and alcohol testing occurred less frequently.
- Treatment agencies were less likely to communicate with the court about participant performance via email or other electronic means.
- Participants were treated by a large number of treatment agencies with divergent practices and expectations.
- Team members were less likely to receive training on Drug Court best practices.

---

hearings. Some court personnel or criminal justice professionals may be referred to as case managers or court case managers to be distinguished from clinical case managers. Court case managers may screen participants and refer them, when indicated, for more in-depth clinical assessments. These professionals do not provide clinical case management because they are not trained or qualified to administer clinical assessments, interpret assessment results, coordinate treatment delivery, or gauge treatment progress.

[7] All comparisons statistically significant at $p < .05$.

These findings are merely correlations and do not prove that a large census produces poor outcomes. Most Drug Courts in the study were staffed by a single judge and a small team of roughly four to five other professionals overseeing a single court docket. Drug Courts can serve far more than 125 participants with effective results if the programs have sufficient personnel and resources to accommodate larger numbers of individuals. In fact, studies have reported positive outcomes for well-resourced Drug Courts serving more than 400 participants (Carey et al., 2012a; Cissner et al., 2013; Marlowe et al., 2008; Shaffer, 2010).

Nevertheless, the above results raise a red flag that as the census increases, Drug Courts may have greater difficulty delivering the quantity and quality of services required to achieve effective results. Therefore, when the Drug Court census reaches 125 active participants, this milestone should trigger a careful reexamination of the program's adherence to best practices. For example, staff should monitor Drug Court operations to ensure the judge is spending at least three minutes interacting with each participant in court [see Standard III, Roles and Responsibilities of the Judge], drug and alcohol testing is being performed randomly at least twice per week [see Standard VII, Drug and Alcohol Testing], team members are attending pre-court staff meetings and status hearings on a consistent basis [see Standard III and Standard VIII, Multidisciplinary Team], and team members are receiving up-to-date training on best practices [see Standards III and VIII]. If the results of this reexamination suggest some operations are drifting away from best practices, the team should develop a remedial action plan and timetable to rectify the deficiencies and evaluate the success of the remedial actions. For example, the Drug Court might need to hire additional staff to ensure it has manageable participant-to-staff caseloads, schedule status hearings on more days of the week, purchase more drug and alcohol tests, or schedule more continuing-education workshops for staff.

Studies have not determined whether censuses greater than 125 participants should trigger additional reexaminations of adherence to best practices. Until research addresses this question, at a minimum Drug Courts are advised to reexamine adherence to best practices when the census increases by successive increments of 125 participants.

B. Supervision Caseloads

In most Drug Courts, probation officers or pretrial services officers are responsible for supervising participants in the community; however, some Drug Courts may rely on law enforcement or specially trained court case managers to provide community supervision. Duties of the supervision officer may include performing drug and alcohol testing, conducting home and employment visits, enforcing curfews and geographic restrictions, and delivering cognitive-behavioral interventions designed to improve participants' problem-solving skills or alter dysfunctional criminal-thinking patterns (Harberts, 2011).

No study has examined the influence of supervision caseloads in Drug Courts. However, many studies have examined supervision caseloads in the context of adult probation. Early studies found that small probation caseloads were paradoxically associated with *increased* rates of technical violations and arrests for new offenses (Gendreau et al., 2000a; Petersilia, 1999; Turner et al., 1992). This counterintuitive finding was attributable to increased surveillance of the probationers coupled with a failure to apply evidence-based practices. Smaller caseloads led to greater detection of infractions, but most infractions received excessively punitive responses, such as probation revocations, rather than evidence-based treatment or gradually escalating incentives and sanctions (Andrews et al., 1990; Gendreau et al., 2000b; Hollin, 1999).

Recent studies have reported improved outcomes when reduced probation caseloads were combined with evidence-based cognitive-behavioral counseling, motivational interviewing, or gradually escalating incentives and sanctions (Jalbert & Rhodes, 2012; Jalbert et al., 2010, 2011; Paparozzi & Gendreau, 2005; Pearson & Harper, 1990; Worrall et al., 2004). Results of these newer studies confirm that detecting infractions alone is insufficient to improve outcomes. To achieve positive results, probation officers must respond to infractions and achievements by delivering effective behavioral contingencies (incentives and sanctions) and ensuring probationers receive effective and adequate evidence-based treatment and social services (Center for Effective Public Policy, 2014; Paparozzi & Hinzman, 2005; Skeem & Manchak, 2008).

Identifying optimal probation caseloads has been a challenging task. In 1990, the American Probation and Parole Association (APPA, 1991) issued caseload guidelines derived from expert consensus. The 1990

guidelines recommended caseloads of 30:1 for high-risk probationers who have a substantial likelihood of failing on probation or committing a new offense (Table 2). In 2006, the APPA guidelines were amended, in part, to add a new category for intensive supervised probation (ISP). ISP was designed for probationers who are both high risk and high need, meaning they pose a substantial risk of failing on probation and also have serious treatment or social-service needs (Petersilia, 1999). Because ISP and Drug Courts are both intended for high-risk and high-need individuals, recommendations for ISP may be particularly instructive for Drug Court best practices. Based on expert consensus, the 2006 APPA amendments recommended caseloads of 20:1 for high-risk and high-need probationers on ISP, and increased the recommended caseloads to 50:1 for moderate- and high-risk probationers who do not have serious treatment or social-service needs (Byrne, 2012; DeMichele, 2007).

TABLE 2	APPA* RECOMMENDED CASELOADS	
Probationer Risk and Need Level	1990 Guidelines	2006 Guidelines
ISP:† high risk and high need	NR§	20:1
High risk	30:1	50:1
Moderate risk	60:1	50:1
Low risk	120:1	200:1

*American Probation and Parole Association
†Intensive supervised probation
§Not reported

Sources: APPA (1991); Byrne (2012); DeMichele (2007)

Recent studies examined the effects of adhering to the 2006 APPA guidelines. A randomized experiment compared the services received and outcomes achieved when probation officers had reduced caseloads of approximately 50:1 for moderate and high-risk probationers as compared to typical probation caseloads of approximately 100:1 (Jalbert & Rhodes, 2012). Results confirmed that probationers on 50:1 caseloads received significantly more probation office sessions, field visits, employer contacts, telephone check-ins, and substance abuse and mental health treatment (Jalbert & Rhodes, 2012). As a consequence of receiving more services, they also had significantly better probation outcomes, including fewer positive drug tests and other technical violations (Jalbert & Rhodes, 2012). Probation officers with caseloads substantially above 50:1 had considerable difficulty accomplishing their core missions of monitoring probationers closely and reducing technical violations.

Another quasi-experimental study examined the effects of reducing caseloads from 50:1 to 30:1 for high-risk and high-need probationers on ISP (Jalbert et al., 2010). A 30:1 caseload is greater than the APPA recommended guideline of 20:1 for ISP, but is considerably smaller than typical probation caseloads of 100:1 (Bonta et al., 2008; Paparozzi & Hinzman, 2005) and recommended caseloads of 50:1 for most high-risk probationers (Byrne, 2012). Results confirmed that probationers on 30:1 caseloads had more frequent and longer contacts with their probation officers, and received more specialized services designed to reduce their risk to public safety, including behavior therapy, domestic-violence counseling, spousal-batterer interventions, and sex-offender treatment (Jalbert et al., 2010). Most striking, probationers on 30:1 caseloads had significantly lower recidivism rates lasting for at least two and a half years, including fewer new arrests for drug, property, and violent crimes (Jalbert et al., 2010).

Taken together, the weight of scientific evidence (Jalbert & Rhodes, 2012; Jalbert et al., 2011) and expert consensus (APPA, 1991; Byrne, 2012; DeMichele, 2007) suggests supervision officers are unlikely to manage high-risk cases effectively and reduce technical violations when their caseloads exceed 50:1. Supervision officers in Drug Courts are unlikely to accomplish their core functions of monitoring participants accurately, applying effective behavioral consequences, and sharing important compliance information with Drug Court team members if their caseloads exceed this critical threshold.

Research in ISP programs suggests long-term reductions in criminal recidivism are most likely to be achieved for high-risk and high-need participants when caseloads stay at or below 30:1 (Jalbert et al., 2010). Whether 30:1 caseloads are required similarly for Drug Courts is an open question. Drug Courts

include several components not encompassed by ISP, which may enhance the influence of supervision officers. For example, Drug Court participants are supervised and treated by a multidisciplinary team of professionals and attend status hearings in court on a frequent basis. Larger caseloads may be manageable for supervision officers in light of these additional service elements. Until research resolves the issue, Drug Courts are advised to monitor their operations carefully when caseloads for supervision officers exceed 30:1; caseloads should never exceed a 50:1 ratio. Assurance is needed that supervision officers can monitor participant performance effectively, contribute critical observations and information during pre-court staff meetings and status hearings, and complete other assigned duties such as performing drug and alcohol testing, conducting field visits, and delivering cognitive-behavioral criminal-thinking interventions.

Bear in mind these caseload guidelines assume the supervision officer is assigned principally to Drug Court and is not burdened substantially with other professional obligations. Smaller caseloads may be required if supervision officers are also managing caseloads outside of Drug Court or if they have supplementary administrative or managerial duties in addition to supervising Drug Court participants.

C. Clinician Caseloads

In Drug Courts, addiction counselors, social workers, psychologists, or clinical case managers are typically responsible for assessing participant needs, delivering or overseeing the delivery of treatment services, charting treatment progress, and reporting progress information to the Drug Court team (Lutze & Van Wormer, 2007; Shaffer, 2010; Van Wormer, 2010). Outcomes are significantly better in Drug Courts when participants meet individually with one of these clinicians on a weekly basis for at least the first phase of the program [see Standard V, Substance Abuse Treatment and Standard VI, Complementary Treatment and Social Services].

National studies of outpatient individual substance abuse treatment consistently find that the size of clinician caseloads is inversely correlated with patient outcomes and clinician job performance (Hser et al., 2001; McCaughrin & Price, 1992; Stewart et al., 2004; Vocisano et al., 2004; Woodward et al., 2006). As caseloads increase, patients receive fewer services, patients are more likely to abuse illicit substances, clinicians are more likely to behave punitively toward patients, and clinicians are more likely to report significant job burnout and dissatisfaction (King et al., 2004; Stewart et al., 2004). Comparable studies are lacking for residential substance abuse treatment and for group clinicians who deliver services to several participants simultaneously.

Determining appropriate caseloads for clinicians in Drug Courts depends largely on their role and the scope of their responsibilities:

- Clinical Case Management Role—Some clinicians in Drug Courts serve principally as clinical case managers, assessing participant needs, brokering referrals for services, and reporting progress information to the Drug Court team (Monchick et al., 2006). They may also represent treatment concerns during pre-court staff meetings and status hearings.
- Treatment Provider Role—Some clinicians serve principally as treatment providers, administering individual therapy or counseling and perhaps facilitating or cofacilitating group interventions (Cissner et al., 2013; Zweig et al., 2012). They may also provide or refer participants for indicated complementary services, such as mental health treatment or vocational counseling.
- Combined Clinical Case Management and Treatment Provider Roles—Some clinicians serve both clinical case management and treatment provider functions. In addition to providing individual therapy or counseling, they are responsible for assessing participant needs, referring participants for complementary services, coordinating care between multiple service providers, reporting progress to the Drug Court team, and representing treatment concerns during pre-court staff meetings and status hearings (Braude, 2005; Monchick et al., 2006).

National practitioner organizations have published broad caseload guidelines based in part on these professional roles and responsibilities (Case Management Society of America & National Association of Social Workers, 2008; North Carolina Administrative Office of the Courts, 2010; Rodriguez, 2011). These guidelines have not been validated empirically in terms of their effects on outcomes. Rather, they are

derived from expert consensus about heavy caseloads that are likely too large to deliver adequate services or that contribute to staff burnout and job dissatisfaction. The guidelines focus exclusively on individual counseling and clinical case management. Comparable guidelines for group counselors have not been published. Table 3 summarizes the consensus conclusions.

TABLE 3 CASELOAD GUIDELINES DERIVED FROM EXPERT CONSENSUS

Principal Role and Responsibilities	Caseload	Reference
Clinical case management	50:1 to 75:1	Rodriguez (2011)
Individual therapy or counseling	40:1 to 50:1	CMSA* & NASW† (2008) Hromco et al. (2003)
Combination of clinical case management and individual therapy or counseling	30:1	CMSA & NASW (2008) NCAOC§ (2010)

*Case Management Society of America
†National Association of Social Workers
§North Carolina Administrative Office of the Courts

To reiterate, these guidelines are derived from expert consensus and have not been validated against outcomes. Moreover, professional roles and responsibilities are rarely so clearly delineated in day-to-day Drug Court operations. Clinicians in Drug Courts may provide clinical case management for some participants and therapy or counseling for others, may have a mixture of individual and group treatment responsibilities, and may have other nonclinical duties, such as drug and alcohol testing, that reduce the time they have available for clinical assessment, treatment, or case management. Caseload expectations need to be adjusted in light of actual job responsibilities.

Nevertheless, these guidelines should serve as broad milestones to alert Drug Courts to the possibility of clinician overload and the need to audit their operations to ensure adequate services are being delivered. Because Drug Courts serve high-risk and high-need individuals, programs are advised to reexamine adherence to best practices when clinician caseloads reach the lowest ratios reported in Table 3. For example, when clinical case management caseloads exceed 50:1, individual counseling caseloads exceed 40:1, or combined caseloads exceed 30:1, staff should monitor Drug Court operations to ensure participants are being assessed appropriately for risk and need [see Standard I, Target Population], participants are meeting individually with a clinician on a weekly basis for at least the first phase of treatment [see Standard V, Substance Abuse Treatment and Standard VI, Complementary Treatment and Social Services], participants are receiving at least 200 hours of cognitive-behavioral treatment [see Standard V], and clinicians are providing reliable and timely progress information to the Drug Court team [see Standard VIII, Multidisciplinary Team]. Drug Courts are unlikely to achieve the goals of rehabilitating participants and reducing crime if clinicians are spread too thin to assess and meet participants' service needs.

REFERENCES

American Probation and Parole Association. (1991). Caseload standards: APPA issues committee report. *APPA Perspectives*, (Summer), 34–36. *Available at* https://www.appa-net.org/eweb/docs/APPA/stances/ip_CS.pdf

Andrews, D.A., Zinger, I., Hoge, R.D., Bonta, J., Gendreau, P., Cullen, F.T. (1990). Does correctional treatment work? A clinically relevant and psychologically informed meta-analysis. *Criminology, 28*(3), 369–404.

Bhati, A.S., Roman, J.K., & Chalfin, A. (2008). *To treat or not to treat: Evidence on the prospects of expanding treatment to drug-involved offenders.* Washington, DC: The Urban Institute.

Bonta, J., Rugge, T., Scott, T., Bourgon, G., & Yessine, A.K. (2008). Exploring the black box of community supervision. *Journal of Offender Rehabilitation, 47*(3), 248–270.

Braude, L. (2005). The Cook County Mental Health Court: Development, implementation, and initial implications. *Offender Substance Abuse Report, 5*(5), 67–76.

Byrne, J.M. (2012). New directions in community supervision: Should we target high risk offenders, high risk times, and high risk locations? *European Journal of Probation, 4*(2), 77–101.

Carey, S.M., Finigan, M.W., & Pukstas, K. (2008). *Exploring the key components of drug courts: A comparative study of 18 adult drug courts on practices, outcomes and costs*. Portland, OR: NPC Research. *Available at* http://www.npcresearch.com /Files/NIJ_Cross-site_Final_Report_0308.pdf

Carey, S.M., Mackin, J.R., & Finigan, M.W. (2012a). What works? The ten key components of drug court: Research-based best practices. *Drug Court Review*, *8*(1), 6–42.

Carey, S.M., Mackin, J.R., & Finigan, M.W. (2012b, May/June). *Top 10 drug court best practices and more! What works? Findings from the latest research*. Symposium conducted at the National Association of Drug Court Professionals 18th Annual Training Conference, Nashville, TN.

Case Management Society of America, & National Association of Social Workers. (2008). *Case management caseload concept paper: Proceedings of the Caseload Work Group*. Little Rock, AR: Author. *Available at* http://www.cmsa.org/portals/0 /pdf /CaseloadCalc.pdf

Center for Court Innovation. (n.d.). Researchers, practitioners and the future of drug courts. *Retrieved from* http://www.courtinnovation .org/research/researchers-practitioners-and-future-drug-courts

Center for Effective Public Policy. (2014). *Dosage probation: Rethinking the structure of probation sentences.* Silver Spring, MD: Author.

Cissner, A., Rempel, M., Franklin, A.W., Roman, J.K., Bieler, S., Cohen, R., & Cadoret, C.R. (2013). *A statewide evaluation of New York's adult drug courts: Identifying which policies work best*. New York: Center for Court Innovation.

DeMichele, M.T. (2007). *Probation and parole's growing caseloads and workload allocation: Strategies for managerial decision making.* Lexington, KY: American Probation & Parole Association. *Available at* http://www.appa-net.org/eweb/docs/appa/pubs/SMDM.pdf

Farole, D.J. (2006). *The challenges of going to scale: Lessons from other disciplines for problem-solving courts*. New York, NY: Center for Court Innovation.

Farole, D.J. (2009). Problem solving and the American bench: A national survey of trial court judges. *Justice System Journal, 30*(1), 50–69.

Farole, D.J., Puffett, N., Rempel, M., & Byrne, F. (2005). Applying problem-solving principles in mainstream courts: Lessons for state courts. *Justice System Journal, 26*(1), 57–75.

Fox, A., & Berman, G. (2002). Going to scale: A conversation about the future of drug courts. *Court Review, 39*(3), 4–13.

Gendreau, P., Goggin, C., Cullen, F.T., & Andrews, D.A. (2000a). The effects of community sanctions and incarceration on recidivism. *Forum on Corrections Research, 12*(2), 10–13.

Gendreau, P., Goggin, C., & Smith, P. (2000b). Intensive supervision in probation and parole. In C. Hollin (Ed.), *Handbook of offender assessment and treatment* (pp. 195–204). Chichester, UK: Wiley.

Harberts, H. (2011). Community supervision. In D.B. Marlowe & W.B. Meyer (Eds.), *The drug court judicial benchbook* (pp. 97–111). Alexandria, VA: National Drug Court Institute. *Available at* http://www.ndci.org/sites/default/files/nadcp /14146 _NDCI_Benchbook_v6.pdf

Hollin, C.R. (1999). Treatment programs for offenders: Meta-analysis, "what works," and beyond. *International Journal of Law and Psychiatry, 22*(3–4), 361–372.

Hromco, J., Moore, M., & Nikkel, R. (2003). How managed care has affected mental health case management activities, caseloads, and tenure. *Community Mental Health Journal, 39*(6), 501–509.

Hser, Y., Joshi, V., Maglione, M., Chou, C., & Anglin, M.D. (2001). Effects of program and patient characteristics on retention of drug treatment patients. *Evaluation and Program Planning, 24*(4), 331–341.

Huddleston, W., & Marlowe, D.B. (2011). *Painting the current picture: A national report on drug courts and other problem solving court programs in the United States.* Alexandria, VA: National Drug Court Institute.

Jalbert, S.K., & Rhodes, W. (2012). Reduced caseloads improve probation outcomes. *Journal of Crime and Justice, 35*(2), 221–238.

Jalbert, S.K., Rhodes, W., Flygare, C., & Kane, M. (2010). Testing probation outcomes in an evidence-based practice setting: Reduced caseload size and intensive supervision effectiveness. *Journal of Offender Rehabilitation, 49*(4), 233–253.

Jalbert, S.K., Rhodes, W., Kane, M., Clawson, E., Bogue, B., Flygare, C., Kling, R., & Guevera, M. (2011). *A multi-site evaluation of reduced probation caseload size in an evidence-based practice setting: Final report.* Cambridge, MA: Abt Associates.

King, R., Meadows, G., & LeBas, J. (2004). Compiling a caseload index for mental health case management. *Australian and New Zealand Journal of Psychiatry, 38*(6), 455–462.

Lutze, F.E., & Van Wormer, J.G. (2007). The nexus between drug and alcohol treatment program integrity and drug court effectiveness: Policy recommendations for pursuing success. *Criminal Justice Policy Review, 18*(3), 226–245.

Marlowe, D.B., Festinger, D.S., Dugosh, K.L., Arabia, P.L., & Kirby, K.C. (2008). An effectiveness trial of contingency management in a felony pre-adjudication drug court. *Journal of Applied Behavior Analysis, 41*(4), 565–577.

McCaughrin, W.C., & Price, R.H. (1992). Effective outpatient drug treatment organizations: Program features and selection effects. *International Journal of Addictions, 27*(11), 1335–1358.

Monchick, R., Scheyett, A., & Pfeiffer, J. (2006). *Drug court case management: Role, function, and utility* [Monograph Series No. 7]. Alexandria, VA: National Drug Court Institute.

North Carolina Administrative Office of the Courts. (2010). *Best practices for North Carolina drug treatment courts.* Raleigh, NC: Author. *Available at* http://www.nccourts.org/Citizens/CPrograms/DTC/documents/dtcbestpractices.pdf

Paparozzi, M.A., & Gendreau, P. (2005). An intensive supervision program that worked: Service delivery, professional orientation, and organizational supportiveness. *Prison Journal, 85*(4), 445–466.

Paparozzi, M.A., & Hinzman, G. (2005). Caseload size in probation and parole. *APPA Perspectives,* (Spring), 23–25. *Available at* http://www.mariopaparozzi.com/uploads/CaseloadSize.pdf

Pearson, F.S., & Harper, A. (1990). Contingent intermediate sanctions: New Jersey's intensive supervision program. *Crime and Delinquency, 36*(1), 75–86.

Petersilia, J. (1999). A decade of experimenting with intermediate sanctions: What have we learned? *Justice Research and Policy, 1*(1), 9–23.

Rodriguez, P.F. (2011). Case management for substance abusing offenders. In C. Leukefeld, T.P. Gullotta, & J. Gregrich (Eds.), *Handbook of evidence-based substance abuse treatment in criminal justice settings* (pp. 173–181). New York: Springer.

Shaffer, D.K. (2010). Looking inside the black box of drug courts: A meta-analytic review. *Justice Quarterly, 28*(3)*, 493–521.*

Skeem, J.L., & Manchak, S. (2008). Back to the future: From Klockars' model of effective supervision to evidence-based practice in probation. *Journal of Offender Rehabilitation, 47*(3), 220–247.

Stewart, D., Gossop, M., & Marsden, J. (2004). Increased caseloads in methadone treatment programs: Implications for the delivery of services and retention in treatment. *Journal of Substance Abuse Treatment, 27*(4), 301–306.

Turner, S., Petersilia, J., & Deschenes, E.P. (1992). Evaluating intensive supervision probation/parole (ISP) for drug offenders. *Crime and Delinquency, 38*(4), 239–256.

Van Wormer, J. (2010). *Understanding operational dynamics of drug courts* (Doctoral dissertation, University of Washington). *Retrieved from* http://research.wsulibs.wsu.edu:8080/xmlui/bitstream/handle/2376/2810/vanWormer_wsu_0251E_10046.pdf ?sequence=1

Vocisano, C., Klein, D.N., Arnow, B., Rivera, C., Blalock, J.A., Vivian, D., . . . & Riso, L.P. (2004). Therapist variables that predict symptom change in psychotherapy with chronically depressed outpatients. *Psychotherapy: Theory, Research, Practice, Training, 41*(3), 255–265.

Woodward, A., Das, A., Raskin, I.E., & Morgan-Lopez, A.A. (2006). An exploratory analysis of treatment completion and client and organizational factors using hierarchical linear modeling. *Evaluation and Program Planning, 29*(4), 335–351.

Worrall, J.L., Schram, P., Hays, E., & Newman, M. (2004). An analysis of the relationship between probation caseloads and property crime rates in California counties. *Journal of Criminal Justice, 32*(4), 231–241.

Zweig, J.M., Lindquist, C., Downey, P.M., Roman, J., & Rossman, S.B. (2012). Drug court policies and practices: How program implementation affects offender substance use and criminal behavior outcomes. *Drug Court Review*, *8*(1), 43–79.

X. MONITORING AND EVALUATION

The Drug Court routinely monitors its adherence to best practice standards and employs scientifically valid and reliable procedures to evaluate its effectiveness.[8]

A. Adherence to Best Practices
B. In-Program Outcomes
C. Criminal Recidivism
D. Independent Evaluations
E. Historically Disadvantaged Groups
F. Electronic Database
G. Timely and Reliable Data Entry
H. Intent-to-Treat Analyses
I. Comparison Groups
J. Time at Risk

A. Adherence to Best Practices

The Drug Court monitors its adherence to best practice standards on at least an annual basis, develops a remedial action plan and timetable to rectify deficiencies, and examines the success of the remedial actions. Outcome evaluations describe the effectiveness of the Drug Court in the context of its adherence to best practices.

B. In-Program Outcomes

The Drug Court continually monitors participant outcomes during enrollment in the program, including attendance at scheduled appointments, drug and alcohol test results, graduation rates, lengths of stay, and in-program technical violations[9] and new arrests.

C. Criminal Recidivism

Where such information is available, new arrests, new convictions, and new incarcerations are monitored for at least three years following each participant's entry into the Drug Court. Offenses are categorized according to the level (felony, misdemeanor, or summary offense) and nature (e.g., person, property, drug, or traffic offense) of the crime involved.

---

[8] Herein, monitoring refers to periodic descriptions of the services delivered and outcomes achieved in a Drug Court without inferring a causal relationship between the services and outcomes. An evaluation includes a comparison condition and other scientific procedures designed to attribute outcomes to the effects of the Drug Court. Most Drug Courts are capable of monitoring their services and outcomes but may require expert consultation to evaluate the causal effects of their program.

[9] A *technical violation* refers to a violation of a court order that does not constitute a crime per se. For example, drinking alcohol is legal for most adults but is usually a technical violation in a Drug Court.

D. Independent Evaluations

A skilled and independent evaluator examines the Drug Court's adherence to best practices and participant outcomes no less frequently than every five years. The Drug Court develops a remedial action plan and timetable to implement recommendations from the evaluator to improve the program's adherence to best practices.

E. Historically Disadvantaged Groups

The Drug Court continually monitors admission rates, services delivered, and outcomes achieved for members of historically disadvantaged groups who are represented in the Drug Court population. The Drug Court develops a remedial action plan and timetable to correct disparities and examines the success of the remedial actions [see also Standard II, Historically Disadvantaged Groups].

F. Electronic Database

Information relating to the services provided and participants' in-program performance is entered into an electronic database. Statistical summaries from the database provide staff with real-time information concerning the Drug Court's adherence to best practices and in-program outcomes.

G. Timely and Reliable Data Entry

Staff members are required to record information concerning the provision of services and in-program outcomes within forty-eight hours of the respective events. Timely and reliable data entry is required of each staff member and is a basis for evaluating staff job performance.

H. Intent-to-Treat Analyses

Outcomes are examined for all eligible participants who entered the Drug Court regardless of whether they graduated, withdrew, or were terminated from the program.

I. Comparison Groups

Outcomes for Drug Court participants are compared to those of an unbiased and equivalent comparison group. Individuals in the comparison group satisfy legal and clinical eligibility criteria for participation in the Drug Court, but did not enter the Drug Court for reasons having no relationship to their outcomes. Comparison groups do not include individuals who refused to enter the Drug Court, withdrew or were terminated from the Drug Court, or were denied entry to the Drug Court because of their legal charges, criminal history, or clinical assessment results.

J. Time at Risk

Participants in the Drug Court and comparison groups have an equivalent opportunity to engage in conduct of interest to the evaluation, such as substance use and criminal recidivism. Outcomes for both groups are examined over an equivalent time period beginning from a comparable start date. If participants in either group were incarcerated or detained in a residential facility for a significantly longer period of time than

participants in the other group, the length of time participants were detained or incarcerated is accounted for statistically in outcome comparisons.

COMMENTARY

A. Adherence to Best Practices

Adherence to best practices is generally poor in most sectors of the criminal justice and substance abuse treatment systems (Friedmann et al., 2007; Henderson et al., 2007; McLellan et al., 2003; Taxman et al., 2007). Programs infrequently deliver services that are proven to be effective and commonly deliver services which have not been subjected to careful scientific scrutiny. Over time, the quality and quantity of the services provided may decline precipitously (Etheridge et al., 1995; Van Wormer, 2010). The best way for a Drug Court to guard against these prevailing destructive pressures is to monitor its operations routinely, compare its performance to established benchmarks, and seek to align itself continually with best practices. Not knowing whether one's Drug Court is in compliance with best practices makes it highly unlikely that needed improvements will be recognized and implemented; therefore, evaluating a Drug Court's adherence to best practice standards is, itself, a best practice.

Studies reveal that Drug Courts are significantly more likely to deliver effective services and produce positive outcomes when they hold themselves accountable for meeting empirically validated benchmarks for success. A multisite study involving approximately seventy Drug Courts found that programs had more than twice the impact on crime and were more than twice as cost-effective when they monitored their operations on a consistent basis, reviewed the findings as a team, and modified their policies and procedures accordingly (Carey et al., 2008, 2012).

Like many complex service organizations, Drug Courts are highly susceptible to *drift*, in which the quality of their services may decline appreciably over time (Van Wormer, 2010). Management strategies such as continuous performance improvement (CPI), continuous quality improvement (CQI), and managing for results (MFR) are designed to avoid drift and enhance a program's adoption of best practices. Each of these management strategies emphasizes continual self-monitoring and rapid-cycle testing. This process involves collecting real-time information about a program's operations and outcomes, feeding that information back to key staff members and decision makers on a routine basis, and implementing and evaluating remedial action plans where indicated. Research consistently shows that continual self-monitoring and rapid-cycle testing are critical elements for improving outcomes and increasing adoption of best practices in the health care and criminal justice systems (Damschroder et al., 2009; Rudes et al., 2013; Taxman & Belenko, 2013). These strategies are essential for programs that require cross collaboration and interdisciplinary communication among multiple service agencies, including Drug Courts (Bryson et al., 2006; Wexler et al., 2012).

Studies have not determined how frequently programs should review performance information and implement and evaluate self-corrective measures. Common practice among successful organizations is to collect performance data continually and meet at least annually as a team to review the information and take self-corrective measures (Carey et al., 2012; Rudes et al., 2013; Taxman & Belenko, 2013).

Reporting outcomes from Drug Courts without placing those findings into context by describing the quality of the programs is no longer enough. Meta-analyses (Aos et al., 2006; Latimer et al., 2006; Lowenkamp et al., 2005; Mitchell et al., 2012; Shaffer, 2010; Wilson et al., 2006) and large-scale multisite studies (Rossman et al., 2011) have already clearly established that Drug Courts reduce crime by approximately 8% to 14% on average. These averages, derived from evaluations of more than 100 Drug Courts, mask a great deal of variability between programs. Some Drug Courts reduce crime by more than 50%, others have no impact on crime, and still others increase crime rates in their communities (Carey et al., 2012; Carey & Waller, 2011; Cissner et al., 2013; Downey & Roman, 2010; Government Accountability Office, 2011; Mitchell et al., 2012; Shaffer, 2010). The important question is no longer whether Drug Courts can work,

but rather how they work and what services contribute to better outcomes (Marlowe et al., 2006). Understanding what distinguishes effective Drug Courts from ineffective and harmful Drug Courts is now an essential goal for the field. Unless evaluators describe each Drug Court's adherence to best practices, there is no way to place that program's outcomes in context or interpret the significance of the findings.

B. In-Program Outcomes

One of the primary aims of a Drug Court is to rehabilitate seriously addicted individuals, which means that retaining participants in treatment, reducing drug and alcohol use, and helping participants to complete treatment successfully are important indicators of short-term progress. However, policymakers, the public, and other stakeholders are likely to judge the merits of a Drug Court by how well it reduces crime, incarceration rates, and taxpayer expenditures. Therefore, Drug Courts need to measure in-program outcomes that not only reflect clinical progress, but are also significant predictors of postprogram criminal recidivism and other long-term outcomes.

At minimal cost and effort, Drug Courts can evaluate short-term outcomes while participants are enrolled in the program. These short-term outcomes provide significant information about participants' clinical progress and the likely long-term impacts of the Drug Court on public health and public safety. Studies have consistently determined that postprogram recidivism is reduced significantly when participants attend more frequent treatment and probation sessions, provide fewer drug-positive urine tests, remain in the program for longer periods of time, have fewer in-program technical violations and arrests for new crimes, and satisfy other conditions for graduation (Gifford et al., 2014; Gottfredson et al., 2007, 2008; Huebner & Cobbina, 2007; Jones & Kemp, 2011; Peters et al., 2002). Drug Courts should, therefore, monitor and report on these in-program outcomes routinely during the course of their operations.

Several resources are available to help Drug Courts define and calculate performance measures of in-program outcomes (Berman et al., 2007; Heck, 2006; Marlowe, in press; Peters, 1996; Rubio et al., 2008a). In 2006, NADCP convened leading Drug Court researchers and evaluators to form the National Research Advisory Committee (NRAC). One goal of this committee was to define a core data set of in-program performance measures for adult Drug Courts (Heck, 2006). NRAC selected measures that are simple and inexpensive to track and evaluate and proven to predict long-term outcomes. These performance measures include the following:

- *Retention*—the number of participants who completed the Drug Court divided by the number who entered the program
- *Sobriety*—the number of negative drug and alcohol tests divided by the total number of tests performed
- *Recidivism*—the number of participants arrested for a new crime divided by the number who entered the program, and the number of participants adjudicated officially for a technical violation divided by the number who entered the program
- *Units of Service*—the numbers of treatment sessions, probation sessions, and court hearings attended
- *Length of Stay*—the number of days from entry to discharge or the participant's last in-person contact with staff

Longer lists of performance measures addressing a wide range of outcomes in Drug Courts and other problem-solving courts have been published by expert organizations including the National Center for State Courts (Rubio et al., 2008a; Waters et al., 2010), the Center for Court Innovation (Rempel, 2006, 2007), American University (Peters, 1996), the Organization of American States (Marlowe, in press), the National Center for DWI Courts (Marlowe, 2010), and the National Institute of Justice (NIJ, 2010). Drug Courts are advised to consult these and other resources for further information on how to calculate and interpret additional performance measures for their evaluations.

C. Criminal Recidivism

For many policymakers and members of the public, reducing criminal recidivism is one of the primary aims of a Drug Court. Recidivism is defined as any return to criminal activity after the participant entered the Drug Court. Recidivism does not include crimes that occurred before the participant entered Drug Court even if those crimes are charged or prosecuted after entry.

Recidivism is measured most commonly by new arrests, new convictions, or new incarcerations occurring over a two- or three-year period (Carey et al., 2012; King & Elderbroom, 2014; Rempel, 2006). For example, the Bureau of Justice Statistics (BJS) tracks new arrests, convictions, and incarcerations occurring within three years of the date that state and federal inmates are released from jail or prison (Durose et al., 2014).

Based on scientific considerations, evaluators should follow participants for at least three years, and ideally up to five years, from the date of entry into the Drug Court or from the date of the arrest or technical violation that made the individual eligible for Drug Court. The date of entry should be the *latest* start date for the evaluation because that is when the Drug Court becomes capable of influencing participant behavior directly.

Starting from the date of arrest or technical violation takes into account the potential impact of delays in admitting participants to Drug Court. The sooner participants enter Drug Court after an arrest or probation violation, the better the results (Carey et al., 2008, 2012); therefore, evaluators may wish to examine how delayed entry affects outcomes. However, because Drug Courts cannot always control what transpires before participants enter the Drug Court program, attributing to the Drug Court any recidivism occurring before entry may not fairly represent the Drug Courts' effects on recidivism. Starting from the date of entry ensures recidivism may be attributed fairly to the effects of the Drug Court. No one answer fully addresses the issues surrounding selection of a start date for evaluation; therefore; evaluators should state clearly what start date was selected and the rationale for choosing that start date.

Rates of criminal recidivism among drug-involved offenders become relatively stable after approximately three to five years (King & Elderbroom, 2014). After three years, statistically significant between-group differences in recidivism are likely to remain significant going forward (e.g., Knight et al., 1999; Martin et al., 1999; Wexler et al., 1999). For example, if Drug Court participants have significantly lower rearrest rates than comparison group subjects after three years, this difference is likely (although not guaranteed) to remain significant after an additional two years (DeVall et al., 2015). After five years, recidivism rates tend to reach a plateau, meaning that most (but not all) participants who will recidivate have likely done so by then (e.g., Gossop et al., 2005; Inciardi et al., 2004; Olson & Lurigio, 2014).

Importantly, these findings do not suggest Drug Courts must wait three to five years before reporting recidivism outcomes. Recidivism occurring during enrollment and shortly after discharge from Drug Court may be of considerable interest to practitioners, policymakers, and other stakeholders. However, implying that recidivism rates occurring within the first two years are likely to reflect the long-term effects of a Drug Court is inappropriate. Evaluators should state clearly that such recidivism rates are preliminary and likely to increase over time.

No one basis exists for deciding whether new arrests, new convictions, or new incarcerations are likely to be the most valid or informative indicator of recidivism. As discussed below, each measure has advantages and disadvantages that the evaluator must take into account. Because no one measure is clearly superior to another, whenever possible evaluators are advised to report all three measures of recidivism, discuss the implications and limitations of each, or indicate why a particular measure is not being reported.

Analyzing new arrests as a measure of criminal recidivism provides at least two advantages. First, arrests are often substantially closer in time to the alleged offense than convictions. Resolving a criminal case and determining guilt or innocence may take months or years. Evaluators can usually report arrest outcomes in much less time than waiting for lengthy legal proceedings to resolve. Second, criminal cases are often dismissed or pled down to a lesser charge for reasons having little to do with factual guilt, such as

insufficient evidence or plea bargains. As a result, the absence of a conviction or conviction on a lesser charge may not reflect the offense that occurred.

However, some individuals are arrested for crimes they did not commit. This fact may lead to an overestimation of the true level of criminal recidivism. Relying on conviction data rather than arrest data may provide greater assurances that the crimes did, in fact, occur.

Incarceration has substantial cost impacts that may far exceed those of arrests and convictions. A day in jail or prison can cost between five and twenty times more than a day on probation or in community-based treatment (Belenko et al., 2005; Zarkin et al., 2012). Evaluators typically distinguish between incarceration that occurred while participants were enrolled in the Drug Court and incarceration that occurred after discharge. In-program incarceration often reflects brief jail sanctions that may be imposed for misconduct in the program, whereas postprogram incarceration typically reflects pretrial detention for new charges, sentences for new charges, or (for terminated participants) sentencing on the original charge that led to participation in Drug Court. In cost evaluations, in-program jail sanctions are typically counted as an investment cost for the Drug Court whereas postprogram detention is typically counted as an outcome cost (Carey et al., 2012).

Evaluators must also consider the timeliness and accuracy of information contained in criminal justice databases. In some jurisdictions, arrest data may be recorded in a more timely and faithful manner than conviction or incarceration data. Evaluators must familiarize themselves with how and when information is entered into national, state, and local criminal justice records and should describe clearly in their evaluation reports any limitations that may relate to the accuracy or timeliness of the data.

Self-report information could potentially provide the most accurate assessment of criminal recidivism because it does not require detection or prosecution by law enforcement. Because many crimes are unreported by victims and undetected by the authorities (Truman & Langton, 2014), arrest and conviction data may underestimate true levels of criminal activity. For obvious reasons, however, individuals cannot be relied upon to acknowledge their crimes unless they receive strict assurances that the information will be kept confidential and will not be used against them in a criminal proceeding. Drug Courts will typically be required to hire an independent evaluator who has no connection to the court or criminal justice system to confidentially survey participants. This method is likely to be prohibitively costly for many Drug Courts, which explains why it has rarely been employed with the notable exception of one highly funded national study (Rossman et al., 2011).

Whether measured by arrests, convictions, or incarcerations, categorizing recidivism according to the level (i.e., felony, misdemeanor, or summary offense) and nature (e.g., drug offenses, property and theft offenses, violent offenses, technical violations, prostitution, and traffic offenses) of the crimes involved is highly informative and necessary. Different categories of crime can have very different implications for public safety and cost. For example, violent offenses may have serious victimization costs and may result in substantial jail or prison sentences, whereas drug possession may not involve an identifiable victim and is more likely to receive a less costly probation sentence (Zarkin et al., 2012).

As a final note, not all Drug Courts have reasonable access to data on new arrests, convictions, or incarcerations occurring after participants have been discharged from the program. In some jurisdictions, these records may be in the possession of other executive agencies, such as the police department or department of corrections, and the Drug Court may not be entitled to the information. Under such circumstances, Drug Courts should make every effort to negotiate access to the data, but of course, Drug Courts cannot be held accountable for reporting information beyond their reach.

D. Independent Evaluations

In addition to monitoring their own performance, Drug Courts benefit greatly from having an independent evaluator examine their program and issue recommendations to improve their adherence to best practices. Drug Courts that engaged an independent evaluator and implemented at least some of the evaluator's recommendations were determined in one multisite study to be twice as cost-effective and nearly twice as

effective at reducing crime as Drug Courts that did not engage an independent evaluator (Carey et al., 2008, 2012).

Drug Courts benefit from an independent evaluation for several reasons. Every program has blind spots that prevent staff from recognizing their own shortcomings. Some team members, such as the judge, may have more social influence or power than others, making it difficult for some team members to call attention to problems in court or during team meetings. Drug Courts also operate in a political environment and staff may be hesitant to criticize local practices for fear of reprisal. An independent evaluator from another jurisdiction can usually offer frank criticisms of current practices with less fear of repercussions (Heck & Thanner, 2006).

Although most Drug Courts are capable of keeping descriptive statistics about their program, considerably more expertise is required to perform *inferential analyses*, which compare Drug Court outcomes to those of a comparison group. Controlling statistically for preexisting group differences that could bias one's results is often necessary. For example, if Drug Court participants had fewer previous convictions than comparison subjects before entering the study, better outcomes for the Drug Court might simply reflect the fact that it treated a less severe population. Evaluators must take numerous scientific matters into consideration and may need to apply several levels of statistical corrections to produce valid and reliable results.

Studies also reveal that participant perceptions are often highly predictive of outcomes in Drug Courts. For example, perceptions concerning the procedural fairness of the program (Burke, 2010; McIvor, 2009), the manner in which incentives and sanctions are delivered (Goldkamp et al., 2002; Harrell & Roman, 2001; Marlowe et al., 2005), and the quality of the treatment services provided (Turner et al., 1999) are often predictive of recidivism and correlate significantly with adherence to best practices. Needless to say, participants are more likely to be forthright with an independent evaluator about their perceptions of the Drug Court than with staff members who control their fate in the criminal justice system.

Studies have not determined how frequently Drug Courts should be evaluated by an independent investigator. Generally speaking, a new evaluation should be performed whenever a program or the environment within which it operates changes substantially. Staff turnover and evidence of drift from the intended model are critical events that call for a new evaluation (Yeaton & Camberg, 1997). Evidence suggests that staff turnover and model drift occur within five-year intervals in Drug Courts. Within five years, between roughly 30% and 60% of Drug Courts experience substantial turnover in key staff positions (Van Wormer, 2010). The highest turnover rates, commonly exceeding 50%, are among substance abuse and mental health treatment providers (Lutze & Van Wormer, 2007; McLellan et al., 2003; Taxman & Bouffard, 2003; Van Wormer, 2010). Evidence further reveals that staff turnover correlates significantly with drift in the quality of the services provided (Van Wormer, 2010). Therefore, five years is a reasonable outside estimate of how frequently Drug Courts should be evaluated independently. If resources allow, Drug Courts should engage independent evaluators at more frequent intervals to detect drift readily and prevent services from worsening with time.

Drug Courts need to select competent evaluators. The first step in selecting a competent evaluator is to request recommendations from other Drug Courts and national organizations that are familiar with Drug Court operations and research. Senior staff at NADCP and NDCI are familiar with the evaluation literature and the skill sets of dozens of evaluators nationally. When selecting an evaluator, review prior evaluation reports, especially those involving Drug Courts or other problem-solving courts. If prior evaluations failed to follow the practices described herein, consider selecting another evaluator who has demonstrated expertise in applying best practices related to Drug Court program evaluations. One of the most important questions to consider when reviewing prior evaluations is whether the report recommended concrete actions the Drug Court could take to enhance its adherence to best practices and improve its outcomes. The most effective evaluators are aware of the literature on best practices, measure Drug Court practices against established performance benchmarks, and promote useful strategies to improve each program's operations and results.

Many Drug Courts do not have sufficient resources to hire independent evaluators. One way to address this problem is to contact local colleges or universities to determine whether graduate or undergraduate students may be interested in evaluating the Drug Court as part of a thesis, dissertation, or capstone project. Because

such projects require close supervision from senior academic faculty, the Drug Court can receive high-level research expertise at minimal or no cost. Moreover, students are likely to be highly motivated to complete the evaluation successfully because their academic degree and standing depends on it.

E. Historically Disadvantaged Groups

The term *historically disadvantaged groups* refers to socio-demographic groups that have historically experienced sustained discrimination or reduced social opportunities due to their race, ethnicity, gender, sexual orientation, sexual identity, physical or mental disability, religion, or socioeconomic status. Best practices for ensuring equivalent treatment of historically disadvantaged groups in Drug Courts are described in Standard II, Historically Disadvantaged Groups.

Evidence suggests racial and ethnic minority individuals are underrepresented in some Drug Courts and may have lower graduation rates than other participants [see Commentary in Standard II, Historically Disadvantaged Groups]. Drug Courts have an affirmative obligation to determine whether racial and ethnic minority individuals and members of other historically disadvantaged groups are being disproportionately burdened or excluded from their programs; and if so, to take reasonable corrective measures to rectify the problem and evaluate the success of the corrective actions [see Standard II]. Not knowing whether one's Drug Court is disproportionately burdening disadvantaged groups is itself a violation of best practice standards (Marlowe, 2013).

Studies have not determined how frequently Drug Courts should review performance information for members of historically disadvantaged groups. Consistent with the general literature on CPI, CQI and MFR, the Drug Court team should review performance information at least annually and implement and evaluate self-corrective measures on a rapid-cycle basis (Rudes et al., 2013; Wexler et al., 2012).

A number of resources are available to help Drug Courts identify and rectify disparate impacts for historically disadvantaged groups (e.g., Casey et al., 2012; Rubio et al., 2008b; Yu et al., 2009). Seasoned evaluators and university faculty are likely to be familiar with this literature and to know how to perform these types of analyses. Many analyses, such as comparing graduation rates between different racial groups, are relatively simple and straightforward to perform. Other analyses, such as determining whether disadvantaged groups have equivalent access to Drug Court, are considerably more difficult. Many Drug Courts may not have adequate information about the relevant arrestee population to determine whether disadvantaged groups are gaining access to the Drug Court at equivalent rates. For example, information might not be available to determine what proportion of racial-minority arrestees have serious drug problems and are therefore eligible for participation in Drug Court. The primary challenge for such Drug Courts may be to gain better access to a wider range of information on the arrestee population, and as a practical matter, such analyses may be beyond the ability and expertise of some programs to accomplish.

F. Electronic Database

Paper files have minimal value for conducting program evaluations. Evaluators are typically required to extract information from handwritten notes and progress reports that are difficult to read, contain contradictory information, and have numerous missing entries. As a consequence, many evaluations are completed months or years after the fact when the results may no longer reflect what is occurring in the program. Such evaluations often contain so many gaps or caveats in the data that the conclusions which may be drawn are tentative at best.

Drug Courts are approximately 65% more cost-effective when they enter standardized information concerning their services and outcomes into an electronic management information system (MIS), which is capable of generating automated summary reports (Carey et al., 2008, 2012). The cost of purchasing an MIS is offset many times over by providing greater efficiencies in operations and yielding the type of performance feedback that is necessary to continually improve and fine-tune one's Drug Court program.

Appendix E provides examples of MISs that have been developed for use in Drug Court evaluations. Some of the older and less sophisticated systems can be obtained free of charge. For example, the Buffalo System (so named because it was developed in a Drug Court in Buffalo, New York) is a Microsoft Access database

that can be obtained at no cost by contacting NADCP. Newer systems must be purchased or licensed, but are more likely to be web-based and can be accessed simultaneously by multiple users and agencies. Allowing multiple agencies to use the same MIS, each with its own secured and encrypted access, can spread the cost of the system across several budgets. Newer systems are also more likely to have preprogrammed analytic reports that provide important summary information for staff at the push of a button. Finally, newer systems are more likely to include a data-extraction tool. A data-extraction tool allows information to be imported readily into a statistical program, such as SAS or SPSS, which skilled evaluators then can use to conduct sophisticated statistical analyses.

G. Timely and Reliable Data Entry

The biggest threat to a valid program evaluation is poor data entry by staff. The adage "garbage in/garbage out" is particularly apt in this regard. If staff members do not accurately record what occurred, no amount of scientific expertise or sophisticated statistical adjustments can produce valid findings.

The best time to record information about services and events is when they occur. For example, staff members should enter attendance information into an MIS or written log during court hearings and treatment sessions. This is referred to as *real-time recording*. The typical staff person in a Drug Court is responsible for dozens of participants and each participant has multiple obligations in the program, such as appearing at court hearings, attending treatment sessions, and delivering urine specimens. Only the rare staff person can recall accurately what events transpired or should have transpired days or weeks in the past. Attempting to reconstruct events from memory is likely to introduce unacceptable error into a program evaluation.

Data should ordinarily be recorded within no more than forty-eight hours of the respective events. Medicare, for instance, requires physicians to document services within a "reasonable time frame," defined as twenty-four to forty-eight hours (Pelaia, n.d.). After forty-eight hours, errors in data entry have been shown to increase significantly. After one week, information is so likely to be inaccurate that it may be better to leave the data as missing than attempt to fill in gaps from faulty memory (Marlowe, 2010).

Staff members who are persistently tardy when entering data pose a serious threat to the integrity of a Drug Court. Not only are evaluation results unlikely to be accurate, but those same staff persons are unlikely to be delivering appropriate services. Good-quality treatment and supervision require staff to monitor participant behavior vigilantly, record performance information in a timely and actionable fashion, and adjust services and consequences accordingly. Failing to record performance information in a timely and reliable manner undermines the quality and effectiveness of a Drug Court and seriously jeopardizes participant care.

H. Intent-to-Treat Analyses

A serious error in some Drug Court evaluations is to examine outcomes only for participants who graduated successfully from the program. The logic for performing such an analysis is understandable. Evaluators are often interested in learning what happens to individuals who received all of the services the program has to offer. If individuals who dropped out or were terminated prematurely from the Drug Court are included in the analyses, the results will be influenced by persons who did not receive all of the intended services.

Although this reasoning might seem logical, it is scientifically flawed (Heck, 2006; Heck & Roussell, 2007; Marlowe, 2010, in press; Peters, 1996; Rempel, 2006, 2007). Outcomes must be examined for all eligible individuals who participated in the Drug Court regardless of whether they graduated, were terminated, or withdrew from the program. This is referred to as an *intent-to-treat analysis* because it examines outcomes for all individuals whom the program initially set out to treat. Reporting outcomes for graduates alone is not appropriate because such an analysis unfairly and falsely inflates the apparent success of the program. For example, individuals who graduated from the Drug Court are more likely than terminated participants to have entered the program with less severe drug or alcohol problems, less severe criminal propensities, higher motivation for change, or better social supports. As a result, they might have been less likely to commit future offenses or relapse to substance abuse regardless of the services they received in Drug Court.

This issue is particularly important when outcomes are contrasted against those of a comparison sample, such as probationers. Selecting the most successful Drug Court cases and comparing their outcomes to all of the probationers unfairly skews the results in favor of the Drug Court. It is akin to selecting the A+ students from one classroom, comparing their scores on a test to those of all of the students in a second classroom, and then concluding the first class had a better teacher. Such a comparison would clearly be slanted unfairly in favor of the first teacher.

This is not to suggest that outcomes for graduates are of no interest. Drug Courts may, indeed, want to know what happens to individuals who receive all of the services in the program. This, however, should be a *secondary analysis* that is performed after the intent-to-treat analysis has shown positive results. If it is first determined that the Drug Court achieved significantly improved outcomes on an intent-to-treat basis, it may then be appropriate to proceed further and determine whether outcomes were even better for the graduates. If the intent-to-treat analysis is not significant, then it is not acceptable to move on to evaluate outcomes for graduates alone.

Importantly, if secondary analyses are performed on Drug Court graduates, then the comparison sample should also comprise successful completers. For example, outcomes for Drug Court graduates should be compared to those of probationers who satisfied the conditions of probation. Comparing outcomes for Drug Court graduates to all probationers, including probation failures, would unfairly favor the Drug Court.

The only exception to an intent-to-treat analysis is for what are sometimes referred to as *neutral discharges*. Some Drug Courts assign a neutral discharge to participants who are withdrawn from the program for reasons beyond the control of the participant and the program. A neutral discharge is assigned most commonly when the Drug Court discovers a participant was admitted to the program erroneously. For example, a participant might need to be withdrawn from Drug Court if he or she had a prior conviction that precluded eligibility for the Drug Court or resided in a judicial district that was not within the jurisdictional boundaries of the Drug Court. A neutral discharge may also be assigned to participants who are withdrawn from the program because they enlisted in the military or moved out of the jurisdiction with the court's permission. A neutral discharge should never be assigned to cases in which termination was related to a participant's performance in Drug Court.

I. Comparison Groups

The mere fact that individuals perform well after participating in Drug Court does not prove the Drug Court was responsible for their favorable outcomes. Those same individuals might have functioned just as well if they had never entered Drug Court. To examine the important question of causality, the performance of Drug Court participants must be compared against that of an equivalent and unbiased comparison group. Comparing what happened in the Drug Court to what would most likely have happened if the Drug Court did not exist is referred to as testing the *counterfactual hypothesis,* or the possibility that the Drug Court was ineffective (Popper, 1959).

Some comparison groups are reasonably unbiased and can yield a fair and accurate assessment of what would most likely have occurred without the Drug Court. Others, however, may be systematically biased in such a manner as to make the Drug Court look better or worse than it deserves. This may lead to the unwarranted conclusion that the Drug Court was effective or ineffective when, in fact, the reverse could be true.

Random Assignment—The strongest inference of causality may be reached when eligible individuals are randomly assigned either to the Drug Court or to a comparison group. Random assignment provides the greatest assurance that the groups started out with an equal chance of success; therefore, better outcomes for one group can be confidently attributed to the effects of the program (Campbell & Stanley, 1963; Farrington, 2003; Farrington & Welsh, 2005; National Research Council, 2001; Telep et al., 2015). Even when an evaluator employs random assignment, there is still the possibility (albeit a greatly diminished possibility) that the groups differed on important dimensions from the outset. This possibility requires the evaluator to perform a confirmation of the randomization procedure. The evaluator will need to check for preexisting differences between the groups that could have affected the results. If the groups differed significantly on variables that are correlated with outcomes (such as the severity of participants' criminal

histories or drug problems), the evaluator might employ statistical procedures to adjust for those differences and obtain defensible results.

As a practical matter, conducting random assignment is often very difficult in Drug Courts. Some staff members may have ethical objections against denying potentially effective services to eligible individuals. Moreover, some Drug Courts may have difficulty filling their slots and may not wish to turn away eligible individuals. The evaluator will also need to gain approval and buy-in for random assignment from numerous professionals and agencies, including the court, prosecution, and defense counsel. Finally, random assignment usually requires implementation of ethical safeguards (National Research Council, 2001). For example, participants may need to provide informed consent to random assignment, and an independent ethics review board may need to oversee the safety and fairness of the study. Local colleges and universities often have institutional review boards (IRBs) or data and safety monitoring boards (DSMBs) which have the authority and expertise to provide ethical oversight for randomized studies.

Random assignment poses far fewer challenges if a Drug Court has insufficient capacity to treat many individuals who would otherwise be eligible for its services. If many eligible people must be turned away, then it would arguably be fairest to select participants randomly rather than allow staff members to pick and choose who gets into the program. Under such circumstances, random assignment may provide the best protection against unfair discrimination and unconscious bias (National Research Council, 2001). In fact, a number of Drug Court studies have used random assignment successfully in light of insufficient program capacity (e.g., Gottfredson et al., 2003; Jones, 2011; Turner et al., 1999).

Quasi-Experimental Comparison Group—In many Drug Courts, engaging in random assignment is simply impractical. The next best approach is to use a quasi-experimental comparison group (Campbell & Stanley, 1963). This refers to individuals who were eligible for the Drug Court but did not enter for reasons that are unlikely to have influenced their outcomes. Perhaps the best example is individuals who were eligible for and willing to enter the Drug Court, but were denied access because there were no empty slots available. This is referred to as a *wait-list comparison group*. The mere happenstance that the Drug Court was full is unlikely to have led to the systematic exclusion of individuals who had more severe problems or poorer prognoses to begin with, and therefore is unlikely to bias the results.

Less optimal, but still potentially acceptable, quasi-experimental comparison groups include individuals who would have been eligible for the Drug Court but were arrested in the year or so before the Drug Court was established, or were arrested in an immediately adjacent county that does not have a Drug Court (Heck, 2006; Heck & Roussell, 2007; Marlowe, 2010, in press; Peters, 1996). Because these individuals were arrested at an earlier point in time or in a different geographic region than the Drug Court participants, such comparison groups might still be different enough from the Drug Court group to bias the results. For example, socioeconomic conditions might differ significantly between neighboring communities, or law enforcement practices might change from year to year. The likelihood of this occurring, however, is usually not substantial and these may be the only practical comparison conditions that can be used for many Drug Court evaluations.

When using a quasi-experimental comparison group, the evaluator must check for preexisting differences between the groups that could have affected the results (Campbell & Stanley, 1963). For example, the comparison individuals may have had more serious criminal histories than the Drug Court participants to begin with. This, in turn, might have put them at greater risk for criminal recidivism. If so, then superior outcomes for the Drug Court participants might not have been due to the effects of the Drug Court, but rather to the fact that it treated a less severe population. A skilled evaluator can use a number of statistical procedures to adjust for such differences and potentially obtain scientifically defensible results.

Matched Comparison Group—Evaluators do not always have a quasi-experimental comparison group at their disposal. Under such circumstances, they may be required to construct a comparison group out of a large and heterogeneous pool of offenders. For example, an evaluator might need to select comparison subjects from a statewide probation database. Many of those probationers would not have been eligible for Drug Court, or are dissimilar to Drug Court participants on characteristics that are likely to have influenced their outcomes. For example, some of the probationers might not have had serious drug problems, or might have been charged with offenses that would have excluded them from participation in Drug Court. The

evaluator must, therefore, select a subset of individuals from the entire probation pool that are similar to the Drug Court participants on characteristics that are known to affect outcomes. For example, the evaluator might pair each Drug Court participant with a probationer who has the same or similar criminal history, demographic characteristics, and substance use diagnosis (Heck, 2006; Marlowe, 2010, in press). Because the evaluator will choose only those probationers who are similar to the Drug Court participants on multiple characteristics, it is necessary to start out with a large sample of potential candidates from which to select comparable individuals.

The success of any matching strategy will depend largely on whether the evaluator has adequate information about the comparison candidates to make valid matches (Campbell & Stanley, 1963). If data are not available on such important variables as the probationers' criminal histories or substance abuse problems, evaluators and Drug Courts will not be able to place confidence in the validity of the matches. Simply matching the groups on variables that are easy to measure and readily available, such as gender or race, is not sufficient because the groups might differ on other important dimensions that were not taken into account.

Propensity Score Analysis—An evaluator may also use an advanced statistical procedure called a propensity score analysis to mathematically adjust for differences between the Drug Court and comparison groups. This procedure calculates the statistical probability that an individual with a given set of characteristics would be in the Drug Court group as opposed to the comparison group—in other words, the relative similarity of that individual to one group as opposed to the other (Dehejia & Wahba, 2002). The analysis then mathematically adjusts for this relative similarity when comparing outcomes. Advanced statistical expertise is required to implement and interpret this complicated procedure.

As with any statistical adjustment, the success of a propensity score analysis will depend on whether the evaluator has adequate information about the comparison subjects to make valid adjustments. If data are not available on such important variables as the comparison subjects' criminal histories or substance abuse problems, evaluators and Drug Courts will not be able to place confidence in the adjustments (Peikes et al., 2008). Again, merely adjusting the scores based on easily measured variables, such as gender or race, is not sufficient because the groups might differ on other important dimensions that were never taken into account.

Invalid Comparison Groups—Several comparison groups have been used in Drug Court evaluations that quite likely produced seriously biased results. Comparing outcomes from a Drug Court to those of individuals who refused to enter the Drug Court, were denied access to the Drug Court because of their clinical or criminal histories, dropped out of the Drug Court, or were terminated prematurely from the Drug Court is rarely, if ever, justified (Heck, 2006; Heck & Thanner, 2006; Marlowe, 2010, in press; Peters, 1996). The probability is unacceptably high that such persons had poorer prognoses or more severe problems to begin with. For example, they very likely had more serious criminal or substance abuse histories, lower motivation for change, or lesser social supports. Given the high likelihood that these individuals were seriously disadvantaged from the outset, statistical adjustments cannot be relied upon to overcome the differences (Campbell & Stanley, 1963).

J. Time at Risk

For an evaluation to be valid, Drug Court and comparison participants must have the same time at risk, meaning the same opportunity to engage in substance abuse, crime, and other behaviors of interest to the evaluation. If, for example, an evaluator measured criminal recidivism over a period of twelve months for Drug Court participants, but over a period of twenty-four months for the comparison group, this would give an unfair advantage to the Drug Court participants. The comparison group participants would have twelve additional months in which to commit new crimes or other infractions.

Ensuring an equivalent time at risk requires the evaluator to begin the analyses from a comparable start date for both groups. As was mentioned earlier, Drug Court evaluations typically use the date of entry into Drug Court or the date of the arrest or technical violation that made the individual eligible for Drug Court as the start date for analyses. If the comparison group is comprised of probationers, comparable start dates might be the date the individual was placed on probation or the date of the arrest that led to a probation sentence.

If the time at risk differs significantly between groups, the evaluator might be able to compensate for this problem by adjusting statistically for time at risk in outcome comparisons. For example, the evaluator might enter time at risk as a covariate in the statistical analyses. A *covariate* is a variable that is entered first into a statistical model. The independent effect of the variable of interest (in this case, being treated in a Drug Court) is then examined after first taking the effect of the covariate into account. This procedure would indicate whether Drug Court participants had better outcomes after first taking into account the influence of their shorter time at risk. The use of covariates is not always successful, however, and the best course of action is to ensure the groups have equivalent follow-up windows.

A related issue is referred to as *time at liberty.* Time at liberty and time at risk are similar in that both affect a participant's opportunity to reoffend or engage in other behaviors of interest to the evaluation. The difference is that time at liberty relates to whether restrictive conditions were placed on the participant. The most obvious restrictive conditions involve physical barriers to freedom, such as incarceration or placement in a residential treatment facility. These physical barriers severely restrict a participant's ability to use drugs, commit new offenses, obtain a job, or engage in other behaviors of interest to evaluators.

A potential error in Drug Court evaluations is to neglect time at liberty when performing outcome comparisons. In some jurisdictions, for example, individuals who do not enter Drug Court may be more likely to receive a jail sentence. If they are jailed for a portion of the follow-up period, they might have fewer opportunities to reoffend or use drugs than Drug Court participants who are treated in the community. The evaluator might conclude, erroneously, that Drug Court caused participants to reoffend or use drugs more often, when in fact they simply had more time at liberty to do so. Under such circumstances, the evaluator would need to adjust statistically for participants' time at liberty in the outcome analyses. For example, the evaluator might need to enter time at liberty as a covariate in the statistical models. This would indicate whether Drug Court participants had better outcomes after first taking into account their longer time at liberty. As was noted earlier, such adjustments are not always successful and Drug Courts will require expert consultation to ensure the analyses are carried out appropriately.

Note that evaluators are not always advised to adjust for time at liberty. In cost analyses, for example, the time participants spend in jail or a residential treatment facility is an important outcome in its own right and should be valued accordingly from a fiscal standpoint. Deciding whether to adjust for time at liberty, like many evaluation-related decisions, requires scientific expertise and careful consideration of the aims of the study. For such analyses, Drug Courts are strongly advised to obtain expert statistical and scientific consultation.

REFERENCES

Aos, S., Miller, M., & Drake, E. (2006). *Evidence-based public policy options to reduce future prison construction, criminal justice costs, and crime rates*. Olympia: Washington State Institute for Public Policy.

Belenko, S., Patapis, N., & French, M.T. (2005). *Economic benefits of drug treatment: A critical review of the evidence for policy makers*. Philadelphia: Treatment Research Institute.

Berman, G., Rempel, M., & Wolf, R.V. (Eds.). (2007). *Documenting results: Research on problem-solving justice.* New York: Center for Court Innovation.

Bryson, J.M., Crosby, B.C., & Stone, M.M. (2006). The design and implementation of cross-sector collaborations: Propositions from the literature. *Public Administration Review, 66*(Suppl.1), 44–55.

Burke, K.S. (2010). Just what made drug courts successful? *New England Journal on Criminal & Civil Confinement, 36*(1), 39–58.

Campbell, D.T., & Stanley, J.C. (1963). *Experimental and quasi-experimental designs for research.* Chicago: Rand McNally College Publishing Company.

Carey, S.M., Finigan, M.W., & Pukstas, K. (2008). *Exploring the key components of drug courts: A comparative study of 18 adult drug courts on practices, outcomes and costs.* Portland, OR: NPC Research.

Carey, S.M., Mackin, J.R., & Finigan, M.W. (2012). What works? The ten key components of drug court: Research-based best practices. *Drug Court Review, 8*(1), 6–42.

Carey, S.M., & Waller, M.S. (2011). *Oregon drug courts: Statewide costs and promising practices.* Portland, OR: NPC Research.

Casey, P., Warren, R., Cheesman, F., & Elek, J. (2012). *Helping courts address implicit bias: Resources for education.* Williamsburg, VA: National Center for State Courts.

Cissner, A., Rempel, M., Franklin, A.W., Roman, J.K., Bieler, S., Cohen, R., & Cadoret, C.R. (2013). *A statewide evaluation of New York's adult drug courts: Identifying which policies work best.* New York: Center for Court Innovation.

Damschroder, L.J., Aron, D.C., Keith, R.E., Kirsh, S.R., Alexander, J.A., & Lowery, J.C. (2009). Fostering implementation of health services research findings into practice: A consolidated framework for advancing implementation science. *Implementation Science, 4*(50). doi:10.1186/1748-5908-4-50

Dehejia, R.H., & Wahba, S. (2002). Propensity score-matching methods for nonexperimental causal studies. *Review of Economics and Statistics, 84*(1), 151–161.

DeVall, K.E., Gregory, P.D., & Hartmann, D.J. (2015, June 10). Extending recidivism monitoring for drug courts: Methods, issues and policy implications. *International Journal of Offender Therapy and Comparative Criminology: Online.* doi:10.1177/0306624X15590205.

Downey, P.M., & Roman, J.K. (2010). *A Bayesian meta-analysis of drug court cost-effectiveness.* Washington, DC: The Urban Institute.

Durose, M.R., Cooper, A.D., & Snyder, H.N. (2014). *Recidivism of prisoners released in 30 states in 2005: Patterns from 2005 to 2010.* Washington, DC: U.S. Dept. of Justice, Bureau of Justice Statistics.

Etheridge, R.M., Craddock, S.G., Dunteman, G.H., & Hubbard, R.L. (1995). Treatment services in two national studies of community-based drug abuse treatment programs. *Journal of Substance Abuse, 7*(1), 9–26.

Farrington, D.P. (2003). A short history of randomized experiments in criminology: A meagre feast. *Evaluation Review, 27*(3), 218–227.

Farrington, D.P., & Welsh, B.C. (2005). Randomized experiments in criminology: What have we learned in the last two decades? *Journal of Experimental Criminology, 1*(1), 9–38.

Friedmann, P.D., Taxman, F.S., & Henderson, C.E. (2007). Evidence-based treatment practices for drug-involved adults in the criminal justice system. *Journal of Substance Abuse Treatment, 32*(3), 267–277.

Gifford, E.J., Eldred, L.M., McCutchan, S.A., & Sloan, F.A. (2014). The effects of participation level on recidivism: A study of Drug Treatment Courts using propensity score matching. *Substance Abuse Treatment, Prevention, and Policy, 9*(40). doi:10.1186/1747-597X-9-40

Goldkamp, J.S., White, M.D., & Robinson, J.B. (2002). An honest chance: Perspectives on drug courts. *Federal Sentencing Reporter, 14*(6), 369–372.

Gossop, M., Tradaka, K., Stewart, D., & Witton, J. (2005). Reductions in criminal convictions after addiction treatment: 5-year follow-up. *Drug & Alcohol Dependence, 79*(3), 295–302.

Gottfredson, D.C., Kearley, B.W., & Bushway, S.D. (2008). Substance use, drug treatment, and crime: An examination of intra-individual variation in a drug court population. *Journal of Drug Issues, 38*(2), 601–630.

Gottfredson, D.C., Kearley, B.W., Najaka, S.S., & Rocha, C.M. (2007). How Drug Treatment Courts work: An analysis of mediators. *Journal of Research on Crime & Delinquency, 44*(1), 3–35.

Gottfredson, D.C., Najaka, S.S., & Kearley, B. (2003). Effectiveness of Drug Treatment Courts: Evidence from a randomized trial. *Criminology & Public Policy, 2*(2), 171–196.

Government Accountability Office. (2011). *Adult drug courts: Studies show courts reduce recidivism, but DOJ could enhance future performance measure revision efforts* [No. GAO-12-53]. Washington, DC: Author.

Harrell, A., & Roman, J. (2001). Reducing drug use and crime among offenders: The impact of graduated sanctions. *Journal of Drug Issues, 31*(1), 207–232.

Heck, C. (2006). *Local drug court research: Navigating performance measures and process evaluations* [Monograph Series No. 6]. Alexandria, VA: National Drug Court Institute. *Available at* http://www.ndci.org/sites/default/files/ndci/Mono6.Local Research.pdf

Heck, C., & Roussell, A. (2007). Record keeping and statistics. In J.E. Lessenger & G.F. Roper (Eds.), *Drug courts: A new approach to treatment and rehabilitation* (pp. 401–413). New York: Springer.

Heck, C., & Thanner, M.H. (2006). Evaluating drug courts: A model for process evaluation. *Drug Court Review, 5*(2), 51–82.

Henderson, C.E., Young, D.W., Jainchill, N., Hawke, J., Farkas, S., & Davis, R.M. (2007). Program use of effective drug abuse treatment practices for juvenile offenders. *Journal of Substance Abuse Treatment, 32*(3), 279–290.

Huebner, B.M., & Cobbina, J. (2007). The effect of drug use, drug treatment participation, and treatment completion on probationer recidivism. *Journal of Drug Issues, 37*(3), 619–641.

Inciardi, J., Martin, S., & Butzin, C. (2004). Five-year outcomes of therapeutic community treatment of drug-involved offenders after release from prison. *Crime & Delinquency, 50*(1), 88–107.

Jones, C. (2011, November). Intensive judicial supervision and drug court outcomes: Interim findings from a randomized controlled trial. *Crime & Justice Bulletin, 152,* 1–16. *Available at* http://www.bocsar.nsw.gov.au/Documents/cjb152.pdf

Jones, C., & Kemp, R.I. (2011). The relationship between early-phase substance use trajectories and drug court outcomes. *Criminal Justice & Behavior, 38*(9), 913–933.

King, R., & Elderbroom, B. (2014). *Improving recidivism as a performance measure.* Washington, DC: The Urban Institute. *Available at* http://www.urban.org/UploadedPDF/413247-improving-recidivism.pdf

Knight, K., Simpson, D.D., & Hiller, M.L. (1999). Three-year reincarceration rates outcomes for in-prison therapeutic community treatment in Texas. *Prison Journal, 79*(3), 337–351.

Latimer, J., Morton-Bourgon, K., & Chretien, J. (2006). *A meta-analytic examination of drug treatment courts: Do they reduce recidivism?* Ottawa, ON: Canada Dept. of Justice, Research & Statistics Division.

Lowenkamp, C.T., Holsinger, A.M., & Latessa, E.J. (2005). Are drug courts effective? A meta-analytic review. *Journal of Community Corrections, 15*(1), 5–28.

Lutze, F.E., & Van Wormer, J.G. (2007). The nexus between drug and alcohol treatment program integrity and drug court effectiveness: Policy recommendations for pursuing success. *Criminal Justice Policy Review, 18*(3), 226–245.

Marlowe, D.B. (2010). *Introductory handbook for DWI court program evaluations.* Alexandria, VA: National Center for DWI Courts. *Available at* http://www.dwicourts.org/sites/default/files/nadcp/DWI%20Ct%20Eval%20Manual%20REVISED-8-10.pdf

Marlowe, D.B. (2013). Achieving racial and ethnic fairness in drug courts. *Court Review, 49*(1), 40–47.

Marlowe, D.B. (in press). *Manual for scientific monitoring and evaluation of drug treatment courts in the Americas.* Washington, DC: Inter-American Drug Abuse Control Commission, Organization of American States.

Marlowe, D.B., Festinger, D.S., Foltz, C., Lee, P.A., & Patapis, N.S. (2005). Perceived deterrence and outcomes in drug court. *Behavioral Sciences & the Law, 23*(2), 183–198.

Marlowe, D.B., Heck, C., Huddleston, C.W., & Casebolt, R. (2006). A national research agenda for drug courts: Plotting the course for second-generation scientific inquiry. *Drug Court Review, 5*(2), 1–31.

Martin, S.S., Butzin, C.A., Saum, C.A., & Inciardi, J.A. (1999). Three-year reincarceration outcomes of therapeutic community treatment for drug-involved offenders in Delaware: From prison to work release to aftercare. *Prison Journal, 79*(3), 294–320.

McIvor, G. (2009). Therapeutic jurisprudence and procedural justice in Scottish drug courts. *Criminology & Criminal Justice, 9*(1) 29–49.

McLellan, A.T., Carise, D., & Kleber, H.D. (2003). Can the national addiction treatment infrastructure support the public's demand for quality care? *Journal of Substance Abuse Treatment, 25*(2), 117–121.

Mitchell, O., Wilson, D.B., Eggers, A., & MacKenzie, D.L. (2012). Assessing the effectiveness of drug courts on recidivism: A meta-analytic review of traditional and nontraditional drug courts. *Journal of Criminal Justice, 40*(1), 60–71.

National Institute of Justice. (2010). Drug court performance measures and program evaluation. Retrieved from http://www.nij.gov/topics/courts/drug-courts/pages/measures-evaluation.aspx

National Research Council. (2001). *Informing America's policy on illegal drugs: What we don't know keeps hurting us.* Washington, DC: National Academy Press.

Olson, D.E., & Lurigio, A.J. (2014). The long-term effects of prison-based drug treatment and aftercare services on recidivism. *Journal of Offender Rehabilitation, 53*(8), 600–619.

Peikes, D.N., Moreno, L., & Orzol, S.M. (2008). Propensity score matching: A note of caution for evaluators of social programs. *American Statistician, 62*(3), 222–231. doi:10.1198/000313008X332016

Pelaia, R.A. (n.d.). Medical record entries: What is timely and reasonable? Retrieved from http://news.aapc.com/index.php/2013/09/medical-record-entries-what-is-timely-and-reasonable/

Peters, R.H. (1996). *Evaluating drug court programs: An overview of issues and alternative strategies.* Washington, DC: Justice Programs Office at American University.

Peters, R.H., Haas, A.L., & Hunt, W.M. (2002). Treatment "dosage" effects in drug court programs. *Journal of Offender Rehabilitation, 33*(4), 63–72.

Popper, K. (1959). *The logic of scientific discovery.* New York: Harper & Row.

Rempel, M. (2006). Recidivism 101: Evaluating the impact of your drug court. *Drug Court Review, 5*(2), 83–112.

Rempel, M. (2007). Action research: Using information to improve your drug court. In G. Berman, M. Rempel & R.V. Wolf (Eds.), *Documenting results: Research on problem-solving justice* (pp. 101–122). New York: Center for Court Innovation.

Rossman, S.B., Rempel, M., Roman, J.K., Zweig, J.M., Lindquist, C.H., Green, M.,… Farole, D.J. (2011). *The multisite adult drug court evaluation: The impact of drug courts (vol. 4).* Washington, DC: Urban Institute Justice Policy Center. Available at https://www.ncjrs.gov/pdffiles1/nij/grants/237112.pdf

Rubio, D.M., Cheesman, F., & Federspiel, W. (2008a). *Performance measurement of drug courts: The state of the state.* Williamsburg, VA: National Center for State Courts. *Available at* http://cdm16501.contentdm.oclc.org/cdm/ref/collection/spcts/id/171

Rubio, D.M., Cheesman, F., & Webster, L. (2008b). *Kentucky drug court statewide technical assistance project: Development of statewide adult drug court performance measures*. Denver, CO: National Center for State Courts.

Rudes, D.S., Viglione, J., & Porter, C.M. (2013). Using quality improvement models in correctional organizations. *Federal Probation, 77*(2). *Available at* http://www.uscourts.gov/uscourts/FederalCourts/PPS/FedProb/2013-09/quality.html

Shaffer, D.K. (2010). Looking inside the black box of drug courts: A meta-analytic review. *Justice Quarterly, 28*(3), 493–521.

Taxman, F.S., & Belenko, S. (2013). *Implementing evidence-based practices in community corrections and addiction treatment*. New York: Springer.

Taxman, F.S., & Bouffard, J.A. (2003). Substance abuse counselors' treatment philosophy and the content of treatment services provided to offenders in drug court programs. *Journal of Substance Abuse Treatment, 25*(2), 75–84.

Taxman, F.S., Perdoni, M.L., & Harrison, L.D. (2007). Drug treatment services for adult offenders: The state of the state. *Journal of Substance Abuse Treatment, 32*(3), 239–254.

Telep, C.W., Garner, J.H., & Visher, C.A. (2015, July 3). The production of criminological experiments revisited: The nature and extent of federal support for experimental designs, 2001–2013. *Journal of Experimental Criminology: Online.* doi:10.1007/s11292-015-9239-6

Truman, J.L., & Langton, L. (2014). *Criminal victimization, 2013.* Washington, DC: Bureau of Justice Statistics, U.S. Dept. of Justice. *Available at* http://www.bjs.gov/content/pub/pdf/cv13.pdf

Turner, S., Greenwood, P., Fain, T., & Deschenes, E. (1999). Perceptions of drug court: How offenders view ease of program completion, strengths and weaknesses, and the impact on their lives. *National Drug Court Institute Review, 2*(1), 61–85.

Van Wormer, J. (2010). Understanding operational dynamics of drug courts (Doctoral dissertation, University of Washington). Retrieved from http://research.wsulibs.wsu.edu:8080/xmlui/bitstream/handle/2376/2810/vanWormer_wsu_0251E_10046.pdf?sequence=1

Waters, N.L., Cheesman, F.L., Gibson, S.A., & Dazevedo, I. (2010). *Mental health court performance measures: Implementation and user's guide*. Williamsburg, VA: National Center for State Courts.

Wexler, H.K., Melnick, G., Lowe, L., & Peters, J. (1999). Three-year reincarceration outcomes for Amity in-prison therapeutic community and aftercare in California. *Prison Journal, 79*(3), 321–336.

Wexler, H.K., Zehner, M., & Melnick, G. (2012). Improving drug court operations: NIATx organizational improvement model. *Drug Court Review, 8*(1), 80–95.

Wilson, D.B., Mitchell, O., & MacKenzie, D.L. (2006). A systematic review of drug court effects on recidivism. *Journal of Experimental Criminology, 2*(4), 459–487.

Yeaton, W., & Camberg, L. (1997). *Program evaluation for managers: A primer.* Boston: Management Decision and Research Center and Office of Research and Development, Dept. of Veterans Affairs. *Available at* http://www.hsrd.research.va.gov/publications/internal/ProgEval-Primer.pdf

Yu, J., Clark, L.P., Chandra, L., Dias, A., & Lai, T.F. (2009). Reducing cultural barriers to substance abuse treatment among Asian Americans: A case study in New York City. *Journal of Substance Abuse Treatment, 37*(4), 398–406.

Zarkin, G.A., Cowell, A.J., Hicks, K.A., Mills, M.J., Belenko, S., Dunlap, L.J., & Keyes, V. (2012, November 5). Lifetime benefits and costs of diverting substance-abusing offenders from state prison. *Crime & Delinquency: Online.* doi:10.1177/0011128712461904

APPENDIX C

COMPLEMENTARY NEEDS ASSESSMENTS

This list provides examples of instruments used to assess complementary needs among substance-involved individuals in the criminal justice system. Additional information about needs assessment instruments may be obtained from the following Web sites:

Alcohol and Drug Abuse Institute Library at the University of Washington

http://lib.adai.washington.edu/instruments/

The National GAINS Center

http://gainscenter.samhsa.gov/pdfs/disorders/ScreeningAndAssessment.pdf

---

MULTIDIMENSIONAL CLINICAL NEEDS ASSESSMENTS

Addiction Severity Index (ASI)

http://www.tresearch.org/wp-content/uploads/2012/09/ASI_5th_Ed.pdf

Global Appraisal of Individual Needs (GAIN)

http://www.gaincc.org/products-services/instruments-reports/

MULTIDIMENSIONAL CRIMINOGENIC NEEDS ASSESSMENTS

Correctional Offender Management Profiling for Alternative Sanctions (COMPAS)

http://www.northpointeinc.com/products/northpointe-software-suite

Inventory of Offender Risk, Needs, and Strengths (IORNS)

http://www4.parinc.com/Products/Product.aspx?ProductID=IORNS

Offender Profile Index (OPI)

https://www.ncjrs.gov/pdffiles1/Digitization/148829NCJRS.pdf

Offender Screening Tool (OST)

http://www.azcourts.gov/apsd/EvidenceBasedPractice/RiskNeedsAssessment/OffenderScreeningTool%28OST%29.aspx

Ohio Risk Assessment System (ORAS)

http://www.ocjs.ohio.gov/ORAS_FinalReport.pdf

Level of Service/Case Management Inventory (LS/CMI)

https://ecom.mhs.com/(S(0aqkan55ovozwq55w2oxt445))/saf_om.aspx?id=Training

Static Risk and Offender Needs Guide (STRONG)

https://www.assessments.com/purchase/detail.asp?SKU=5205

MENTAL HEALTH SCREENS

Beck Depression Inventory-II (BDI-II)

http://www.pearsonclinical.com/psychology/products/100000159/beck-depression-inventoryii-bdi-ii.html?Pid=015-8018-370&Mode=summary

Beck Anxiety Inventory (BAI)

http://www.pearsonclinical.com/psychology/products/100000251/beck-anxiety-inventory-bai.html?Pid=015-8018-400&Mode=summary

Brief Jail Mental Health Screen (BJMHS)

http://gainscenter.samhsa.gov/pdfs/disorders/bjmhsform.pdf

CJ-DATS Co-Occurring Disorder Screening Instrument (CJ-CODSI)

https://www.drugabuse.gov/sites/default/files/files/CJ-CODSI.pdf

Generalized Anxiety Disorder 7-Item Scale (GAD-7)

http://www.integration.samhsa.gov/clinical-practice/GAD708.19.08Cartwright.pdf

Global Appraisal of Individual Needs-Short Screener (GAIN-SS)

http://www.gaincc.org/products-services/instruments-reports/

Mental Health Screening Form-III (MHSF-III)

https://www.idph.state.ia.us/bh/common/pdf/substance_abuse/integrated_services/jackson_mentalhealth_screeningtool.pdf

Modified Mini-Screen (MMS)

http://www.nyc.gov/html/doh/downloads/pdf/qi/qi-mms-scoringsht.pdf

Mood Disorder Questionnaire (MDQ)—Bipolar Disorder

http://www.integration.samhsa.gov/images/res/MDQ.pdf

Symptom Checklist-90-Revised (SCL-90-R)

http://www.pearsonclinical.com/psychology/products/100000645/symptom-checklist-90-revised-scl90r.html

TRAUMA AND PTSD SCALES

Acute Stress Disorder Structured Interview (ASDI)

http://www.istss.org/assessing-trauma/acute-stress-disorder-structured-interview-(asdi).aspx

Clinician-Administered PTSD Scale for DSM-5 (CAPS-5)

http://www.ptsd.va.gov/professional/assessment/adult-int/caps.asp

Life Events Checklist

http://www.integration.samhsa.gov/clinical-practice/life-event-checklist-lec.pdf

Posttraumatic Symptom Scale Interview (PSS-I)

http://www.ptsd.va.gov/professional/assessment/adult-int/pss-i.asp

PTSD Checklist (PCL)

https://www.facs.org/~/media/files/quality%20programs/trauma/vrc%20resources/10_ptsd_checklist_and_scoring.ashx

PTSD Checklist—Civilian Version

http://www.integration.samhsa.gov/clinical-practice/Abbreviated_PCL.pdf

Trauma History Screen

http://www.ptsd.va.gov/professional/assessment/te-measures/ths.asp

HEALTH-RISK BEHAVIOR SCALES

HIV Risk Assessment

http://hivaidsresource.org/hiv-testing/hiv-risk-assessment/

Texas Christian University (TCU) HIV/AIDS Risk Assessment

http://ibr.tcu.edu/wp-content/uploads/2014/07/HIV-AIDS-intake-ara.pdf

University of Pennsylvania Risk Assessment Battery (RAB)

http://www.med.upenn.edu/hiv/rab_download.html

Wisconsin AIDS/HIV Program: Client Assessment Survey

https://wi-ew.lutherconsulting.com/WisconsinCommonFiles/downloads/BehavioralRiskSurvey.pdf

CRIMINAL THINKING SCALES

Criminal Sentiments Scale

https://www.dpscs.state.md.us/publicservs/procurement/QA_5_ATTACHMENT_2_CRIMINAL_SENTIMENT_SCALE.pdf

Texas Christian University Criminal Thinking Scales (TCU-CTS)

http://ibr.tcu.edu/forms/tcu-criminal-thinking-scales/

Psychological Inventory of Criminal Thinking Styles (PICTS)

http://asm.sagepub.com/content/9/3/278.short

APPENDIX D

EVIDENCE-BASED COMPLEMENTARY TREATMENT AND SOCIAL SERVICES

The following Web sites provide information about evidence-based treatments and social services to address the complementary needs of individuals with substance abuse problems in the criminal justice system.

CLINICAL CASE MANAGEMENT

Case Management Society of America

http://www.cmsa.org/Home/CMSA/WhoWeAre/tabid/222/Default.aspx

Commission for Case Management Certification

http://ccmcertification.org/

National Treatment Accountability for Safer Communities

http://nationaltasc.org/resources/

Treatment Accountability for Safer Communities
Crime and Justice Institute, Illinois

http://www2.tasc.org/

EVIDENCE-BASED PREVENTION EDUCATION

Bureau of Justice Assistance
Naloxone Overdose Reversal Toolkit

https://www.bjatraining.org/tools/naloxone/Naloxone%2BBackground

Centers for Disease Control and Prevention (CDCP), HIV/AIDS Prevention Programs

http://www.cdc.gov/hiv/prevention/programs/index.html

SAMHSA
Opioid Overdose Prevention Toolkit

http://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit-Updated-2014/SMA14-4742

EVIDENCE-BASED TREATMENT AND SOCIAL SERVICES

The Campbell Collaboration
Library of Systematic Reviews

http://www.campbellcollaboration.org/lib/

The Cochrane Collaboration

http://www.thecochranelibrary.com/view/0/index.html

CrimeSolutions.gov
National Institute of Justice (NIJ)

http://www.crimesolutions.gov/Programs.aspx

International Society for Traumatic Stress Studies

https://www.istss.org/

National Registry of Evidence-Based Programs and Practices (NREPP)
Substance Abuse and Mental Health Services Administration (SAMHSA)

http://www.nrepp.samhsa.gov/

APPENDIX E

MANAGEMENT INFORMATION SYSTEMS FOR DRUG COURT EVALUATIONS

This list provides examples of management information systems (MISs) developed to assist in evaluating Drug Courts or other problem-solving courts. Information about additional MISs may be obtained by contacting NDCI faculty or other organizations that perform Drug Court program evaluations.

Buffalo, NY, Drug Court Case Management System (contact the NDCI for more information)

http://www.ndci.org/contact

Advanced Computer Technologies
Drug Court Case Management (DCCM) System

http://www.actinnovations.com/solutions/cms.aspx

Treatment Research Institute Court Evaluation Program (TRI-CEP)

http://www.tresearch.org/tools/for-courts/tri-cep/demo/

Criminal Justice—Drug Abuse Treatment Studies (CJ-DATS)
eCourt System

http://www.gmuace.org/documents/prod-pub/cjdats/cjdats-summary-ecourt.pdf

Social Solutions
Adult Drug Court Performance Model, Efforts to Outcomes (ETO) Software

http://www.socialsolutions.com/adc/

Strength Based Digital Connections, LLC
The Virtual File Case Management System for Tribal Courts

www.thevirtualfile.com

Dr. Faye Taxman, Ph.D.
Professor, Criminology, Law and Society Department
Director, Center for Advancing Correctional Excellence
George Mason University

Dr. Faye S. Taxman is a Professor in the Criminology, Law and Society Department and the Director for the Center for Advancing Correctional Excellence at George Mason University. Dr. Taxman specializes in designing and evaluating evidence-based court programs and interventions. She has published numerous articles, including *Tools of the Trade: A Guide to Incorporating Science into Practice*, published by the National Institute on Corrections which provides a guidebook to implementation of science-based concepts into practice. She is the author (with Steve Belenkos) of *Implementing Evidence-Based Community Corrections and Addiction Treatment* (Springer, 2011). Dr. Taxman is on the Editorial Boards of numerous journals, including the Journal of Experimental Criminology, Criminology and Public Policy, and Journal of Offender Rehabilitation. She received her Bachelor of Arts degree from the University of Tulsa and her Ph.D. from Rutgers University-School of Criminal Justice.

Center for Advancing Correctional Excellence
Department of Criminology, Law and Society
4087 University Drive, Ste. 4100, Fairfax, VA 22030
Phone: 703-993-8555; Fax: 703-993-6020
E-Mail: ace@gmu.edu
www.gmuace.org

March 7, 2017

Kathleen Cooper Grill
General Counsel
U.S. Sentencing Commission
One Columbus Circle, NE
Suite 2-500 South Lobby
Washington, DC 20002

Dear Honorable Members of the U.S. Sentencing Commission:

I greatly appreciate the opportunity to provide you with information about alternatives to incarceration programs, particularly court programs. I will limit my comments to the issues with alternatives to incarceration programming and efforts, to the design of solid problem-solving courts (drug courts), to how best to view the evidence about effectiveness, and to the role of the judges in this process.

Alternatives to Incarceration *are* Mainstream Punishments

The concept of "alternatives to incarceration" were that these are a secondary set of punishments or sanctions that can be offered in lieu of incarceration. The "in lieu" suggests that it is an alternative instead of a legitimate, primary tool to punish or sanction a person. In the 1970's and onward, the notion that these sanctions grew out of the notion that there are a range of punishments that are valid and could be offered as a substitute for incarceration. Hence, the focus on alternatives. Over nearly 50 years, these alternatives have now become mainstream where they are integrated into justice systems, and moreso have become routine components for community corrections (probation systems). Drug treatment courts are legitimate tools to provide a vehicle to addressing the addiction disorders that affect involvement in criminal behavior, and utilize justice resources of judges, prosecutors, defense, treatment and probation/case mangers to address these drivers of criminal behavior.

More importantly, these alternatives are effective in reducing recidivism, even more than incarceration. In fact, incarceration has been determined to be criminogenic according to a number of scholars (see Cullen, Jonston, & Nagin, 2011), and long prison terms are considered to be ineffective and also have a harmful (iatrogenic) effect. Overall the punishments that reduce recidivism, based on the available literature and meta-analyses, are: drug treatment courts (Mitchell, et al., 2012), therapeutic communities (Inciardi, 1999), Risk-Need-Responsivity Supervision (Caldwell, et al., 2014; Drake, 2012), cognitive behavioral therapy (NIDA, 2009) with supervision, contingency management (NIDA, 2009). And, research finds that providing medically assisted treatments (such as buprenorphine, suboxone, methadone, etc.) before release from prison followed by continued treatment in the community are effective in

reducing recidivism, increasing continued care in the community, and reducing mortality. These models reduce recidivism, and also serve to protect the community.

In the problem solving court literature, the drug treatment model reduces recidivism (Mitchell, et al., 2012) but studies have not found that other problem solving models for DUI, juvenile drug use, reentry, or other targeted models to achieve the same results. The difference between the drug court model and these other court models is that the focus is on using addiction treatment programs to supplement the court and supervision components of drug testing, status hearings, case management meetings, and ancillary services. Drug treatment courts focus on one behavior—drug use and abuse—whereas some of the other problem solving courts are less specific. And, the therapeutic interventions are less directive and theoretically clear. That could be why those courts do not demonstrate as clear of a pattern of reduced recidivism since the behaviors that they are trying to address do not have a defined set of evidence-based treatments.

Risk and Need Assessment: Assignment to Interventions/Drug Courts

A major challenge confronting judges and corrections is what type of person should be placed into what type of program or service? Risk and need assessment tools are designed to conduct an assessment of the factors that should drive placement in programs or services. These tools are critically important to identify the key drivers of factors that affect which programs/services/correctional options that would benefit the person. The Administrative Office of the Courts has a well-designed tool (PCRA) that could be useful for identify which individuals might be better served by different types of correctional or court programs. The U.S. Sentencing Commission may also desire to have a third or fourth generation risk and need assessment tool to identify who could benefit from different options, and also to assess which criminogenic factors are affecting involvement in criminal behavior.

Risk-need assessment tools are important vehicles to: 1) identify risk factors that affect the likelihood of involvement in the justice system; 2) identify dynamic needs (also risk factors that more likely to be changeable) that affect involvement in criminal behavior; and 3) other factors that affect stability such as housing stability, food stability, motivation to change, developmental issues, intellectual disabilities, and so on. These factors are important to consider in terms of placement in appropriate programs and services—with the general rule that dynamic needs should drive the type of program placement. Risk and other factors should drive the intensity of the programming, as well as the degree to which more social controls are needed as part of a strategy to address public safety factors.

The translation of information from a risk and need assessment tool to determining the appropriate programming options—that is, the option that will result in the reduction of recidivism—requires consideration of prioritizing risk and need information. To facilitate this process, the Center for Advancing Correctional Excellence (ACE!) developed a decision-support tool to advance these decisions. The ***RNR Simulation Tool*** (www.gmuace.org/tools) is designed to take information from a risk and need assessment tool as feeders into a empirically-derived formulas which then identify the programs that are most likely to reduce recidivism. (And, if a jurisdiction has used information to classify programs in the community, then the identification refers to local programs. (For more information, see Taxman, Pattavina, & Caudy, 2014). This process enhances evidence-based practices by focusing attention on using information from risk-needs assessment tools to identify the appropriate programs and services.

In general, drug courts should serve those with substance use disorders but primarily those where the substance use is the primary driver of criminal behavior. Drug courts are well-suited for those with addiction-type disorders. Individuals with addiction disorders need structured, intensive interventions to achieve recovery, and drug courts provide that vehicle. Risk level matters in terms of the length of the program, and the type of social controls that are used to help support recovery. But, drug courts are designed for those with high tolerance for substances, particularly illicit ones where structure, reinforcement, and responses are needed to shape recovery.

Program Quality: Standards

Adhering to quality indicators for programs and services is a major challenge facing programs designed to reduce recidivism. Program quality has been one of the drivers of ineffective efforts to reduce recidivism—that is, many programs, regardless of their name or title, do not necessarily include all of the vital components of a program. Part of this dilemma is due to the lack of specificity in the research literature as to the core components that affect individual-level outcomes, whereas some of it due to programs trying to do too much in too short period of time, without proper staff or resources to replicate the research literature, or without having the quality assurance and control mechanisms in place to know when programs/services are not providing the actual programming to make a difference. Program quality is a critical issue that can not be understated.

The National Association of Drug Court Professionals (NADCP) issued a two-set volume on standards for problem solving courts that describe the rationale for the standard, the scientific premise, and the core components (see http://www.nadcp.org/Standards). There are 10 standards including target populations, inclusion of disadvantaged individuals, role and responsibility of judges, substance abuse treatment, status hearings with sanctions/incentives, drug testing, multidisciplinary teams, supplemental services, evaluation and monitoring. This well-documented set of standards lays a foundation for the design and features of effective drug treatment courts, and problem solving courts. It provides a toolkit to help problem solving courts design and monitor their implemented programs/services.

As part of the continuing support to address quality in programs, the ***RNR Simulation Tool*** has an online survey that program administrators can complete. In the *Assess the Program* arena, the administrator can complete a 90-minute survey of the program and it will generate a report card of how the program meets the standards of evidence-based programming and treatments. Besides scoring the program in six areas (i.e. risk principle, need principle, responsivity, dosage, implementation/staffing/quality improvements, and special features), the results include a list of enhancements that can be used to strengthen the program. We also have a special report for Problem Solving Courts and Reentry Case Management given that there are slightly different standards and evidence-based practices for these efforts than other correctional interventions.

The question is frequently raised regarding an outcome study versus a process or implementation study. Given the robust literature on the effectiveness of drug treatment courts and the reoccurring themes regarding program quality issues, it is important to conduct a process evaluation or at a minimum of program inventory (such as the Assess the Program survey). Such efforts will document the current status of the programs in terms of meeting the NADCP standards, evidence-based practices and treatments, and the management of the program to be high fidelity or adherence to the features that are most important to deliver results. For small programs like problem solving courts with under 30 people, it is worthwhile to

begin with a program review (process evaluation or program inventory). Although, I believe this review is critical for any size of a program to get a better handle on how the program is structured and resourced. Valuable evaluation resources can be devoted to how well the program is structured to meet the standards of evidence-based practices, and what are the areas that need attention to advance practice.

A program quality issue is the working relationship between the individual and the justice actors, particularly the judge in a drug court environment. The general literature reinforces the importance of a working relationship that is built on trust, caring, and respect. In the probation and parole literature, there is clear research literature that supports the importance of the working relationship in improving outcomes; individuals are more likely to be open and feel that they have a voice when the environment supports behavioral change, and its difficult twists and turns with relapse and remissions. Creating a drug court environment that supports behavioral change and has the judge, prosecutor, and defense attorney provide a supportive platform are important to make headways in fostering behavioral change.

Conclusion

In conclusion, the empirical literature recognizes that drug treatment courts are part of the landscape of effective programs. Incarceration is costly to the individual (in terms of social loss and difficult to regain citizenship) and society (in terms of fostering criminogenic behaviors and not breaking the cycle of justice involvement). A full continuum of sanctions is recommended to better use justice resources first, but also to provide punishments that can serve the goals of deterrence, rehabilitation, incapacitation, and retribution. The proliferation of evidence-based practices and treatments now means that there are standards that the system can rely upon for programs and services that are better suited to reduce recidivism. Drug courts are one model that has been shown to be effective just like the risk-need-responsivity supervision model that the Administrative Office of the Courts and federal probation offices are implementing.

The U.S. Sentencing Commission has an opportunity now to revisit the question of what is the most effective punishment given our state of scientific knowledge about effective interventions. As discussed in the attached paper (Taxman, F.S., & Breno, A. (2017, in press) *Alternatives to incarceration are no longer alternatives (hint: they are now mainstream sentencing options)*, to be published in ***Oxford Research Encyclopedia of Criminology and Criminal Justice***), there are a number of mainstream punishments, many of which are more effective than incarceration. Drug treatment courts and RNR Supervision are readily available to address the recidivism reduction issue.

Thank you for this opportunity to share our research findings with you. Feel free to contact me at ftaxman@gmu.edu or 571-205-8282.

Sincerely,

Faye S. Taxman, Ph.D.
University Professor

References:

Blasko, B., Friedmann, P., Rhodes, A., & Taxman, F.S. (2015). The Parolee-Parole Officer Relationship As a Mediator of Criminal Justice Outcomes. *Criminal Justice & Behavior*. 42 (7), 722–740.

Caldwick, N., Dewolf, A., & Serin, R. (2014). Effectively Training Community Supervision: A Meta-Analytic Review of the Impact on Offender Outcomes. *Criminal Justice & Behavior*, vol. 42, 10: pp. 977-989

Cullen, Francis T., Cheryl Lero Jonson, and Daniel S. Nagin.2011. "Prisons Do Not Reduce Recidivism: The High Cost of Ignoring Science," *The Prison Journal* 1: 48S-65S.

Drake, E.K. (2011). "What works" in community supervision: Interim report (Document No. 11-12-1201). Olympia: Washington State Institute for Public Policy. http://www.wsipp.wa.gov/ReportFile/1094

Landenberger, N.A. & Lipsey, M.W. (2005). The positive effects of cognitive-behavioral programs for offenders: A meta-analysis of factors associated with effective treatment. *Journal of Experimental Criminology,* 1, 451-476.

National Institute on Drug Abuse (2009). *Principles of Drug Abuse Treatment for Criminal Justice Populations: A Research-Based Guide*. Bethesda, MD: NIDA. https://www.drugabuse.gov/publications/principles-drug-abuse-treatment-criminal-justice-populations/principles

Mitchell, O.J., Wilson, D., Eggers, A., & MacKenzie, D.L. (2012). Effectiveness of drug courts on recidivism: A meta-analytic review of non-traditional drug courts. *Journal of Criminal Justice*, 40: 60-71

Taxman, F.S., Pattavina, A., & Caudy, M. (2014). Justice Reinvestment in the US: The Case for More Programs. *Victims & Offenders*, 9(1): 50-75.

Alternatives to incarceration are no longer alternatives
(hint: they are now mainstream sentencing options)

Faye S Taxman and Alex Breno

To be published in ***Oxford Research Encyclopedia of Criminology and Criminal Justice***

Summary

Alternatives to incarceration are more than options, they have evolved into sentences of their own accord. Originally, probation and prison were the two major sentences however the concept of intermediate or graduated sanctions emerged in the 1980s, and evolved throughout the 1990s. While alternatives to incarceration were considered options, they are now recognized as intermediate sanctions, graduated sanctions, and just plain sentencing options. This emergence occurred during the time that probation plus conditions sentences spiked so that the average probationer now has over 17 standard conditions (Taxman, 2012). With Justice Reinvestment Initiatives as a national effort to reduce the impact of mass incarceration policies, it has served to legitimize sentences that used to be considered "alternatives", by incorporating risk-need assessments, legislation to reduce sentence lengths and incarceration sentences, and changes in practices to address non-compliant probationers and parolees. In this paper, a new conceptual model is proposed that integrates sentencing options with results from a risk and need assessment depending on various types of liberty restrictions. Given the need to reduce prison overcrowding, there is an even further need to examine how different sentencing options can be used for different type of individuals.

Keywords: Alternatives, sanctions, Justice Reinvestment Initiative, sentencing, probation, incarceration

Alternatives to incarceration is a term coined to signify justice responses that are designed to avoid the use of incarceration at various points in the justice system—arrest, pretrial, jail, prison, and semi-incarceration facilities. For adjudicated individuals, alternatives to incarceration generally signal sentences or sanctions that are provided *in lieu* of a jail or prison sentence, hence the term alternative. These alternatives could actually be considered a class of sentences justified on their own accord as fair, parsimonious, and proportional to the convicted criminal behavior. The term alternative can also signify that the system has a number of sentencing options where incarceration can be used. The distinction between a justified replacement for an incarceration sentence and an appropriate sentence in its own right depends on the state of sentencing in different jurisdictions. Probably most perplexing is that the same sentencing options can be considered both rightful sentences and alternative sentences in the same jurisdiction. In many instances, alternatives are used as sanctions for individuals on probation or parole, only adding to the many ways alternatives are being used. The concept of "alternative" can have different meaning in various contexts, both at the systematic level, as well as individual sentencing level.

Essentially, the concept of alternatives to incarceration is no longer an alternative but part of the legitimate sentencing options. We will first look at what the sentencing options look like, as well as some of the literature behind the various forms. Then, we will examine the legitimatization of sentencing options by looking at the Justice Reinvestment Initiative. We then conclude with a discussion of how these options can build on reducing recidivism, through sentencing options that meet the needs of individuals in the system.

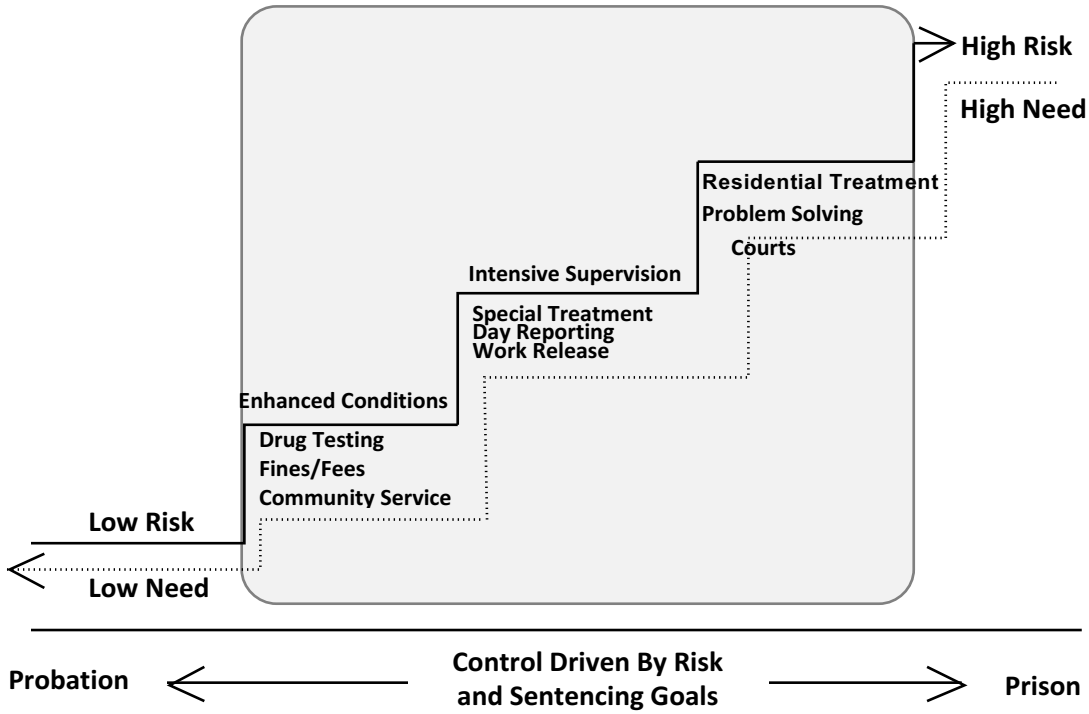
What do sentencing options look like?

Within the framework of sentencing options, there are two polar extremes: probation and prison. Probation is generally considered the sentence option for less serious offenses, and individuals with less serious criminal histories. Incarceration is generally reserved for those with more serious offenses and histories. In-between probation and prison are a number of sentencing options that use features from both probation and incarceration to impose punishment and controls on the individual (Morris and Tonry, 1991). The placement in different settings (incarceration vs. probation) often depends on the sentencing culture of a jurisdiction including guidelines and/or normative expectations. Generally, the sentence is influenced by the severity of the offense, the criminal history of the individual, and the nature of "like" sentences in a jurisdiction. The decision about what type of punishment to use also considers whether the goal is incapacitation, rehabilitation, retribution, or deterrence. Often times the sentencing goals are convoluted with an emphasis on more than one area. However, as shown in Figure 1 below, the sentencing options use a variety of restraints, restrictions, and controls as punishment but can offer a series of treatments, services, and interventions alongside these controls. More specifically, a number of these sentencing options can be, and are, used as a means to reintegrate offenders back into the community, such as halfway houses, some intensive supervision probations/paroles, and electronic monitoring (Bonta & Motiuk, 1987; Hartman, Friday, & Minor, 1994; Petersilia & Turner, 1993; Finn & Muirhead-Steves, 2002).

Below is a depiction of the optimal sentencing scheme that offers a number of options that range from probation to prion. The community sanctions vary based on the number and type of restrictions that occur. Figure 1 predisposes the placement based on the risk and *needs* that an individual presents (to be discussed below). This figure integrates the use of risk for future justice involvement and *needs* (for factors that are changeable) in terms of identifying the

appropriate sentencing option. The degree of restriction is often viewed as a form of punishment, which is based on different application principles.

Figure 1: Overview of Conceptual Model of Sentencing Options



A few cautionary notes regarding intermediate sanctions falling between probation and prison. First, an individual has the right to choose to participate in the programs, particularly treatment programs such as problem solving courts, that new sentencing options offer. For example, an individual may be sentenced to a residential treatment facility, but the individual has the right to refuse participation in the treatment facility. The second issue stems from the question of how individuals are selected for these sentencing options. Some of the programs/options have set eligibility criteria while others do not. That is, a limitation is that sentencing judges can determine a probation or prison/jail sentence but many of the sentencing

options that fall between "probation and prison" often require the agreement of the individual that they would like to participate in this program/sentencing option.

Setting as the Form of Structural Liberty Restrictions

The setting for the punishment outlines the amount and degree of liberty restrictions over an individual. Besides the setting of where the person is serving their sentence, the requirements of the sentence may also define the restrictions, limitations, and civic responsibilities of an individual. That is, the greater the number of restrictions imposed, the more the individual's daily activities are being monitored and/or controlled by the state. This has implications whether the setting of the punishment, or the number of limitations, defines the controls imposed on the individual. With the advent of controls in the community, the line between incarceration and community is often blurred, and this affects the sentencing options. It should also be noted that the length of time that the punishment is imposed—the sentence length—varies by jurisdiction, and that the longer a sentence, the more of an impact the setting (and conditions imposed) has on the person. Following, we discuss the literature on the effectiveness of incarceration and numerous alternatives that have emerged over the past few decades.

Incarceration

Incarceration can occur in a prison or jail setting. The imposition of an incarceration sentence punishes the person by imposing the most extreme liberty restrictions that include total confinement (that is, 24/7) as well as total control over daily decisions. Liberty restrictions during confinement involve a loss of the ability to make decisions about movements and activities as well as key survival decisions of food, clothing, and shelter. The "total institution" actually exercises controls over every aspect of a person's life, including psychological, spatial,

and financial, to the point where they remove the person from their support systems, such as families and children.

With all these restrictions, the question then becomes "is incarceration worth it?" given the overall effectiveness of incarceration on future offending behavior. How well does incarceration do at preventing individuals from committing more crime? In a meta-analytic study of the relationship between incarceration and recidivism, Gendreau, Goggin, Cullen, and Andrews (2000) found that the more time an individual spends in prison, the more likely they are to recidivate. They argue that prisons are actually "schools of crime" rather than a deterring presence. Mears and Bales (2009) found that simply being admitted to a super-max prison increased an individual's likelihood for committing another violent crime within three years of release. Nagin and Cullen (2007) found that incarceration does not reduce recidivism and might be iatrogenic, or increasing failure rates. Since incarceration has not been proven to reduce recidivism, and it seems to increase it, alternatives are seen as suitable punishments that achieve desired goals but do not have the same negative impacts on the ability of individuals to be crime- and/or drug-free (Sung & Lieb, 1993; Gendreau, Goggin, Cullen, & Andrews, 2000; Mears & Bales, 2009).

Shock Incarceration or Boot Camps

The notion of "shock" incarceration is exposure to the prison environment may serve as a deterrent. This is the premise that the "scared straight" program in the early 1980s was built on, even though research studies that it did not affect recidivism (Finckenauer, et al., 2003). The notion of shock incarceration was reformulated in the 1990s via boot camps. Boots camps were designed as a short-term incarceration experience designed to reduce recidivism which again evaluation studies found that the boot camps did not achieve that goal (see MacKenzie, 2006). It

appears that adding incarceration does little to reduce recidivism, even when combined with short-term experiences. The previous literature, stemming from the 1980's to the 2000's, evaluating boot camp programs does not lead to a promising outlook on their effectiveness to reduce recidivism. Sechrest (1989) performed a study in Florida assessing how well the prison boot camps influenced offenders return to prison rates, technical violation rates, and absconding rates. Those who participated in the boot camp program, compared to matched non-participants, were not significantly different in the number of technical violations or return to prison rates (Sechrest, 1989). This finding is consistent with others studies that concluded that juveniles htat participated in boot camps perceived their environment more positively, were less hostile toward others, but viewed they had less freedom than juveniles in traditional facilities. This led to individuals becoming less antisocial and less depressed (MacKenzie, Wilson, Armstrong, and Gover, 2001). Ultimately, boot camps are viewed as ineffective in reducing recidivism. However, participants in therapeutic boot camps fared better than punishment-oriented boot camps (Biere, et al., 2009).

Semi-Incarceration or Half-Back Programming

A series of semi-incarceration facilities exist that serve to incapacitate a person but for shorter periods of time and to provide other forms of punishment: residential treatment facilities, halfway houses, work release centers, and other facilities. Such facilities tend to be smaller facilities (under 200 people) than the traditional jail or prison, and the facilities typically allow for more movement and independent living under the watchful eye of the state. And, these facilities offer offer programs to address factors that affect involvement in the justice system. Most sentences are shorter than a prison and/or jail sentence, and sometimes placement in these programs is similar to transitional release from prison or jail to assist with reentry phase. Except

for residential treatment programs, most individuals are involved in some type of work on or off the premises of the facility.

A plethora of literature has been published assessing the effectiveness of halfway houses throughout the United States and Canada. Generally, studies have found that halfway houses tend to have differential effects depending on the risk level of the individual. Lowenkamp & Latessa (2005) found that participants in halfway houses that were lower risk tended to have higher recidivism rates than those that were higher risk. In other words, higher risk participants of halfway houses fared better.

Day Programming, Intensive Supervision Probation, Problem Solving Courts, and Other Intensive Community Controls

A semi-restrictive environment is a series of programming that exercise more control over the individual in terms of various forms of restrictions that affect the psychological, spatial, or financial resources of an individual. Significant periods of the 24 hour days restrict or define the daily movements of the individual. This serves to place limits on the individual while pursuing options to address substance abuse, mental illness, criminal cognitions, or other factors that affect the individual's ability to be a productive, proactive citizen.

Intensive supervision probations/paroles (ISP) are of the most common types of intensive community controls. ISP are sometimes used in conjunction with other forms of intermediate sanctions, such as electronic monitoring and house arrest (Marciniak, 2000) or even referrals to treatment. The effectiveness of these ISP's varies depending on the goal set by the program. In a review of ISP studies, Byrne (1990) found that there are four different goals that can be identified in an ISP program: punishment, diversion, cost effectiveness, and recidivism. Petersilia and Turner (1991, 1993) studied the relationship between offenders being sentenced to

ISP's and different outcome measures (depending on the goal set). The study included 14 ISP programs that served about 2000 offenders who were randomly assigned to either ISP or routine probation. ISP increased number of contacts with officer and number of drug tests. ISP resulted in more face to face contacts with their officers (average of 5 per month compared to 1.75 per month), underwent more drug testing (1.5 per month compared to .4 per month), received more counseling (48% compared to 22%), and had higher levels of employment (59% compared to 38%) (Turner, Petersilia, and Deschenes, 1992). ISP did not reduce recidivism and, in some sites, the ISP increased technical violations (Petersilia and Turner, 1993).

In the 1990s, the concept of problem solving courts were developed as part of an effort to better handle those that were drug-involved. The problem solving court is generally considered a judicial alternative since it is administered by the court (judge) armed with prosecutors, defenders, treatment providers, probation officers/case managers, and coordinators. Drug treatment courts are considered effective in reducing recidivism in a number of meta-analyses and systematic reviews (Mitchell, Wilson, Eggers, & MacKenzie, 2012). The court model advances comprehensive programming that includes status hearings to monitor the progress of the individual, drug testing, drug and/or other treatment, vocational training or employment options, and a myriad of issues to assist the individual with their drug problem.

Probation

Probation is the least restrictive form of punishment in lieu of incarceration, given that individuals remain in their own residence and are responsible for the conditions of supervision. The conditions of probation may define different ways that an individual can be restricted, even as severe as the ultimate restrictions consistent with incarceration. Since a probation sentence requires the individual to report their whereabouts daily to a third party, it also requires other

conditions. A recent study found that probation can have an average of 17 conditions (Corbett, 2014) such sometimes includes house arrest, financial penalties that restrict oftentimes consume discretionary income which limits the individual's ability to pay for food and clothing, timely meetings with the probation officer and other limitations. Oftentimes, drug and/or alcohol testing are required.

Increasingly, curfews, house arrest, and electronic monitoring are being used for individuals on probation. Probationers participating in electronic monitoring Gainey, Payne, and O'Toole (2000) often have to pay for their equipment, pay for electricity and phone connection, and respond to computer signals. A recent study found that the the number of days on electronic monitoring increased, the chance of re-arrest decreased (Gainey, Payne, and O'Toole, 2000). Electronic monitoring has mixed conclusions (Padgett, Bales, & Blomberg, 2006; Bonta, Wallace-Capretta, & Rooney, 2000; Renzema & Mayo-Wilson, 2005; Finn & Muirhead-Steves, 2002).

Nature of Restrictions as a Form of Punishment

As shown above, there are a number of different strategies to enhance the punishment and to transform the sanction to be tailored to the needs to either treat or control the individual. While sentencing used to be about the setting (i.e. prison/jail or the community), the development and utilization of various forms of rehabilitative and social control techniques have altered the nature of the sentences drastically. The degree of liberty restrictions depends on the setting, but it also depends on the conditions of the sentence that have an impact on the psychological, spatial, and/or financial restrictions that can be imposed directly by the sentencing judge, or even by the probation/correctional system. These are collateral forms of punishment. (Note: these are separate and apart from the collateral consequences such as housing restrictions,

voting restrictions, employment restrictions, and other forms of limitations on participation in civil society activities or what is part of the role of a citizen.) Sentences can be configured to be responsive to the needs of the individual, as well as advance social control.

The emergence of the variety of conditions has transformed probation considerably. In the past, most of the conditions were generally programmatic (i.e. substance abuse treatment, employment, education, etc.). But, as shown above, the advent of a variety of treatment and control conditions has transformed the probation sentence considerably. This has led to increases in various forms of direct and indirect punishments that are inherent in the probation sentence.

Psychological Restrictions

A number of conditions refer to the improvement in the mental health and overall functioning of the individual. Special conditions may include requirements to be evaluated and/or participation in treatment for mental health issues, substance abuse, and/or criminal cognitions. These conditions necessitate the person to attend to physical or mental health issues as part of their sentence. An evaluation is usually part of assessing whether the person has a preexisting condition that affects their involvement in criminal behavior, functionality as a citizen, and ability to be prosocial. Psychological treatment is considered as a means to assist the person in better understanding their own behavior (cognitions) and potential to learn new behavior, skills, or approaches to different matters (behavioral). Both evaluations and treatments are considered appropriate, and used frequently as sentencing conditions. Unless the individual is a harm to him/her self, or a danger to society, sentences cannot generally require the individual to take medications (as per the due process clauses of the fifth and 14th amendment). The individual must make their own independent decisions to take medications for mental illness or

substance use disorders, but the system can also use different incentive structures to encourage the use of medications or participation in behavioral therapies.

Other forms of psychological restrictions refer to the civil life of the individual. Usually being on supervision places pressure on a person, especially with more intensive reporting requirements and having to provide documentation of one's whereabouts to a third party. Another form of psychological strain may involve the number and type of requirements for supervision—in fact, most probationers have an average of 17 conditions (Taxman, 2012), which means that the probation supervision affects many aspects of their lives. For example, probation can involve requirements to be employed, to stay away from certain friends or family members, to perform community service (even in a place that the person may not desire to be at), and other intrusions in a person's life. The degree of psychological strain is two-pronged: the number of requirements; and, the degree to which they affect daily activities and the potential threat of being considered non-compliant and subject to revocation. The degree of psychological strain has not been measured, although there is increasing attention to this issue. One particular example in the early years of probation programming with strict conditions, Petersilia and Deschenes (1994) found that one-third of probationers prefer jail to an intermediate sanction sentence (probation with many conditions).

Spatial restrictions

More conditions refer to spatial constraints that limit the movement of the individual person. These include curfews, area restrictions, requirements to be a particular place for a set period of time (i.e. for treatment, for community service, etcetera), and requirements that limit interaction with friends, colleagues, or support systems. House arrest is one specific form of spatial restriction that involves total control over the areas a person can occupy. Additionally, as

discussed earlier, there are geographical tools to monitor the location of an individual, such as electronic monitors or Global Positioning Systems, trackers on cell phones, and other technological tools. These restrictions can create "walls" in the community by placing barriers on geographical areas that one can travel.

Financial restrictions

Being on probation, as compared to incarceration, can involve a number of financial obligations. These include probation fees, drug testing fees, mandated restitution or other fee payments, and the use of other financial requirements that use the individual's resources as a form of punishment. Each type of financial burden may have a different purpose, but collectively they impose a burden and responsibility on the individual. The various forms are: 1) restitution for the victim; 2) probation fees for being in the community instead of being incarcerated; 3) program fees pay for services; 4) court fees pay for the cost of the courts; 5) punishment specific fees, an example includes paying for electronic monitoring equipment; and 6) other financial penalties such as transaction fees, activities fees, etcetera. That is, many jurisdictions have imposed fees on those who are supervised in the community, whereas an incarceration sentence does not have that type of penalty. It is quite probable that in some of the residential programming and/or day programming that fees will be imposed. One study found that the average probationer paid $1.57 per day to be on probation (consequentially in this same jurisdiction, they contributed $1.63 per day for probation services which means that the probationers are partially paying to be on probation) (Alper & Ruhland, 2016). Other studies have noted that the financial burdens from being on probation contribute to further involvement in the justice system, and create an unequal justice system (Human Rights Watch, 2014).

Identifying Who Should Receive What Type of Sentence

The decisions about who receives what type of sentence, and what types of restrictions are included in the sentence, are generally left to the sentencing judge. Or, it could be that certain regulations define the programs, services, and components of the program. This means that the conditions and requirements may or may not be most appropriate for the person. In 21 states and the federal government, there are sentencing guidelines that define who is likely to be incarcerated based on the person's criminal history and offense severity. However, mandatory guidelines are in 10 states and 11 states have more "voluntary" guidelines, where the judge has more discretion over the incarceration decision. The presence of guidelines, however, are predominantly used to define the "incarcerated/not-incarcerated" decision, where the additional requirements are left to the judge, but sometimes they are used to determine the length of the sentence.

A current movement in the field is to use a risk-*need* assessment tool (RNA), preferably one that includes static risks and dynamic risks (*needs*) to inform the decisions of the sentencing judge and/or the probation system. That is, the RNA is promoted as an objective tool to identify which individuals need what types of controls and treatments to reduce their likelihood of participating in criminal behavior. Additionally, the RNA has the potential to identify major *needs* and then relate those *needs* to the setting and restrictions needed to promote positive behavior. The risk-*need* framework offers the potential to consider how best to use alternatives to incarceration to promote balanced distribution of restrictions to be sensitive to the public safety factors of the individual.

The RNA framework outlines the necessity to consider risk for future criminal justice involvement as a major premise as well as the *needs* of the individual. We can divide the *needs* into areas that affect criminal behavior, and should guide the nature and type of sentencing

system to respond to these *needs*. That is, as risk increases so does the need for more restrictions, including the use of confinement as a tool to address risk behaviors; but, as *needs* increase so should the use of psychological restrictions or semi-incarceration facilities to assist with handling risky *need* behaviors. Also, the type of restrictions can be tied to the risk-*need* profile of the individual. In Table 1 below, the application of the setting and restrictions to the risk-*need* profile of individuals is depicted. The conceptual model is that the higher the risk level, the more there is a need to use confinement or semi-incarceration settings for individuals. Similarly, the greater the *need*, the more there is a need for psychological interventions (restrictions) as part of the effort to minimize the *needs* of the individual.

A key to this utilization is that the type of *needs* of the individual has to be discerned. Meaning, it is important for the *needs* to be identified based on areas that are linked to criminal behavior, or that affect stability in the community, and the completion of supervision conditions. The simplistic version of this application is that as the risk level increases, so should the number of restrictions with more spatial restrictions for moderate and high risk offenders. There needs to be a cap on the restrictions given that there is a human capacity to manage multiple restrictions simultaneously, and those that are devoted to cognitive or behavioral change have an even greater impact since implicitly they require the person to make changes in related facets of their lives, such as social support networks, living arrangements, travel routes, and so on. More importantly, the focus of the attention is on obtaining gains in these areas.

Table 1: Imposition of Setting and Restrictions Based on Risk and *Needs*

	Needs		
Risk	**High**	**Moderate**	**Low**
High*	Confinement or Semi-Incarceration Setting tailored to psychological restrictions and spatial restrictions	Confinement or Semi-Incarceration Setting tailored to psychological restrictions and limited spatial restrictions	Confinement
Moderate	Semi-Incarceration or Probation with Tailored psychological and limited spatial restrictions	Semi-Incarceration or Probation with Tailored Psychological Conditions	Probation with Financial Penalties
Low	Probation with Tailored Psychological Conditions and limited Spatial Restrictions	Probation with Tailored Psychological Conditions	Probation with Financial Penalties

*High risk would have to be defined as those that are a threat to public safety which may require reducing the number of criminal convictions for low level offenses (i.e. public disorder, petty theft, etc.) that may be included in some risk assessment tools.

This framework reframes sentencing guidelines and/or practices that focus only on the "incarceration," or not, dilemma. Instead, the focus should be on transforming risk-*needs* information into a grid that redefines this incarceration dilemma. As shown in Table 1, incarceration is recommended to be limited to those individuals that are high risk according to a standardized risk-*need* assessment tool. This generally amounts to around 20 to 25 percent of the population, where the majority of the individuals are placed in community settings. Although, there is an argument for using semi-confinement facilities for specialized programming to assist individuals, who have behavioral health or criminal cognitions, make a transition to begin the recovery process. In the end, prison or incarceration is then only used for those individuals that are considered a threat to public safety or harm to themselves.

Exploring the Justice Reinvestment Initiative as Legitimate Sentencing Options

In 2010, the Bureau of Justice Assistance, with the PEW Foundation Public Safety Performance Project, launched an approach to tackle problems in the criminal justice realm, appropriately titled Justice Reinvestment Initiatives (JRI's). JRI's provide states with numerous means to accomplish the goal of reducing the demand for incarceration by reducing correctional spending and reinvesting through known recidivism-reducing strategies. Another related goal is to strengthen neighborhoods with concentrations of criminal justice populations by addressing the factors that are correlated with criminal behavior while increasing public safety.

JRI is a data driven process to facilitate system change. Beginning with an interagency team (typically including all political perspectives), the emphasis is on using data to understand how the system works and areas where policy enhancements are needed. This process breaks down into two phases. Phase 1 includes:

- Analyze data: sites receive intensive, on-sight assistance to analyze crime, arrest, conviction, jail, prison, probation, and parole data for the last 5-10 years including the cost effectiveness of the systems' policies, practices, and programs.
- Develop policy options: develop practical, data-driven, consensus-based policies that reduce spending on corrections to focus on public safety.
- Adopt new policies: Legislative bodies transform initiatives into active policies.[i]

Phase 2 includes:

- Implement new policies: after legislation, implementation should proceed as a deliberative change process.
- Reinvest: with the estimated savings, reallocate that money to public safety strategies and programs in the community.

- Measure performance: all sites monitor their performance and outcome measures to make sure they achieve projected outcomes and goals. The performance reports are provided to oversight communities to assess how well the initiative is doing. [ii]

The states who are currently participating in the JRI framework include: Alabama, Alaska, Arkansas, Delaware, Georgia, Idaho, Hawaii, Kansas, Kentucky, Louisiana, Maryland, Michigan, Mississippi, Missouri, Nebraska, New Hampshire, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Utah, Washington, and West Virginia. Those who have used JRI's, or JRI policies, also include: Arizona, Connecticut, Nevada, Texas, Vermont, and Wisconsin. Collectively, 33 of the 50 states are using, or have used, some kind of JRI framework to actively impact their sentencing and justice systems.[iii]

The common issue addressed focuses on the factors behind prison growth and corrections spending. These influential factors are: parole/probation revocations, sentencing policies for low risk offenders to incarceration, inefficient community supervision, and parole system processing delays and denials.[iv] These issues have led to a number of policy responses in a majority of the state sites that ranged on where they're targeting. Many sites started integrating risk and *needs* assessments, accountability measures, incentives for community compliance, sentencing changes, swift and certain responses to technical violations, mandatory supervision post-incarceration, conflict-resolving courts, quicker and more expansive parole process, and more inclusive re-entry programs.[v]

Impact of JRI

There have been a few evaluation studies assessing the influence that JRI's, or JRI type policies, have on the issues of the criminal justice system. The VERA Institute of Justice assessed that the judicial and probation systems are the reason for Delaware's prison

overcrowding. A majority of Delaware's prison population consisted of those who were awaiting trial, people who were over-supervised on probation, and long sentences without an opportunity for reduction (James and Agha, 2013). In response to these issues, Delaware drafted Senate Bill 226, requiring risk assessments to be performed and available to judges, and create incentives for those who are incarcerated to complete evidence-based programs (James and Agha, 2013). The reasons for this legislation are to allow magistrates and judges to make precise risk assessment decisions when it comes to sentencing people and/or selecting people for parole, as well as decreasing the likelihood of recidivism for those who are completing the scientifically proven programs.

Another assessment of JRI programs was performed by the Urban Institute in their review of 17 JRI using states. Consistent with the assessment of Delaware, they found that the largest influences on prison population and cost include parole and probation revocations, sentencing policies, ineffective community alternatives, and parole system delays/denials (LaVigne et al., 2014). Over the 17 states, however, there was a wide array of policies that were put into action to target the different influences each state faced. A majority of these policies focused on: performance and use of risk and *needs* assessments, accountability measures, credit earnings, more intermediate sanctions, community based treatment, sentencing policy changes, problem solving courts, and revise parole system processes (LaVigne et al., 2014). Similarities exist across systems regarding the drivers of incarceration and the facilitators for changing practices.

The estimated monetary savings for the 17 states is $4.6 billion, ranging from saving $7.7 million to $398 million over 5 years per state (LaVigne et al., 2014). All of these costs stem from the averted operating and construction costs of prisons. Additionally, as stated before, JRI

policies reinvest the money saved. The URBAN report discusses two different types of reinvestment that occur. The first is reinvesting money that has already been saved from previous years; the second is investing money that is anticipated to be saved in future years. So far, from all 17 states, $23.7 million have been invested from previous savings and $142.1 million have been invested in anticipation of future savings (LaVigne et al., 2014). In addition to the monetary benefits, 8 of the 17 states (Arkansas, Hawaii, Louisiana, Kentucky, New Hampshire, North Carolina, Ohio, and South Carolina) reduced their prison populations within one year and all states anticipate their prison population reductions will range from .6% to 19% (LaVigne et al., 2014).

In a similar effort, a case study of prison reductions in New York, New Jersey, Michigan, and Kansas from 1999-2009 revealed interesting changes in sentencing. New York and New Jersey, from 1999-2009, experienced a 20% and 19% reduction, respectively, while Michigan experienced a 12% reduction from 2006-2009 and Kansas experienced a 5% reduction from 2003-2009 (Greene and Mauer, 2010). The different drivers of change were:

- New York:
    - Revised Rockefeller drugs laws to reduce mandatory sentences and use more community based options.
    - Identify individuals who can be involved in drug treatment alternatives.
    - Gave inmates good time credit incentives for participating in educational and vocational training and treatment.
- Michigan:
    - Revised 650 Lifer Law,[vi] eliminated mandatory minimums for drug offenses, and restructured community corrections to create incentives to target "straddle-cell"

cases with intermediate sanctions.[vii]

  - Identify lower risk individuals for intermediate sanctions and designation of two reentry prisons to help plan for future releases.
  - Established Michigan prisoner reentry initiative, which implemented local services targeting aspects that make it difficult to reenter society.

- Kansas:
  - Revised sentencing guidelines to use treatment for drug possession rather than prison and eliminated sentence enhancements for prior convictions.
  - Provide services in community setting to reduce rule violations.
  - Allocated funds to community programs that strengthened the neighborhood, substance abuse and mental health treatments, and housing services.
- New Jersey:
  - Permitted "open pleas" in lower level drug free zone cases.[viii]
  - Used risk assessments for individuals going onto parole, as well as, used daily reports and electronic monitoring for those on parole.
  - Set up regional assessment centers which allowed for information to be given to parole board on whether violators should be allowed to continue on parole.[ix]

The common features of the four states in targeting prison overcrowding and cost include: using risk assessments, revising sentencing guidelines, and expanding sentencing options.

Taxman, Pattavina, and Caudy (2014), performed hypothetical simulations to assess how JRI treatment policies, using the RNR tool,[x] would affect individual offenders within a prison system. Their four measures included the availability rate, the participation rate, the access rate, and the responsivity rate (percentage of offenders with a specific *need* who can access services

for that *need*) for each prison. In order to assess how these measures influenced recidivism, two different analyses were performed, an outcome oriented analysis, which tested how re-arrest was influenced by expanding access to, and effectiveness of, treatment, and a process oriented analysis, which tested how re-incarceration was affected by improving the quality of treatments and using risk, *needs* assessments. The outcome oriented analysis found that the more people who are treated, the stronger the effects are going to be; the example given is increasing the percentage of inmates receiving treatment from 10% to 50% decreases the recidivism rate by 8% (Taxman, Pattavina, and Caudy, 2014). Additionally, as more people are exposed to treatment, it becomes more frequent within the prison leading to an increase in the quality of treatment. In conjunction with the findings for the outcome oriented analysis, the process oriented analysis found that using the RNR tool, alone, will reduce re-incarceration by 3.4% in 9 years (Taxman, Pattavina, and Caudy, 2014). If the quality of treatments are improved, the reduction becomes 6.7% (Taxman, Pattavina, and Caudy, 2014). Overall, the results suggest that allowing treatment options as part of sentencing to be more available coupled with matching the treatment to the specific *needs* of the individual, will not only enhance the reduction in recidivism, but accelerate the time it takes for the treatment to be effective. The analyses found that applying the risk-*need* framework reduced 1 recidivist event for every 5 people, whereas the incarceration model reduces 1 recidivist event for every 33 people. The JRI framework enhances change in recidivism behavior.

Case study: Texas

Fabelo (2010) compared California to Texas in terms of how prison overcrowding is addressed. California and Texas are extremely similar in terms of the size of their prison system; as of 2008, California had 173,320 inmates, whereas Texas had 173,232 inmates. Both were

operating at or over their limit, however, California spent four times the amount that Texas was spending.

Texas had problems with prison overcrowding due to long sentences and increasing intakes into the system. Consistent with the previous literature discussed, the 300% increase in Texas's prison population from 1980 to 2005 was a direct result of probation revocations, lack of treatment and diversion programs, and low parole grant rates. In 2007, their political officers debated on spending half a billion dollars to build and operate new prisons. However, they decided against this, and instead, decided to launch the Public Safety Performance Project. Texas allocated $241 million specifically for the use of diversion and treatment programs. This amount, plus the reductions spent on the construction and operation of prisons, resulted in net savings of $443.9 million (Fabelo, 2010). The legislation Texas implemented consisted of:

- Establishing maximum caseloads of 60 probationers/parolees per officer.[xi]
- Reducing maximum probation terms from 10 years to 5 years for drug and property offenders.
- Providing funding for counties who use progressive sanctions for violators which included the development of semi-incarceration and residential treatment program for those that are having difficulties on probation/parole.
- Expand drug and specialty courts to ensure that lower risk offenders received treatment instead of prison.

Aside from the monetary savings, the results of the legislation primarily affected lower risk individuals. Fabelo (2010) compared recidivism rates for the offenders before the legislation went into effect, during the transition period when the legislation was being put into effect, and after the legislation went into effect. He found the recidivism rates, overall, were 29%, 26%, and

24% for the three groups, respectively; however, when he specifically looked at lower risk offenders, the numbers differed significantly with 26%, 10% and 6% for the three groups, respectively (Fabelo, 2010).

Case Study: California

In May of 2011, the Supreme Court stated that California was in violation of the 8th amendment with their prisons being cruel and unusual punishment. The mass amount of overcrowding in their prison systems resulted in the lack of proper health care for the confined individuals. California passed the Assembly Bills 109 and 117, referred to as the policy initiative of Realignment. This set of legislation authorized California to divert and relocate thousands of their low-level, non-serious, non-violent offenders from state prisons to local jails and probation/parole programs to allow these local authorities to manage these individuals.[xii] The main goal of Realignment is to decrease the state-prison population. In 2014, the citizens passed a ballot initiative, Proposition 47, which downgraded the sentencing of drug possession to a misdemeanor as well as authorized misdemeanor sentencing for petty theft. As part of the Realignment initiative, funding from the state was allocated to local communities to enhance their jail and probation/parole efforts. Specifically, funds were allocated to enhance probation and parole services to manage the individuals released early from prison to the communities, as well as to enhance treatment programming. Each county could exercise their own efforts to enhance efforts to manage the population in the community and in the county instead of a state prison.

Turner, Fain, and Hunt (2015) examined the impact of Realignment on whether individual counties made changes to their corrections systems or if they continued to rely on state prisons. The study was of 12 counties: Alameda, Fresno, Kern, Los Angeles, Orange, Riverside,

Sacramento, San Bernardino, San Diego, San Francisco, Santa Clara, and Stanislaus counties. California's prison population decreased by 20.4% from 2009-2010 fiscal year to the 2012-2013 fiscal year.[xiii] For these 12 counties, all of them experienced decreases in sentences to prison admissions and standing prison populations from their counties. San Francisco experienced the biggest reductions of 52.1% and 33.7%, respectively, with Fresno having the smallest reduction of 20.3% for prison admissions and Riverside with 12.8% for standing prison population (Turner, Fain, and Hunt, 2015). In this study, they noted that the local jail population for California increased by a total of 12% from June 2011 to June 2012. Funding from Realignment was also used to enhance their services for education, employment, drug treatment, and mental health treatment for those in the community setting (Turner, Fain, and Hunt, 2015). Realignment, in the early years, led to a larger local jail population but after the imposition of Proposition 47 (which reduced the sentencing of drug possession and petty theft to a misdemeanor), the incarcerated jail populations also declined.

A question is raised about the impact of Realignment on recidivism and crime rates. It was expected that Realignment could influence recidivism rates by having increased resources from the state to expand local criminal justice services and implement effective interventions. Also, the local communities would be more vested in addressing individual needs to reduce recidivism.[xiv] A study found that the percentage of early releases from state prison (referred to as AB 109), who committed a crime and returned to prison, dropped 25 percentage points. This also resulted in a reduction of 7% of new intakes to prison from parole revocations (Bird & Grattet, 2016). The overall re-arrest and reconviction rates were not as substantial with only a 2 percentage point reduction in recidivism, and the reconviction rate decreased by 1 percentage point for felonies and .2 percentage points for misdemeanors. These results suggest that the

primary objective of Realignment was accomplished, with the reduction of people in state prisons. Another study found that early release from prison reduced incarceration, and the use of a variety of local sentencing options had no impact on violent or property crimes; there was a minor impact on auto theft in one-year post-Realignment, but no long term effects (Sundt, Salisbury, & Harmon, 2016).

Justice Reinvestment Initiatives Internationally

Internationally, there has not been nearly as much of an effort with JRI's as there has been in the United States (Fox, Albertson, and Warburton, 2011), but it is a growing effort. Two studies, in particular, looked at JRI's, for the over-incarcerated indigenous population in Australia and a pilot study in England. In both studies, they discuss the reasons why JRI's were not effective in their respective communities.

Schwartz (2010) examined the incarceration options for the indigenous population in Australia. The population is imprisoned at a rate of 1,891 per 100,000, as compared to the non-indigenous at a rate of 136 per 100,000; 73% of the indigenous prisoners have prior criminal justice experience (Schwartz, 2010). One of the main reasons why they are so heavily concentrated in the prison system is a result of 25% living in remote locations, where community supervision cannot thrive. In addition, there is very little public support for the indigenous population. They are social outcasts, and as Schwartz (2010) states, public support is crucial in order for the JRI policies to work in Australia, such as examples of Kansas or in Oregon with the juvenile offender initiative (Tucker and Cadora, 2003; Council of State governments, 2010).[xv]

In England, Wong et al. (2013) assessed a local justice reinvestment initiative using interviews, focus groups, and workshops, where the JRI-like initiative rewarded partners if they reduced the demand on criminal justice services by 5% for adults and 10% for juveniles. From

these qualitative assessments, they found that only one of the six sites, Manchester, experienced any type of benefit. In Manchester, the project managers provided narratives to help stakeholders buy into the project, used the best available data to make decisions, and had cooperation from numerous agencies (Wong et al., 2013), which was not the case in other areas of the UK. For the other five sites, the emphasis for potentially making the process better modeled after what worked in Manchester and included: better reinforcing incentives, better leadership and communication for the goals/aims, better performance management, use of the best evidence available, and integration of all agencies involved (Wong et al., 2013). More work is needed to see what type of sentencing options can be developed and implemented.

Conclusion

In the 1990's the concept of alternatives to incarceration or graduated sanctions gained favor as a strategy to expand sentencing between prison and probation. In the 1990's, there was a push to develop new efforts to expand the probation-plus options that was designed to enhance the punitiveness of probation as well as give new options to avoid incarceration. In that era, the concept of shock incarceration/boot camps, day reporting programs, probation with numerous required mandates, treatment with sanctions, and other variations of identifying needs that could be diverted to treatment programs were tested with varying success. Programs were designed and tested but funding and available resources limited the options. Even so, in the mid-2000's, a survey of jails, prisons, and community corrections reported that around 10 percent of the correctional population could take advantage of the programming and sentencing options (Taxman, Perdoni, & Harrison, 2007). Drug treatment courts were developed for drug offenders but, even with their available funding, less than 3 percent of the estimated drug involved offenders participate in specialized courts (Taxman, Perdoni, & Harrsion, 2007), demonstrating

the great challenges of shifting populations into an array of sentences. Part of the drawback was that alternatives to incarceration were still considered alternatives—sending a symbolic message that these are not necessarily legitimate sanctions.

Justice reinvestment offered the political coverage to expand the use of a broad array of correctional options as sentencing alternatives, with the emphasis on legislation that altered the "incarceration/not" rules. JRI initiatives focused on the intake to prison which included downgrading the sentences for some offenders and altering how probation and parole revocations are handled—both of these efforts were to reduce the intake into prison/jails (incarceration) and to use community options to address the offenders. JRI-related efforts have not drastically affected the length of sentence for most offenders, except in a few states that have downgraded sentence structures for drug offenders that are treatment eligible to semi-incarceration settings, probation with treatment or other treatment options. But, the efforts have also served to improve the acceptability of "alternatives to incarceration" as rightful sentences that align with socio-political dynamics in reform states. This lays the groundwork for longer term changes in the political acceptability of using a broader range of sentences and perhaps reducing the sentence lengths.

A pressing is the development and maintenance of consensus among policymakers (LaVigne et al., 2014). With the quick turnover for political offices, results need to be immediate; therefore, if results do not occur quickly, funding may be revoked, or even the initiative all together. While more than half of the 50 states have used JRI's, where almost all have seen some kind of benefit in the short term, the question is whether funding will be available to develop community based services. And, the question becomes whether individuals will be placed into

these options instead of traditional sentences of incarceration, either in terms of long or short term periods of incarceration. Generally these incarceration sentences also include probation.

The concept of alternatives to incarceration is morphing into sentencing options, options that are legitimate and that draw upon the broad variety of sanctions that are needed to adequately punish (and treat) the incarcerated population. The proposed risk-need framework integrated objective, standardized tools into the decision-making framework where judges and others are guided by the answer to three questions: 1) what is the likelihood that an individual will recidivate for a serious crime? 2) what are the underlying needs that affect involvement in criminal behavior that are amendable to treatment; and, 3) what combination of restrictions are needed to facilitate punishment and change in the behavior of individuals. Table 1 presents a vision of sentencing where the risk and needs are combined to provide the most suitable sentence, and restrictions are used interchangeably to tailor to the individual. In a nutshell, this model embraces proportionality and parsimony in the sentencing framework. In many ways, it also tries to integrate the concept of citizenship—maintaining the concern for preserving the positive role of the individual in the sentencing process. It also serves to hold the system accountable for using the least restrictive means that can beneficial to the individual in how they are treated by the justice system. The end result is justice served.

Further Reading

Bonta, J., & Motiuk, L. L. (1985). Utilization of an Interview-Based Classification Instrument A Study of Correctional Halfway Houses. *Criminal Justice and Behavior*, *12*(3), 333-352.

Clear, T. R. (2011). A private-sector, incentives-based model for justice reinvestment. *Criminology & Public Policy*, *10*(3), 585-608.

Council of State Governments. 2010a. *About the Project*. Retrieved July 1, 2010 from justicereinvestment.org/about.

Council of State Governments. 2010b. *Connecticut Overview*. Retrieved July 6, 2010 from justicereinvestment.org/states/connecticut.

Council of State Governments. 2010c. *Texas Justice Reinvestment*. Retrieved December 27, 2010 from justicereinvestment.org/states/texas

Cullen, Francis T., Cheryl Lero Jonson, and Daniel S. Nagin.2011. "Prisons Do Not Reduce Recidivism: The High Cost of Ignoring Science," The Prison Journal 1: 48S-65S.

Finckenauer, J. Gavin, P.w., Hovland, A., & Storvoll, E. (2012) Scared Straight: The Panacea Phenomenon Revisited. Waveland Press.

Friedmann, P.D., Taxman, F.S., & Henderson, C. (2007). Evidence-based treatment practices for drug-involved adults in the criminal justice system. *Journal of Substance Abuse Treatment*, 32(3): 267-277. PMID: 17383551. PMCID: PMC1885209

Henggeler, S. W., & Schoenwald, S. K. (1994). Boot camps for juvenile offenders: Just say no. *Journal of Child and Family Studies*, *3*(3), 243-248.

Latessa, E., & Allen, H. E. (1982). Halfway houses and parole: A national assessment. *Journal of Criminal Justice*, *10*(2), 153-163.

Lipsey, M.W. & Cullen, F.T. (2007). The effectiveness of correctional rehabilitation: A review of systematic reviews. *Annual Review of Law and Social Science,* 3, 297-320.

Ohio Division of Youth Services. 2010. *RECLAIM Ohio*. Retrieved July 29, 2010 from dys.ohio.gov/dnn/Community/ReclaimOhio/tabid/131/Default.aspx.

Petersilia, J., & Turner, S. (1990). Comparing intensive and regular supervision for high-risk probationers: Early results from an experiment in California. *Crime & Delinquency*, *36*(1), 87-111.

Renzema, M., & Mayo-Wilson, E. (2005). Can electronic monitoring reduce crime for moderate to high-risk offenders?. *Journal of Experimental Criminology*, *1*(2), 215-237.

Taxman, F.S. & Pattavina, A. (2013). *Simulation strategies to reduce recidivism: Risk need responsivity (RNR) modeling in the criminal justice system.* New York: Springer.

Taxman, F.S., Perdoni, M., & Harrison, L. (2007). Drug treatment services for adult offenders: The state of the state. *Journal of Substance Abuse Treatment*, 32(3): 239-254. PMID: 17383549. PMCID: PMC2266078.

Wilson, D. B., MacKenzie, D. L., & Mitchell, F. N. (2005). Effects of correctional boot camps on offending.

References

Alper, M.E., Ruhland, E.L. (2016). Probation Revocation and Its Causes: Profiles of State and Local Jurisdictions. Robina Institute of Criminal Law & Criminal Justice, *Wharton & Matagorda Counties, Texas*.

Bird, M., & Grattet, R. (2016). Realignment and Recidivism. *The ANNALS of the American Academy of Political and Social Science*, *664*(1), 176-195.

Bonta, J., & Motiuk, L. L. (1987). The diversion of incarcerated offenders to correctional halfway houses. *Journal of Research in Crime and Delinquency*,*24*(4), 302-323.

Bonta, J., & Motiuk, L. L. (1990). Classification to halfway houses: a quasi-experimental evaluation. *Criminology*, *28*(3), 497-506.

Bonta, J., Wallace-Capretta, S., & Rooney, J. (2000). Can electronic monitoring make a difference? An evaluation of three Canadian programs.*Crime & Delinquency*, *46*(1), 61-75.

Bottcher, J., & Ezell, M. E. (2005). Examining the effectiveness of boot camps: A randomized experiment with a long-term follow up. *Journal of Research in Crime and Delinquency*, *42*(3), 309-332.

Byrne, J. M. (1990). The future of intensive probation supervision and the new intermediate sanctions. *Crime & Delinquency*, *36*(1), 6-41.

Council of State Government Justice Center. (2010) *Work in the States: Kansas*. http://www.justicereinvestment.org/states/kansas/howks/quantify-ks

Council for State Governments. (2016). *States Receiving technical assistance from the CSG Justice Center*. Justice Center. Retrieved from: https://csgjusticecenter.org/jr/

Department of Justice. (2016). *Justice Reinvestment Initiative*. Office of Justice Programs: Bureau of Justice Assistance. Retrieved from: https://www.bja.gov/programs/justicereinvestment/what_is_jri.html

Department of Justice. (2016). *Justice Reinvestment Initiative Maximizing State Reforms*. Office of Justice Programs: Bureau of Justice Assistance. Retrieved from: https://www.bja.gov/funding/JRImaximizing.pdf

Fabelo, T. (2010). Texas Justice Reinvestment: Be More Like Texas?. *Justice research and Policy*, *12*(1), 113-131.

Finn, M. A., & Muirhead-Steves, S. (2002). The effectiveness of electronic monitoring with violent male parolees. *Justice Quarterly*, *19*(2), 293-312.

Fox, C., Albertson, K., & Warburton, F. (2011). Justice reinvestment: Can it deliver more for less?. *The Howard Journal of Criminal Justice*, *50*(2), 119-136.

Freeman, B., & Frierson, R.L. (2009). Court-Mandated, Long Acting Psychotropic Medication as a Condition of Supervised Release. J Am Acad Psychiatry Law 37:2:268-270 doi:

Gainey, R. R., Payne, B. K., & O'Toole, M. (2000). The relationships between time in jail, time on electronic monitoring, and recidivism: An event history analysis of a jail-based program. *Justice Quarterly*, *17*(4), 733-752.

Gendreau, P., Goggin, C., Cullen, F. T., & Andrews, D. A. (2000, May). The effects of community sanctions and incarceration on recidivism. In *Forum on Corrections Research* (Vol. 12, No. 2, pp. 10-13). Correctional Service of Canada.

Greene, Judith and Marc Mauer. (2010). *Downscaling Prisons: Lessons from Four States*. Washington, DC: The Sentencing Project.

Hartman, D. J., Friday, P. C., & Minor, K. I. (1994). Residential probation: A seven-year follow-up study of halfway house discharges. *Journal of criminal justice*, *22*(6), 503-515.

Human Rights Watch (2014). Profiting from Probation. "Offender-Funded" Probation Industry. NY: Human Rights Watch. https://www.hrw.org/report/2014/02/05/profiting-probation/americas-offender-funded-probation-industry

James, J., & Agha, S. (2013). Justice reinvestment in action: the Delaware model. *New York: Vera Institute of Justice*.

LaVigne, N., Bieler, S., Cramer, L., Ho, H., Kotonias, C., Mayer, D., ... & Samuels, J. (2014). Justice reinvestment initiative state assessment report.*Washington, DC: Urban Institute*.

MacKenzie, D. L., Wilson, D. B., Armstrong, G. S., & Gover, A. R. (2001). The impact of boot camps and traditional institutions on juvenile residents: Perceptions, adjustment, and change. *Journal of Research in Crime and Delinquency*, *38*(3), 279-313.

MacKenzie, D. L., Wilson, D. B., & Kider, S. B. (2001). Effects of correctional boot camps on offending. *The Annals of the American Academy of Political and Social Science*, *578*(1), 126-143.

Marciniak, L. M. (2000). Addition of Day Reporting to Intensive Supervision Probation: A Comparison of Recidivism Rates, The. *Fed. Probation*, *64*, 34.

Mears, D. P., & Bales, W. D. (2009). Supermax incarceration and recidivism. *Criminology*. *47*(4), 1131-1166.

Morris, N., & Tonry, M. (1991). *Between prison and probation: Intermediate punishments in a rational sentencing system*. Oxford University Press.

Padgett, K. G., Bales, W. D., & Blomberg, T. G. (2006). Under surveillance: An empirical test of the effectiveness and consequences of electronic monitoring. *Criminology & Public Policy*, *5*(1), 61-91.

Petersilia, J.. Deschenes, E. (1994). "Perceptions of Punishment: Inmates and Staff Rank the Severity of Prison versus Intermediate Sanctions," The Prison Journal, Vol. 74, No. 3, pp. 306-328.

Petersilia, J., & Turner, S. (1991). An evaluation of intensive probation in California. *The Journal of Criminal Law and Criminology (1973-)*, *82*(3), 610-658.

Petersilia, J., & Turner, S. (1993). Evaluating Intensive Supervision Probation/Parole: Results of a Nationwide Experiment. Washington, DC: National Institute of Justice.

Petersilia, J., & Turner, S. (1993). Intensive probation and parole. *Crime and justice*, 281-335.

Schwartz, M. (2010). Building communities, not prisons: Justice reinvestment and Indigenous over-representation. *AILR*, *14*(1).

Sechrest, D. K. (1989). Prison boot camps do not measure up. *Fed. Probation*, *53*, 15.

Sundt, J., Salisbury, E.J., & Harmon, M.G. (2016). The Effect of California's Realignment Act on Public Safety. Criminology and Public Policy, 15(2): 1- 27. doi:10.111/1745-9133.12199.

Sung, L., & Lieb, R. (1993). *Recidivism: The effect of incarceration and length of time served*. Olympia, WA: Washington State Institute for Public Policy.

Taxman, F. S., Pattavina, A., & Caudy, M. (2014). Justice reinvestment in the United States: An empirical assessment of the potential impact of increased correctional programming on recidivism. *Victims & Offenders*,*9*(1), 50-75.

Taxman, F.S. (2012). Probation, intermediate sanctions, and community-based corrections. In J. Petersilia and K. Reitz (Eds.), *Oxford handbook on sentencing and corrections* (pp. 363-388). New York: Oxford University Press.

Tella, R. D., & Schargrodsky, E. (2009). *Criminal recidivism after prison and electronic monitoring* (No. w15602). National Bureau of Economic Research.

Tucker, S, and Cadora, E. (2003). 'From Prisons to Parks in Oregon.' *Open Society Institute Occasional Papers*. 3(3). 6

Turner, S., Fain, T., & Hunt, S. (2015). *Public safety realignment in twelve California counties*. California: Rand Corporation.

Turner, S., Petersilia, J., & Deschenes, E. P. (1992). Evaluating intensive supervision probation/parole (ISP) for drug offenders. *Crime & Delinquency*,*38*(4), 539-556.

Watts, A.L., (2016). Probation in-Depth: The Length of Probation Sentences. Minnesota: Robina Institute of Criminal Law & Criminal Justice.

Wong, K., Meadows, L., Warburton, F., Webb, S., Young, H., & Barraclough, N. (2013). The development and year one implementation of the local justice reinvestment pilot.

[i] Taken from https://www.bja.gov/programs/justicereinvestment/what_is_jri.html
[ii] Taken from https://www.bja.gov/programs/justicereinvestment/what_is_jri.html
[iii] For more information on any or all of these specific states, visit https://csgjusticecenter.org/jr/

[iv] Taken from: https://www.bja.gov/funding/JRImaximizing.pdf
[v] Taken from: https://www.bja.gov/funding/JRImaximizing.pdf
[vi] 650 Lifer Law imposed life sentences for drugs offenses of over 650 grams, regardless of prior offense history.
[vii] There are three types of "cells." The most serious receives prison, the lease serious receives a non-custodial penalty, and the "straddle-cell" allows the judge to choose either prison or intermediate sanction.
[viii] These are cases where the individual was in possession of drugs within 100 feet of a school related area or 500 feet of a public park, public building, or public housing building.
[ix] All of these states were described in Greene, Judith and Marc Mauer. 2010. *Downscaling Prisons: Lessons from Four States*.
Washington, DC: The Sentencing Project
[x] RNR tool stands for Risk, Needs, and Responsivity tool. It is an assessment to identify an individual's risks and needs that need to be targeted.
[xi] Texas Legislature, House Bill 3736, "An Act Relating to Establishing Parole Officer Maximum Caseloads," enacted 2007.
[xii] Taken from http://www.cdcr.ca.gov/realignment/docs/realignment-fact-sheet.pdf
[xiii] Dropped from 167,176 inmates to 133,217 inmates.
[xiv] The ability of sending revocations to prison was revoked with Realignment.
[xv] Juvenile Offender Initiative placed juveniles on community supervision and partnered with organizations, such as Habitat for Humanity, and substantially gained public support due to actively helping the community.

The Center for Advancing Correctional Excellence

CRIMINOLOGY, LAW & SOCIETY, GEORGE MASON UNIVERSITY

January 2013

The Risk-Need-Responsivity Simulation Tool

Solutions For Justice Professionals

With goals to safely manage the offender population, justice professionals are tasked with responding to the risk and needs of individuals.

The RNR Simulation Tool is designed to help corrections and treatment agencies meet demands to be responsive to the needs and risks of individuals in the justice system. Increasing responsivity is needed to reduce the risk of future offending.

Decision-support tools were funded by the Center for Advancing Correctional Excellence (ACE!) at George Mason University, the Bureau of Justice Assistance (2009-DG-BX-K026), the Substance Abuse and Mental Health Services Administration (202171), and The Public Welfare Foundation.

For people involved in the criminal justice system, evidence-based practice (EBP) and treatments emphasize that assessment and programming should target criminal justice, criminogenic need, and other behavioral issues. The notion is that individual outcomes can be improved by assessing for a number of related and often overlapping dimensions such as offending (e.g. criminal history risk), needs (e.g. antisocial peers, antisocial cognitions, antisocial values/thinking) and behavioral health factors (e.g. substance use, mental health, trauma). This evidence-based practice is referred to as the Risk-Need-Responsivity (RNR) Model (Andrews and Bonta, 2010; Caudy et al., 2013).

Another component of the EBP model is the nature of the programs and interventions offered to individuals. Effective programs must be able to address the criminal justice, behavioral health, and criminogenic needs of individuals to achieve positive results.

The RNR framework focuses on improving outcomes by encouraging the justice system to respond to its clients in a manner that is likely to yield better outcomes. While effective *programs* can reduce recidivism for *individual* offenders, effective *systems* can reduce recidivism for *populations* of offenders. This requires individual assessments to pay particular attention to a broader range of factors that directly relate to individuals' risk for reoffending and prioritize these needs for targeted treatment. It also requires practitioners to implement programs that target certain profiles of offenders with specific needs. The RNR framework reinforces the need for jurisdictions to have a range of effective, well-implemented programs that target the varying needs of the justice-involved population. It is important to address gaps in services to develop responsive programs and ultimately, a responsive system.

This web-based decision-support system—the RNR Simulation Tool—was developed to help jurisdictions and providers implement the RNR framework. The system assists justice and behavioral health agencies (government, private, or non-profit) who wish to translate EBPs into practice. This approach integrates the science around effective screening, assessment, programs, and treatment matching (responsivity) to improve individual and system outcomes. To that end, the RNR Simulation Tool has three portals: 1) The RNR Program Tool for Adults; 2) Assess an Individual; and 3) Assess Jurisdiction's Capacity.

This document provides users with general information about each portal and the intended uses. Please email rnrtool@gmu.edu for more specific information or to answer any questions about the tool. The RNR Simulation Tool is available online at: http://www.gmuace.org/tools/

Three Easy-to-Use Web Portals

THE RNR PROGRAM TOOL

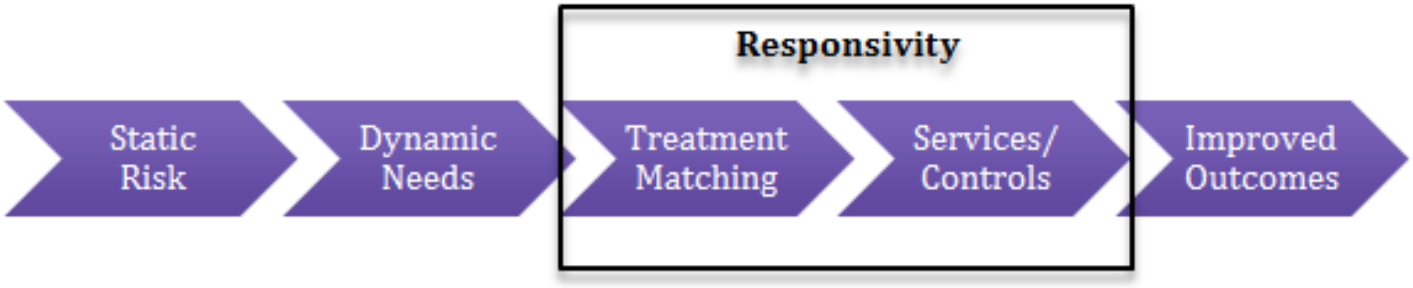
This 30-minute program assessment tool examines the content, quality, dosage, and other factors of services/ treatments/controls offered for justice-involved individuals. Jurisdiction administrators or program managers simply input information about a specific program offered and the tool provides detailed feedback indicating what risk-need profiles the program is best suited to meet. The portal also rates the program's overall quality according to the RNR principles and core correctional practice. When applicable, the tool provides recommendations for how program administrators can refine the program to better achieve responsivity and improve outcomes. The three main goals of the program tool are: 1) to classify programs to facilitate treatment matching, 2) to explore how programs currently target the risk level and criminogenic needs of their clients, and 3) to assess programs on their use of evidence-based practices. The tool is intended to help criminal justice agencies better understand the resources available to them and to foster responsivity to specific risk-need profiles.

ASSESS AN INDIVIDUAL

The Assess an Individual portal emphasizes using data from criminal justice and behavioral health screenings and assessments to determine the most effective type of program and controls to reduce individual recidivism. This portal can be used with a jurisdiction's instruments, by itself, or in combination with other tools. Designed for line staff, users are asked to answer 17 questions about individual offenders' risk, needs, and lifestyle factors. The system then provides a recommendation regarding the type of program that would best fit the individual and lead to the greatest recidivism reductions. If certain information is not available, the RNR Simulation Tool will rely upon its underlying database of offender risk-need profiles to estimate likely attributes based on the prevalence of each attribute in the national population. Users can integrate jurisdiction-specific data regarding the prevalence of individual attributes to produce customized feedback. This portal also estimates a percent reduction in recidivism that one might expect if the offender is matched to the level of programming that is consistent with their unique needs (i.e., a program of best fit).

ASSESS JURISDICTION'S CAPACITY

The Assess Jurisdiction's Capacity portal uses inputted information to assess a jurisdiction's capacity to be responsive to the risk-need profiles of individuals in its jurisdiction. Based on data from 18 questions about the prevalence of risk and needs of individuals in the jurisdiction, the portal provides an initial recommendation of the amount and type of programming needed to adequately respond to the jurisdiction's population. When users enter information regarding the available programs in a jurisdiction, the portal also identifies system-level gaps in the jurisdiction's capacity to provide responsivity and recommends levels of programming the jurisdiction may need to augment in order to better respond to the needs of their population.



EYE ON IT

The latest on evidence-based programming.

While there is no magic program that will work for every offender every time (Lipsey & Cullen, 2007), recent meta-analytic research indicates that certain correctional treatments tend to be more effective than others. Programs showing some of the largest reductions in offending include Cognitive-Behavioral Therapy (CBT), Medically-Assisted Treatment (MAT), Drug Courts, and Therapeutic Communities (TCs) (see Caudy et al., 2013).

The RNR Simulation Tool relies on these types of evidence to provide feedback to users. The RNR Program Tool portal allows users to enter information for each program or service they offer, whether it exists as a separate program or within a justice setting. The tool also includes the latest in implementation knowledge to assist programs with determining the degree to which their program adheres to the RNR model.

Classifying Programs to Guide Responsivity and Outcomes

The **RNR Program Tool** portal uses program-specific information to categorize programs into six different program groups. Each group has a different target area that reflects the program's focus to address offending behaviors.

GROUP A	• Dependence on "Hard" Drugs
GROUP B	• Criminal Thinking/Cognitive Restructuring
GROUP C	• Self Improvement & Management
GROUP D	• Interpersonal Skills
GROUP E	• Life Skills
GROUP F	• Punishment Only

RNR Program Group Primary Target Areas

*Hard Drugs are those substances that exhibit a direct link with offending behavior. These substances include amphetamines, opiates, and crack/cocaine.

Q: What are some essential features of effective correctional programs?

A. There are many different factors that can impact the effectiveness of a program including risk, needs, responsivity, implementation, and dosage. Programs with good adherence to each of these key features tend to have better outcomes. The key is what criminogenic behaviors the program addresses and the different cognitive and behavioral tools used to assist individuals in changing these behaviors. The RNR Program Tool provides users with feedback and scores on the essential features of programs to allow users to understand a program's strengths and areas where it can be improved. The tool also provides examples of high-quality programs to guide improvements. Program managers can use overall program ratings or scores on essential features to work with justice agencies to maximize exposure to effective programs.

High-Quality Programs:

- Use cognitive behavioral therapy (CBT) and social learning interventions that focus on assisting with restructuring prosocial thinking;
- Offer programs that adhere to a core model, use an evidence-based treatment curriculum, and have staff that are skilled in service delivery;
- Manage dosage and intensity of interventions based on criminal justice risk factors, criminogenic needs, and behavioral health needs;
- Identify a primary target for cognitive interventions (e.g. substance dependence, criminal thinking);
- Collaborate with justice agencies to ensure that controls are integrated into treatment programming;
- Create an environment where individuals can improve by emphasizing motivation to change and building commitment to treatment; and
- Provide feedback to individual participants in programs to ensure long-term success.

Example of the RNR Program Tool Feedback Report for a Reentry Program

Below is a sample feedback report from the RNR Program Tool portal for a jail-based program that primarily targets criminal thinking. The feedback includes a summary of program components and scores in each of the six scoring areas as well as suggestions for improvement where applicable.

RISK: 100%

- Program targets moderate- to high-risk offenders.
- Program uses a validated risk-needs instrument.

NEED: 100%

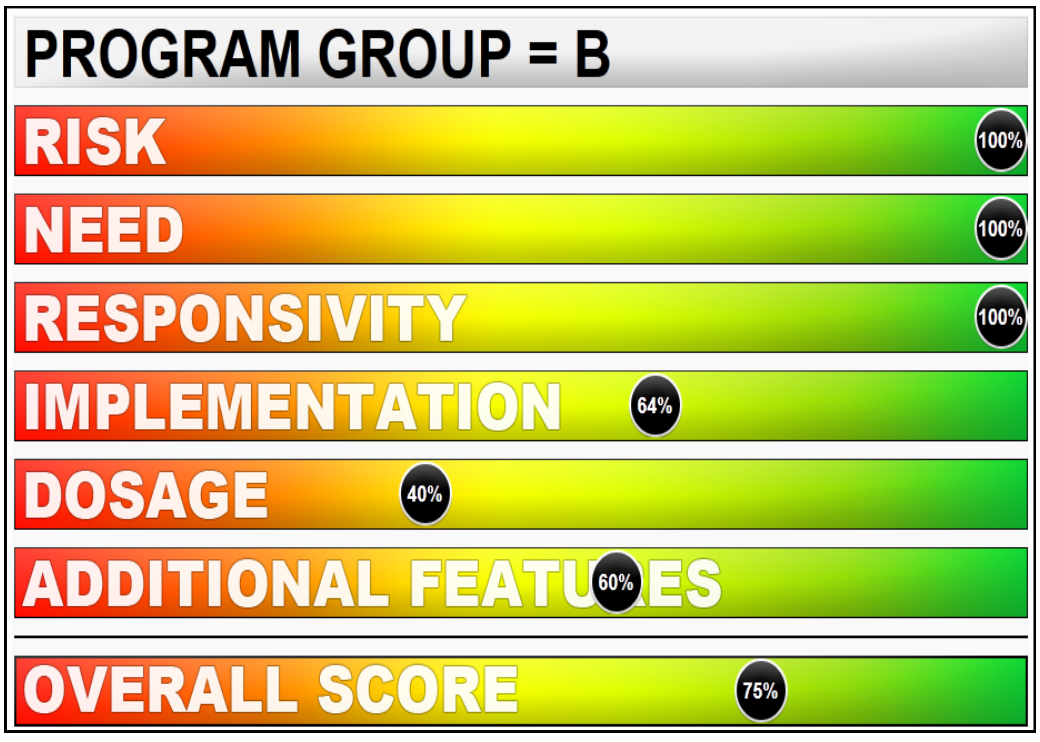
- Program targets criminal thinking including antisocial thinking, criminal peers, and self-control.
- Program uses target-specific assessment criteria or instrument to determine eligibility.

RESPONSIVITY: 100%

- Research indicates the primary modality used in the program is effective (CBT, specifically the *Thinking for a Change* curriculum).
- The program uses both rewards and sanctions.
- The program is available for specific offender populations (e.g. offenders who are 18-30 years old).

IMPLEMENTATION: 64%

- Program requires attendance at a minimum of 75% of sessions for successful completion.
- Program is administered by either clinical staff or a mix of clinical and corrections staff.
- All program staff have at least a bachelor's degree and prior experience delivering the *Thinking for a Change* curriculum.
- Program staff regularly communicate with supervision staff about participants' progress.
- Program has been externally evaluated.
- Program uses *Thinking for a Change* manual to guide implementation.
- Program uses trained supervisors to coach staff on questions that arise during the course of instruction.
- Program has an internal team that monitors quality assurance.



To Improve Score:

- Change program completion criteria to require change in thinking errors.
- Integrate staff who have advanced degrees (e.g., MASW, LCSW, PhD).
- Program director can arrange for external evaluation of the program.

DOSAGE: 40%

- Program provides approximately 180 hours of treatment to participants.
- Treatment is spread across 13 to 17 weeks.
- Services are provided on a daily basis, for approximately 10 to 14 hours per week.

To Improve Score:

- Increase dosage to provide 200+ hours of direct treatment to participants.
- Extend program length to deliver services for 26+ weeks.
- Increase program hours to 15+ hours per week or 3+ hours per day.
- Offer program in phases and include aftercare.

ADDITIONAL FEATURES: 60%

- Program includes a number of complementary programing including: contingency management, educational services, psychosocial education, alcohol or drug education, moral reasoning, relapse prevention, and motivational interviewing.
- Program is located in a criminal justice facility (local jail).
- Program includes random monthly drug testing.

To Improve Score:

- Increase participation in other programs to complement the *Thinking for a Change* curriculum.

Finding the Right Programs for Justice-Involved Individuals

USING RISK AND NEED INFORMATION TO IMPROVE RESPONSIVITY AND REDUCE OFFENDING.

The **Assess an Individual** portal of the RNR Simulation Tool assists users in selecting appropriate controls and treatment for individuals.

Q: What type of programming would this individual benefit from?

A. The first step in matching offenders to appropriate programming groups is to identify their risk of recidivism and criminogenic needs. Risk information includes criminal history, age at first arrest, prior terms of probation or incarceration, and violations. Needs information refers to factors that influence an individual's current situation, such as substance abuse or dependence, mental health, employment, associates, and criminal thinking. Often, this information can be obtained from a jurisdiction's validated risk and need assessment instrument. Certain information (e.g. substance use severity and mental health) may require additional assessment. To determine what programming would most benefit an individual, agencies should prioritize individuals' needs to ensure that criminogenic needs (those related to offending behaviors) receive immediate treatment.

Review case information with offenders to build an understanding of risk and to reinforce strengths.

Q: What if the type of program recommended is not available?

A. The Assess an Individual portal provides three recommendations of programming for each individual. The "best fit" programming recommendation will result in the highest recidivism reduction. The tool also provides second– and third-best fitting program recommendations. For each program recommendation made, the model also provides estimated reduced recidivism rates based on completion of a program. Users should keep in mind that the highest recidivism reductions will result from the best fitting programs.

Q: Does the tool consider individual strengths?

A. The RNR Simulation Tool assesses individual strengths to recognize the positive factors in individuals' lives. Strengths include education, housing stability, employment, financial stability, and prosocial supports. These positive factors act as important stabilizers to help a person successfully complete supervision and treatment, and take positive steps in their lives. Reviewing the risk and need profile with an individual builds their knowledge and understanding of their own needs and helps strengthen commitment to address these factors.

THE CASE OF THE MODERATE-RISK OFFENDER

Moderate-risk offenders may pose a special challenge for justice professionals. While they tend to have shorter criminal histories than higher-risk offenders, they may also have a number of criminogenic needs and destabilizing factors which contribute to the risk of reoffending.

For example, a young adult with few prior arrests, but who is dependent on heroin, may be classified as moderate-risk despite a clear dependence disorder. It is important to assess criminogenic needs in addition to risk to determine factors linked to offending behaviors.

In responding to moderate-risk offenders, interventions should emphasize their criminogenic needs. Often such individuals do not need the same level of supervision controls placed on them. However, they may still benefit from evidence-based programming to help reduce their needs and build stabilizers in their lives.

Example of the RNR Simulation Tool Individual Assessment

A DRUG-ADDICTED OFFENDER:

Jessica is a 39-year-old female offender on probation for possession of cocaine. She is a moderate-risk offender with a DSM-IV classification of dependence on cocaine. She does not display any patterns of criminal thinking, nor does she have any mental illness. She has someone she can depend on for emotional support. She does not have a high school diploma, and is not employed. She regularly depends on public shelters and has many financial difficulties. She also has a number of friends that are criminally active. Her environment does not promote a drug- and crime-free lifestyle.

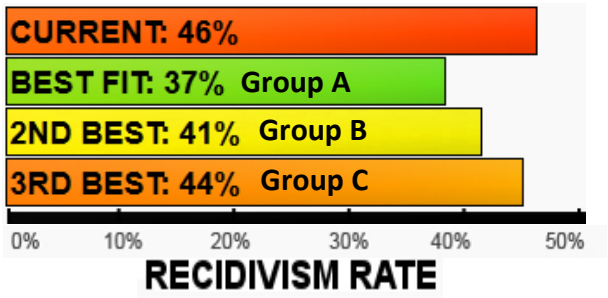
Best Fit Program: Group A

Prioritize Treatment to Address Substance Dependence

System Outputs

Estimated Recidivism Rate: Three Year Rearrest =

46%



Target Needs

Substance Abuse

Antisocial Peers/Family

Education

Employment

Housing

Financial

Family Support

The RNR Assess an Individual portal estimates that an individual like Jessica has a 46% chance of being rearrested within three years. Although she is only moderate-risk, given her substance dependence the tool recommends that a program in Group A would be the "best fit" for her and result in the greatest reduction in recidivism. As indicated, the system estimates Jessica's likelihood of being arrested within three years can be reduced to 37% if she successfully completes a Group A program. In the event that such a program is not available, the system also provides second– and third-best fitting program recommendations. Since Jessica is a female offender, a Group A program that targets females may provide increased responsivity.

Jessica is a moderate-risk offender with a primary need of substance dependence. It is important to target this primary need for treatment to elicit the largest recidivism reduction.

PROGRAM GROUP A - SUBSTANCE DEPENDENCE

Group A programs predominately target drug dependence on hard drugs (e.g., crack/cocaine, opioids, and amphetamines), but also include interpersonal and social skills interventions. These programs target offenders with substance dependence, and offer a range of dosage levels across a continuum of care. Staff who implement these programs should have advanced degrees and use an evidence-based treatment manual. Program settings may include residential drug treatment, therapeutic communities, specialty courts, or intensive outpatient treatment.

AN OFFENDER WITH CRIMINAL THINKING:

Connor is a 30-year-old male who was just released from jail. He served a sentence for breaking and entering (general offender). He has a long criminal history (both juvenile and adult) and is a high-risk offender with criminal thinking patterns. He meets DSM -IV criteria for dependence on marijuana and has a mental health condition. He says that he has no one he can count on for emotional or social support. He graduated from high school, but he does not currently have a job. He often sleeps at his friends' houses and occasionally will stay at a shelter. He uses his money to buy marijuana and often has trouble meeting his financial obligations. His friends are not criminally involved, but his environment is not supportive of a drug- and crime-free lifestyle.

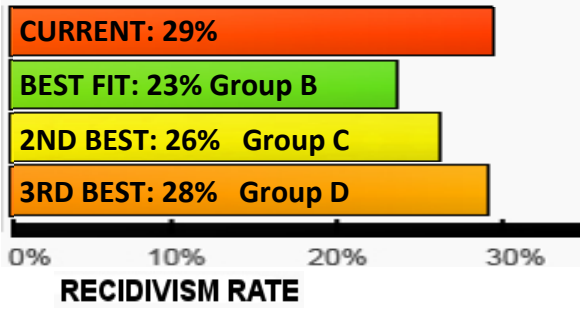
Best Fit Program: Group B

Prioritize Treatment to Address Criminal Thinking and Co-Occurring Substance Dependence

System Outputs

Estimated Recidivism Rate: One Year Reconviction =

29%



Target Needs

Criminal Thinking/Lifestyle

Substance Abuse

Mental Health

Social Supports/Relationships

Employment

Housing

Financial

Family Support

The RNR Assess an Individual portal estimates that an individual like Connor has a 29% chance of being reconvicted within one year. Given his criminal thinking/lifestyle and other risk and need factors the tool recommends that a program in Group B would be the "best fit" for him and result in the greatest recidivism reduction . As indicated, the system estimates that Connor's likelihood of recidivism can be reduced to 23% if he successfully completes a Group B program. In the event a Group B program is not available, second– and third -best fitting program recommendations are also provided.

Connor is a high-risk offender with a primary need of criminal thinking. He also has co-occurring substance dependence and mental illness. Treatment should be prioritized to target criminal thinking while also working to stabilize his substance use and mental illness.

PROGRAM GROUP B - CRIMINAL THINKING

Group B programs primarily target criminal thinking/lifestyle by using cognitive restructuring techniques, but also include interpersonal and social skills interventions. These programs use cognitive-behavioral or behavioral based methods and offer a range of dosage levels across a continuum of care. Staff who implement the program should have advanced degrees in related fields and use an evidence-based treatment manual. Programs in Group B may include cognitive-based criminal thinking curriculums, therapeutic communities, behavioral interventions, and intensive supervision paired with treatment to change criminal thinking patterns.

Building a Responsive System

CLOSING THE GAP BETWEEN RISK-NEED PROFILES AND AVAILABLE SERVICES

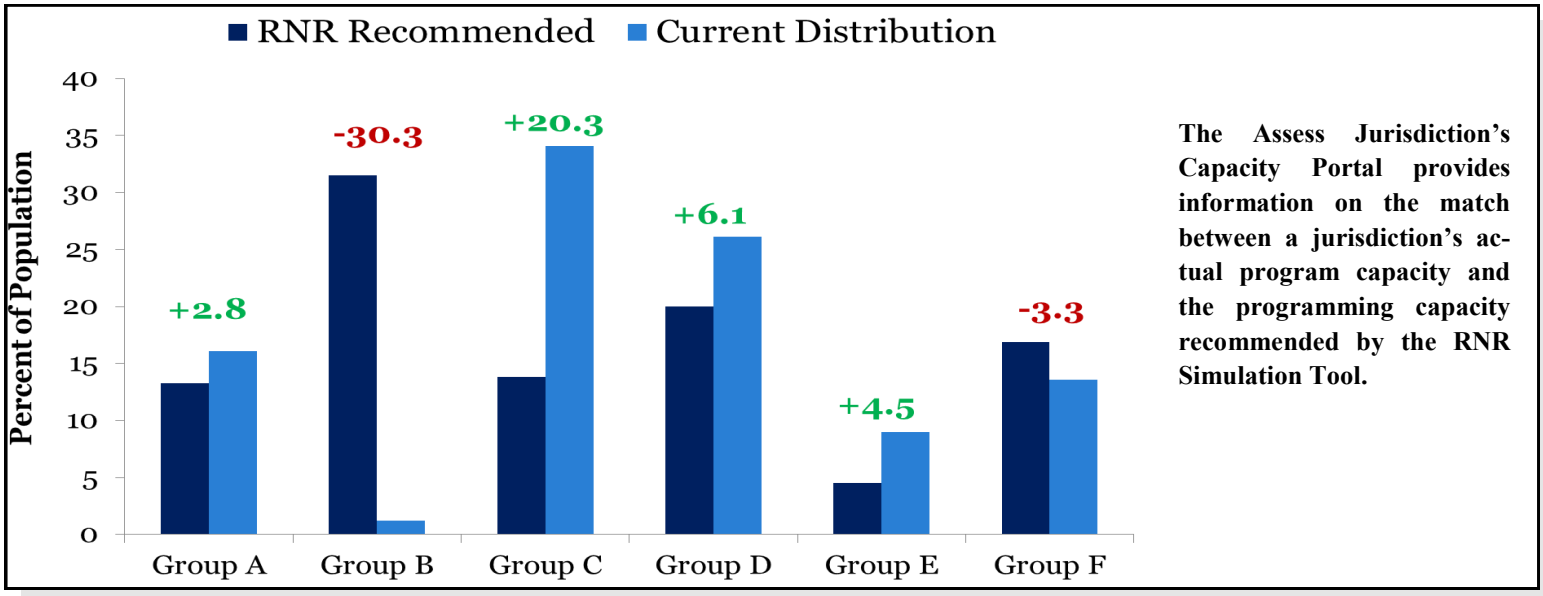
The **Assess Jurisdiction's Capacity** portal uses population-level data to asses a jurisdiction's capacity to provide responsivity. Based on inputted data about the prevalence of aggregate risk and needs in a jurisdiction, the tool will recommend the type and quantity of services that would best match the needs of that jurisdiction. For maximum responsivity, we recommend jurisdictions use this portal in conjunction with the RNR Program Tool portal.

Q: How can my jurisdiction keep track of what programs we have available?

A. The RNR Simulation Tool offers a unique opportunity for program administrators to enter and save information about the programs they have available in their jurisdiction. Other site users can then view the available programs, including the programs' intended targets (e.g., substance abuse, criminal thinking), to guide responsivity and effectively match offenders to available programs.

Q: How can the RNR Simulation Tool help my jurisdiction prepare for changes associated with the Affordable Care Act (ACA)?

A. The RNR Simulation Tool will assist justice professionals in preparing for and responding to the expected influx in offender populations who will require access to behavioral health treatment services under the Affordable Care Act. The tool enables jurisdictions to classify their programs based on offender needs and helps determine if adequate programming exists to accommodate the offender population. Where sufficient programming is lacking, the portal provides recommendations to fill the treatment gap.



The Assess Jurisdiction's Capacity Portal provides information on the match between a jurisdiction's actual program capacity and the programming capacity recommended by the RNR Simulation Tool.

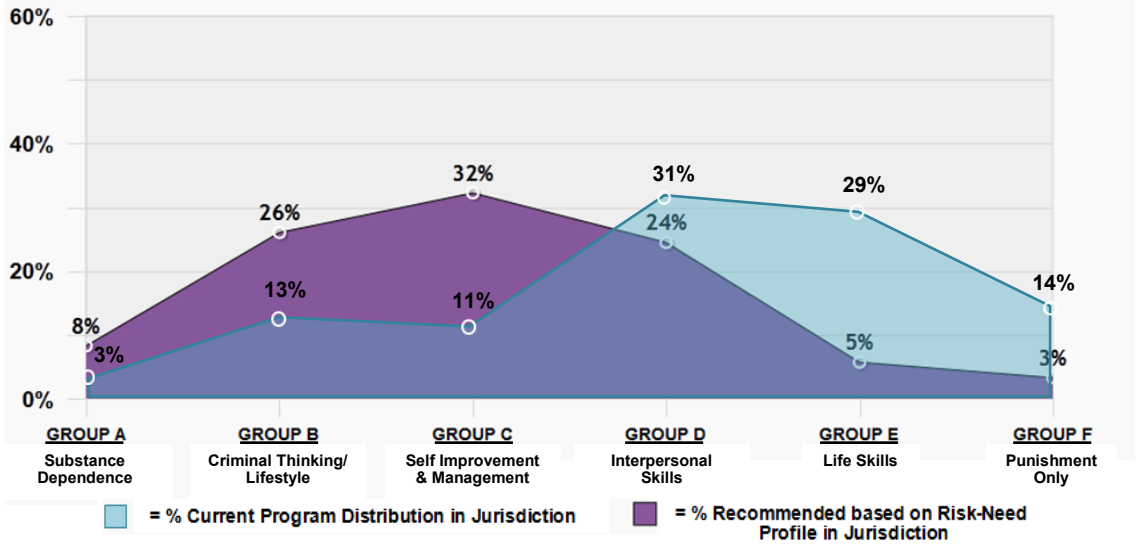
Example: Reducing Recidivism through System-Wide Responsivity

Jurisdiction A serves over 35,000 justice-involved individuals with community-based substance abuse and mental health treatments. Fifty-five percent of the population is high risk, 26% is moderate risk, and 19% is low risk.

The individuals in this jurisdiction also have varying substance use disorders. Thirteen percent of the population meets DSM-IV criteria for substance dependence on a criminogenic drug, 32% is dependent on marijuana or alcohol, 38% abuses a non-criminogenic drug, and 17% of the population does not meet DSM-IV criteria for substance use disorder. The population is also characterized by a number of other dynamic needs, with 68% of the population in need of employment assistance, 54% in need of educational services, 2% in need of housing assistance, and 41% in need of a combination of two or more services.

The RNR Simulation Tool performed a gap analysis to determine if treatment needs are being met by the programs in this jurisdiction. This gap analysis revealed that despite the availability of programming, a gap exists for services which target the most severe substance dependencies. At the same time, there is an excess of programming that targets interpersonal skill development (Group D).

Administrators can use this information to build the capacity of their system to provide appropriately targeted treatment to meet the needs of their offender population. This should help reduce offender needs, reduce individuals' risk of recidivism, and increase public safety.



Jurisdiction A's gap analysis indicates that they are currently lacking adequate programming in Groups A, B, and C, and have an excess of programming in Groups D, E, and F. The RNR Simulation Tool not only identifies this gap in service provision, but also provides recommendations of programs to help fill the gap and increase the jurisdiction's capacity for responsivity.

REFERENCES

Andrews, D. A., & Bonta, J. (2010). *The Psychology of Criminal Conduct,* (5th ed.). Anderson.

Caudy, M., Tang, L., Ainsworth, S. A., Lerch, J., & Taxman, F. S. (2013). Reducing recidivism through correctional programming: Using meta-analyses to inform the RNR Simulation Tool. In F. S. Taxman & A. Pattavina (Eds.), *Simulation Strategies to Reduce Recidivism: Risk Need Responsivity (RNR) Modeling in the Criminal Justice System*. Springer.

Lipsey, M. W., & Cullen, F. T. (2007). The effectiveness of correctional rehabilitation: A review of systematic reviews. *Annual Review of Law and Social Science*, *3*, 297–320.

Lowenkamp, C. T., Latessa, E. J., & Holsinger, A. M. (2006). The risk principle in action: What have we learned from 13,676 offenders and 97 correctional programs? *Crime & Delinquency*, *52*(1), 77 –93.

Smith, P., Gendreau, P., & Swartz, K. (2009). Validating the principles of effective intervention: A systematic review of the contributions of meta-analysis in the field of corrections. *Victims & Offenders*, *4*(2), 148.

Taxman, F. (2006). Assessment with a flair: Accountability in supervision plans. *Fed. Probation*, *70*, 2.

Taxman, F. S., & Marlowe, D. (2006). Risk, needs, responsivity: In action or inaction? *Crime & Delinquency*, *52*(1), 3–6.

The RNR Simulation Tool is part of a larger suite of web-based translational tools for practitioners. The CJ-TRAK Knowledge Translation Tool Suite is also home to SOARING 2, an eLearning software package to train community corrections officers in evidence-based practices, and EMTAP, a synopsis of research findings in corrections and related fields. For more information on these or other ACE! projects, please contact ace@gmu.edu.

Center for Advancing Correctional Excellence (ACE!)
Department of Criminology, Law & Society
George Mason University
10519 Braddock Rd., Suite. 1900
Fairfax, VA 22032
703.993.4859 phone
703.993.6020 fax
rnrtool@gmu.edu

http://www.gmuace.org/tools/

CJ-TRAK was developed by the Center for Advancing Correctional Excellence (ACE!) (www.gmuace.org) at George Mason University. The RNR Simulation Tool involved the contributions from the Center for Advancing Correctional Excellence (ACE!), the University of Massachusetts, Lowell; Maxarth, LLC; and Slonky, LLC under grant BJA 2010 DG-BX-K026, with additional funding from SAMHSA under grant number 202171, the Public Welfare Foundation, and ACE!.

PUBLIC HEARING ON
ALTERNATIVE TO INCARCERATION
COURT PROGRAMS AND SYNTHETIC DRUGS
MARCH 15, 2017
WASHINGTON, DC

Panel II. Alternatives to Incarceration: View from the Bench

Honorable Dolly M. Gee
United States District Court
Central District of California

Honorable Bruce Hendricks
United States District Court
District of South Carolina

Honorable Leo Sorokin
United States District Court
District of Massachusetts

Honorable Dolly M. Gee
United States District Court Judge
Central District of California

Judge Dolly M. Gee has served as a United States District Judge for the United States District Court for the Central District of California since 2010. She currently presides over the Conviction and Sentence Alternatives ("CASA") Program. Prior to taking the bench, Judge Gee was in private practice at the Los Angeles law firm of Schwartz, Steinsapir, Dohrmann & Sommer LLP, as an associate from 1986 to 1990, and as partner from 1990 until 2010.

Judge Gee received both her Bachelor of Arts degree and her J.D. from University of California, in 1981 and 1984, respectively. After law school, she clerked for the Honorable Judge Milton Schwartz of the United States District Court for the Eastern District of California from 1984 to 1986.

UNITED STATES DISTRICT COURT
Central District of California
Western Division
350 W. 1st Street
Los Angeles, CA 90012

Chambers of
Dolly M. Gee
United States District Judge

WRITTEN STATEMENT OF DOLLY M. GEE UNITED STATES DISTRICT JUDGE CENTRAL DISTRICT OF CALIFORNIA WESTERN DIVISION

March 7, 2017

To Members of the United States Sentencing Commission:

Thank you for providing the Central District of California with an opportunity to showcase its Conviction And Sentence Alternatives ("CASA") program, which celebrates its five-year anniversary this year. The CASA program is a "no-entry" post-guilty plea, presentence diversion program. As will be explained in greater detail below, it diverts some participants from the criminal justice system entirely by dismissal of the charges, and steers others away from prison through probationary sentences agreed upon under Federal Rule of Criminal Procedure 11(c)(1)(C)—contingent on successful completion of the program.

I. INTRODUCTION

Launched in 2012, the CASA program was developed through a year-long collaborative discussion and negotiation between key representatives of the District Court, the United States Attorney, the Federal Public Defender, and the Pretrial Services Agency in our District. Each of these stakeholders executed an Interagency Agreement setting forth the basic contours of the program. Although inspired by certain re-entry programs, including one in our own District, CASA is not based directly on any other state or federal program, because it was the first of its kind in the federal system.

Our District operates a separate post-sentence re-entry program (the Substance Abuse Treatment And Reentry Program, aka "STAR") that focuses solely on individuals who have served their sentence but have significant substance abuse

issues. While no social scientist was directly involved in the development of CASA, the basic program model borrowed many concepts from STAR which, in turn, had been established using the key elements and standards published by the National Association of Drug Court Professionals (NADCP). In the earlier days of STAR, team members also participated in group trainings presented by the Federal Judicial Center (in Washington, D.C., Virginia and Utah), wherein various examples of reentry and drug courts were reviewed. Many of the team members involved in the STAR program were also instrumental in implementing CASA. It is important to recognize, however, that CASA is not a drug court.

CASA's goals are to: (a) identify criminal offenders who committed their offenses for specific and identifiable reasons capable of remedy; (b) provide intensive supervision and resources tailored to each individual participant to address the underlying basis for his or her criminal conduct; and (c) lower rates of recidivism and substance abuse, at lower costs, than through the traditional sentencing and incarceration model. CASA participants typically have substance abuse problems, mental health disorders, medical concerns, life skill deficits (educational problems, lack of a steady job), or family members or partners who drew them into criminal conduct. We use a combination of outside service providers, court resources, and one-on-one and group meetings to address these issues.

II. HOW THE PROGRAM WORKS

The CASA Team – Four district judges in various parts of the Central District preside over the CASA Program. There are two judges who preside over the program in the Western Division (Los Angeles—André Birotte and Dolly Gee); one judge oversees the program in the Southern Division (Santa Ana—Josephine Staton); and one judge supervises the program in the Eastern Division (Riverside—Jesus Bernal). Each of these district judges is part of a separate "team": the CASA Teams consist of one district judge, one or two magistrate judges, and representatives from the United States Attorney's Office ("USAO"), the Office of the Federal Public Defender ("FPD"), and the Pretrial Services Agency ("PSA"). All team members volunteer their time and receive no additional compensation or relief from their existing workload.

Track 1 or Track 2 – CASA participants are designated as "Track 1" or "Track 2" at the time of their acceptance into the program.

Typically, Track 1 participants are those who have minimal criminal histories, and whose criminal conduct appears to be an aberration that could appropriately be addressed by a one-year period of supervision with terms including:

- restorative penalties such as restitution and community service and, where appropriate,

  programs intended to address any contributing causes for the aberrational criminal conduct, such as substance abuse, behavioral issues, lack of education or employment training, or unhealthy associations

Track 2 participants tend to have more serious criminal histories or had a role in the underlying criminal offense that cannot be described as minor. Their criminal conduct appears to be motivated primarily by substance abuse, mental illness, or the negative influence of more culpable co-defendants. Track 2 CASA participants have Criminal History Categories ranging from I through VI, but the CASA Team has determined through the vetting process that future criminal behavior can be deterred by a one to two-year period of intensive supervision accompanied by drug or mental health treatment and other penalties and resources similar to those mentioned above as to Track 1 participants.

Examples of criminal offenses to which CASA participants have pled guilty include, for example, narcotics distribution (the most common offense), bank robberies not involving a firearm or violence, embezzlement, credit card fraud, identity theft, mail theft, and tax fraud.

Participant Selection – Defense lawyers and, on occasion, prosecutors, judges, and Pretrial Services Officers recommend defendants for the program. CASA Team members review the criminal history and written submissions of proposed participants and often meet with them in person to determine their suitability for admission. Certain types of criminal cases generally preclude participation in CASA—for example, crimes involving child exploitation (including possession or distribution of child pornography), national security, crimes of violence, and more than minor involvement in large scale fraud or narcotics distribution. The admission screening process involves collaborative discussions between CASA Team members representing the USAO, FPD, and PSA. These discussions center on not only whether the defendant is suitable for admission into CASA, but also the Track to which the defendant will be designated. Each CASA Team member has the ability to veto participation. Applicants who have consensus

support are presented to both the CASA judge and the judge presiding over the defendant's criminal case ("the originating judge") for acceptance into and transfer to the CASA program. The CASA judge and the originating judge can veto participation or change the Track to which the defendant is designated.

Plea – If approved for acceptance into the CASA program, the defendant signs a detailed contract explaining the terms of the CASA program. The individual also enters into a written plea agreement with the government to resolve the underlying action, which contains an explication of the relevant advisory sentencing guidelines calculations for the base offense level and the amount of restitution, if applicable. The criminal case is transferred from the docket of the originating district judge to one of the CASA judges. The defendant pleads guilty to the charged offense before the CASA judge. The Court orders the Probation Office to prepare a modified presentence investigation report consisting of criminal history only, but sentencing is deferred until the completion of the CASA program. If a CASA participant is in custody, the CASA judge sets release terms (bond, drug rehabilitation, mental health treatment, etc.). Pretrial supervision is transferred to a specific CASA Pretrial Services officer. A CASA Deputy Federal Public Defender becomes the defendant's lawyer during the pendency of his or her participation in CASA (even if another DFPD, appointed counsel, or private lawyer provided initial representation).

Pre-Meetings – Immediately before each CASA session, the CASA Team meets for one to two hours to discuss the status of each participant. Participants are expected to call the assigned PSA officer weekly by a designated time to report any changes, problems, or law enforcement contacts. The purpose of the pre-meetings is to allow the CASA Team to candidly assess each participant's progress and to confer regarding any issue or problem that may have arisen during the course of the week or were reported in the participant's weekly call-in report, and to decide upon a specific course of action to address the problem.

Meetings – Following the guilty plea, CASA participants meet weekly, bi-weekly, or monthly (depending on the court division and circumstances of each case) with the CASA Team in the district judge's courtroom. These CASA sessions can touch upon a wide range of topics, including analytical conversations on ethical questions and hypothetical criminal scenarios, sharing of homework assignments, or specific discussion of issues that participants face. We also regularly invite outside speakers to present to the group regarding employment search skills and interviewing techniques, financial literacy, health, nutrition, stress management, and

other issues of common interest. On occasion, enthusiastic CASA alumni return to speak with current participants about their experiences. In addition to the meetings, some participants are required to complete moral reconation therapy, parenting class, anger management counseling, and community-based drug abuse programs or mental health counseling, as needed.

Expectations and Consequences – The CASA program places a great deal of emphasis on honesty and integrity. It is incorporated into the CASA Agreement signed by each participant, stressed at the outset of the defendant's participation, and reinforced directly and indirectly throughout the course of the program. In addition, each CASA participant is expected to attend the weekly or biweekly meetings (without excessive absenteeism), do periodic homework assignments, and be constructively occupied for at least 40 hours per week with employment, job search, schooling, substance abuse treatment, mental health treatment and counseling, community service, child care, or a combination of the aforementioned activities. There are consequences for all forms of non-compliance. For example, absences, tardiness, or failure to do homework or keep appointments can result in extra CASA sessions or an additional homework assignment; repeated non-compliance may result in a one-on-one counseling session with the CASA Team; positive drug tests or infractions may result in the imposition of location monitoring, flash incarceration, or an intensified treatment regimen; dishonesty or new criminal conduct will result in termination from the program. Court hearings for the purpose of program termination are always conducted during the CASA sessions in order that all participants may witness the proceedings.

Graduation – CASA participation may last from 12 to 24 months, depending on the defendant's progress. Graduation from CASA is not automatic. Rather, participants must hold a job or make progress toward an educational goal, be substance free (for at least six months, but preferably more), pay restitution (if applicable), and show stability in their lives. Additionally, the CASA Teams look for a solid and realistic life plan that convinces us that each participant is ready for graduation and is not likely to reoffend in the future. This can involve, for example, resolving outstanding fines or warrants, paying off debts, taking responsibility for child care and child support, obtaining affordable housing, and/or disassociating from negative influences.

Sentencing and Dismissal – Track 1 graduates have their criminal convictions dismissed – resulting in no felony record – and are subject to no supervision following graduation. Track 2 individuals typically have a prior

criminal record or committed significant offenses. Track 2 graduates are sentenced at a formal hearing to a term of probation in accordance with their binding plea agreement. Whether Track 1 or 2, CASA graduates are not sentenced to time in federal prison.

Termination from CASA – A handful of participants have been discharged from the program before graduation for misconduct (e.g., committing offenses while on release, persistent failure to comply with CASA requirements, and/or engaging in dishonesty toward the CASA Team). Pursuant to the terms of the original CASA plea agreement, those individuals are sentenced based on their underlying criminal conviction. The CASA judge – who typically has had considerable interaction with the defendant during the course of program – sentences the defendant at a traditional, adversarial proceeding. The CASA judge refers to the Sentencing Guidelines calculation in the defendant's plea agreement, reviews a modified presentence report from the Probation Office, and considers written submissions from the parties as part of the typical sentencing.

III. CASA PARTICIPANT STATISTICS

A chart reflecting CASA participant statistics as of March 2017 is attached hereto. To date, 222 defendants have been accepted into the CASA program. Of these, 52 are currently participating in the program, 137 graduated successfully, 18 were terminated from the program for cause, and nine did not participate (usually because the originating judge did not approve participation in and transfer to the CASA program). Track 1 participants comprise approximately 73% of the graduates, whereas about 27% of the graduates were in Track 2. Comparing the graduation rate to the termination rate of those who at least started participation in the program and are now no longer in the program, 88% have graduated, whereas 12% were terminated prior to completion of the program.

IV. METRICS OF SUCCESS AND POST-GRADUATION TRACKING

In the short term, CASA measures success by graduation, as discussed above. In the long term, success will be gauged mainly by cost-savings and recidivism rates.

According to the Bureau of Prisons ("BOP"), the *average* annual per capita cost of incarceration in a federal correctional facility in fiscal year 2014 was

$27,744.[1] Assuming that each CASA graduate would have received a one-year sentence, the estimated savings solely in terms of incarceration cost are $3,800,928 for 137 graduates. This is, of course, a very rough and conservative estimate because, based upon the Sentencing Guidelines and the nature of the offense and criminal history category (the most common offense being for drug distribution), many CASA participants, even those with a Criminal History Category I, likely would have received considerably more than a one-year prison term.

Although CASA participants have received approximately $1,036,861 in PSA services for substance abuse and/or mental health treatment from June 2012 through December 2016, these PSA funds or the equivalent likely would have been used for these individuals even if they had not been accepted into CASA. These are services commonly provided to defendants on pretrial release, federal custodies, and individuals sentenced to a term of probation or supervised release. The same principle applies to the cost of the volunteers who comprise the CASA Teams – the judges, the prosecutors, the public defenders, and the PSA officers are paid from existing resources and would be paid the same amount even in the absence of the CASA program. Since its inception, CASA has used approximately $35,000 in grants received from the Central District of California's Attorney Admissions Fund to cover outlays for graduation ceremonies, transportation costs, and other miscellaneous incidental costs. Whether or not these negligible costs are deducted from the estimated savings, it is clear that the benefits far outweigh the costs of the CASA program.

With regard to recidivism among CASA graduates, there is currently only anecdotal information. To date, the anecdotal evidence has been very positive as there have been few reports of recidivism among CASA graduates during the past five years. We are aware of only one Track 1 graduate who may have reverted to substance abuse, though there has been no law enforcement contact and only periodic communications from her mother. No CASA judges report having had probation revocation proceedings for Track 2 graduates. Although Track 1 graduates are not supervised, many maintain contact with CASA Team members or return as guest speakers. Plans are currently afoot to obtain privacy waivers from graduates, current participants, and incoming participants in order to enable the PSA

[1] *See* https://www.bop.gov/foia/fy14_per_capita_costs.pdf. Since the CASA program commenced in 2012, the average annual per capita cost of incarceration has gradually increased during the relevant period of 2012 through 2016. We use the 2014 figure as a middle point for purposes of illustration.

to conduct at least biannual criminal record checks for up to five years after a participant's graduation date to determine if any new arrests or convictions have been sustained. That information will be used anonymously for research and statistical analysis.

Although CASA has not devised a methodology to measure the growth of human potential or the indirect impact of the program on participants' family members, employers, the criminal justice system, and society as a whole, there can be no doubt among those of us who work with the CASA participants that the ripple effect of their successful integration into society as responsible citizens has had immense tangible and intangible benefits.

Nonetheless, our District is committed to evidence-based practices and recognizes that anecdotal evidence cannot take the place of rigorous and reliable statistical and data-driven analysis. Thus, in or about January 2016, the Central District of California requested the Federal Judicial Center ("FJC") to conduct a process-descriptive empirical evaluation of the CASA program. The evaluation will identify, define, and empirically measure the components of the program. The goals are to (1) identify areas that may affect the efficacy of the program; (2) better inform the District as to the relationship between the program's stated goals and any observed program outcomes; and (3) provide a stronger basis for any follow-up evaluation to assess the program's impact. That evaluation is ongoing and is expected to be completed in 2017.

V. THE ROLE OF THE SENTENCING GUIDELINES AND SECTION 3553

Many CASA participants face considerable prison sentences under the relevant guidelines for their offenses (typically involving drug trafficking, fraud, bank robbery, theft, or regulatory crimes). The plea agreements uniformly include a calculation of the base offense level, but the precise guidelines range is contingent upon a number of variables, including the calculation of the defendant's Criminal History Category and the defendant's ability to successfully complete the CASA program. Our successful Track 2 participants have a sentencing hearing at which the judge calculates and announces the guidelines range, but imposes the probationary sentence and other terms and conditions that the parties have agreed upon in their binding plea agreement. The end result of all successful CASA cases is no prison term – either dismissal of the charged offense or a probationary sentence. Individuals who are terminated from CASA before graduation (discussed above) are

subject to traditional criminal sentencing based on consideration of the advisory Guidelines and Section 3553(a) factors.

VI. AWARDS AND ACCOLADES

In remarks made to the American Bar Association's Annual Convention on August 12, 2013, then United States Attorney General Eric Holder said:

> By targeting the most serious offenses, prosecuting the most dangerous criminals, directing assistance to crime 'hot spots,' and pursuing new ways to promote public safety, deterrence, efficiency, and fairness – we can become both smarter *and* tougher on crime.
>
> (Emphasis in original.)

In August 2013, the United States Department of Justice ("DOJ") issued a publication at the direction of then Attorney General Holder entitled "Smart on Crime: Reforming the Criminal Justice System for the 21st Century." In it, the DOJ stated that it intended to issue a "best practices" memorandum to U.S. Attorney offices encouraging more widespread adoption of diversion programs when appropriate. *Id*. at 4. Cited as an example of such a "best practice" was the Central District of California's CASA program. *Id*.

In October 2014, both Attorney General Holder and then California Attorney General Kamala Harris (now a United States Senator from California) attended a CASA graduation. State Attorney General Harris was so impressed with the CASA program that she awarded it one of her Department's "Smart on Crime" awards in 2015.[2]

Since that time, many representatives from Districts across the country have come to observe CASA in action. Many have adopted their own unique programs and have used CASA as a model. We are encouraged by the development of these programs, but they are still too few in number. We hope to see more in the future.

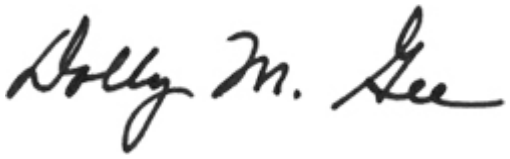
VII. CONCLUSION

The Central District of California and its CASA Team members are pleased to have had the opportunity to share our information and data about CASA with the

[2] *See* https://oag.ca.gov/smartoncrimeawards.

members of this Commission. We welcome your insights regarding how our program can be improved and look forward to working with you to expand the development of programs like CASA in the federal system and to engender more broad-based support for their implementation.

Sincerely,



Dolly M. Gee

Attachment

CONVICTION AND SENTENCING ALTERNATIVES PROGRAM STATISTICS
MARCH 2017

TOTAL DOCUMENTED REFERRALS: 578

TOTAL ACCEPTED: 222

TOTAL TRACK 1: 138

TOTAL TRACK 2: 83

TRACK UNKNOWN: 1 (DEFENDANT DID NOT PARTICIPATE)

TOTAL ACCEPTED BUT DID NOT PARTICIPATE: 9

TOTAL GRADUATES: 137 (TRACK 1-101; TRACK 2-36)

CURRENT NUMBERS: 52

PENDING ENTRY: 6

JUDGE	GRADUATES	TRACK 1	TRACK 2
GEE	39	25	14
PREGERSON/ ABRAMS	41	31	10
PHILLIPS/ BERNAL	31	23	8
STATON	26	22	4

CASA RELEASE TO PARTICIPATE: 17

JUDGE	TOTAL	SUCCESSFUL
GEE	9	7
PREGERSON/ABRAMS	2	2
BERNAL	2	1
CARNEY/STATON	4	3

CASA TERMINATIONS: 18

JUDGE	TOTAL	TRACK 1	TRACK 2
GEE	6	3	3
ABRAMS BIROTTE	3	2	1
PHILLIPS/ BERNAL	5	4	1
CARNEY/STATON	4	2	2

CURRENT NUMBERS: 52

JUDGE	TOTAL	TRACK 1	TRACK 2
BIROTTE/ ABRAMS	18	4	14
BERNAL	10	4	6
GEE	17	7	10
STATON	7	4	3

CASA STATISTICS

OVERALL PARTICIPANT POPULATION

FEMALE: 50.25%

MALE: 49.75%

AVERAGE AGE

FEMALE: 37

MALE: 37

ETHNIC BACKGROUND

ASIAN, 21 (10.66%) BLACK, 30 (15.23%)

WHITE, 56 (28.43%) WHITE HISPANIC, 90 (45.68%)

SUBSTANCE ABUSE HISTORY

NO ISSUES: 77 (39.0%) CANNABINOIDS: 49 (24.87%)

METHAMPHETAMINE: 42 (21.32%) COCAINE: 7 (3.55%)

MENTAL HEALTH

NO ISSUES: 125 (63.45%) MOOD DISORDERS: 31 (15.74%)

ANXIETY, 15 (7.61%) SCHIZOPHRENIA: 3 (1.52%)

EDUCATION LEVEL

HS/GED: 81 (41.11%) NO HS/GED: 56 (28.42%)

SOME COLLEGE: 23 (11.68%) VOCATIONAL: 10 (5.1%)

BA/BS: 14 (7.11%) AA: 7 (3.55%)

MA/MS: 4 (2.31%) PHD: 1 (.5%)

*MOST COMMON CASES (MAJORITY) ACCEPTED INTO THE PROGRAM CONTINUES TO BE THOSE CHARGED WITH NARCOTICS DISTRIBUTION, TRAFFICKING, ETC.

*AS OF DECEMBER 2016, APPROXIMATELY $1,036,861 SPENT ON SERVICES FOR SUBSTANCE ABUSE, MENTAL HEALTH SERVICES AND CO-OCCURRING DISORDERS.

Honorable Bruce Hendricks
United States District Court Judge
District of South Carolina

Judge Bruce Hendricks is a United States District Judge for the United States District Court for the District of South Carolina. Prior to being elevated, Judge Hendricks served as a Magistrate Judge in the District of South Carolina, in Greenville from 2002 to 2010, and in Charleston from 2010 to 2014. From 1991 to 2002, she served as an Assistant United States Attorney in Charleston, South Carolina. Judge Hendricks presided over the BRIDGE Program, the first drug court program in the District of South Carolina.

Judge Hendricks received a Bachelor of Science degree from the College of Charleston in 1983 and a J.D. from the University of South Carolina School of Law in 1990.

U.S. District Court for the District of South Carolina
Written Statement to U.S. Sentencing Commission – Drug Courts

The Honorable Bruce Howe Hendricks
United States District Judge

March 2, 2017

Introduction

These remarks are submitted in light of the Commission's continued study of sentencing approaches that encourage the use of alternatives to incarceration generally, and specifically with regard to the Commission's study of "pre-trial" or "front-end" alternative-to-incarceration programs that now exist in a growing sample of federal districts across the country. My comments will mainly address the District of South Carolina's BRIDGE Program, a pre-trial drug court that I helped to create in Charleston and now supervise on a districtwide basis, with additional locations in Columbia, Florence, and Greenville.

(1) Why South Carolina Sought to Create an Alternative Program

The BRIDGE Program was developed in order to meet a commonly expressed desire among Judges in the District of South Carolina to have more tools at their disposal during sentencing. To be specific, Judges felt that they had inadequate options for sentencing certain non-violent drug offenders, particularly where they

believed a non-incarceratory sentence would best satisfy the purposes of punishment itemized in 18 U.S.C. § 3553(a).

Underlying the BRIDGE Program's inception and development were three core purposes: (1) to provide alternative sentencing tools for a certain class of cases; (2) to better ensure the public safety; and (3) to address the foregoing needs with an eye toward fiscal responsibility. Over six years of operation, Judges in South Carolina have used the BRIDGE Program's resources in a diverse set of sentencing circumstances, to include: (1) "pre-trial" participants who have pled guilty to their offense(s) of conviction and are awaiting sentencing; (2) "post-trial" participants who have already completed an incarceratory sentence and are at risk of being incarcerated again due to ongoing incidences of illegal drug use while on supervised release; and (3) participants whose completion of the Program has been made a special condition of their adjudicated sentence, as imposed by the Judge with jurisdiction over the underlying criminal case. In this way, the BRIDGE Program has proven adaptable to a full range of case postures. Through candid feedback, South Carolina Judges have acknowledged that the Program filled an identified gap in their sentencing tools, and it has been welcomed throughout the District.

(2) How the BRIDGE Program was Developed

The question often arises as to how we developed the BRIDGE Program and whether we received any assistance from a social scientist or like professional. We began by observing a number of federal and state drug court programs that are widely

considered to be successful examples of drug court operations. These programs included Judge Joseph Laplante's "LASER Docket" in the District of New Hampshire, Senior Judge Earl Britt's and Magistrate Judge James Gates' federal drug court in the Eastern District of North Carolina, Judge Keith Starrett's federal drug court in the Southern District of Mississippi, Judge Chuck Simmons'[1] state drug court in Greenville, South Carolina, and Judge Irvin Condon's state drug court in Charleston, South Carolina. Indeed, we specifically borrowed program documentation from some of these courts, to include participation agreements and program policies. Next, we adapted these policies and procedures to local practice and need, and the above articulated goals. Preparation of the Program's documentation and structure was at all times done in specific consideration of the National Drug Court Institute (NDCI) 10 Key Components of a Drug Court[2] and the National Association of Drug Court Professionals ("NADCP") Adult Drug Court Best Practice Standards.[3] A representative of the NDCI performed on-site training and observed the BRIDGE Program in operation in order to provide feedback and advice regarding effective implementation. Finally, we continue to update the training of key personnel through

[1] Judge Simmons is President of the South Carolina Drug Court Association and Chairman of the Board of Directors for the National Association of Drug Court Professionals in Washington, D.C. His advice and counsel have been invaluable in our efforts to establish sound and effective methods and policies in the BRIDGE Program.

[2] The NDCI 10 Key Components of a Drug Court is available at: http://www.ndci.org/publications/more-publications/ten-key-components/.

[3] The NADCP Adult Drug Court Best Practices Standards are available in two volumes at: http://www.ndcrc.org/content/nadcp-adult-drug-court-best-practice-standards-volume-1; and http://www.ndcrc.org/content/nadcp-adult-drug-court-best-practice-standards-volume-ii.

courses offered by the NADCP in order to keep abreast of, and craft responses to, current issues in the community of drug court professionals.

In all of our efforts, we strive to implement evidence-based principles of effective behavior modification, and, importantly, foster cooperative relationships with and among key personnel at the United States Probation Office, United States Attorney's Office, and the Federal Defender's Office. Without these relationships, and a shared vision for adhering to time-tested evidence-based practices, the BRIDGE Program simply could not run.

A related, but distinct, question commonly arises about whether front-end drug courts are suitable for use in federal court. Given that so much of what we know about drug courts has occurred in the laboratory of state court systems, it is sometimes doubted that they can be effectively implemented in the federal system. Preliminary indicators, however, suggest that many federal defendants are actually ideal candidates for drug court. Indeed, property offenders and drug offenders, the two categories of criminal defendants most commonly admitted to drug court, comprise a much larger proportion of the federal inmate population than they do in the state prison system.[4] Although federal defendants often face longer sentences than their state defendant counterparts, this does not mean that they have the violent criminal histories that often exclude defendants from admission to drug court. From 2010 to 2015, approximately 50% of those convicted of federal drug offenses had a

[4] *See* U.S. Department of Justice, Bureau of Justice Statistics, "Prisoners in 2015," tables 9 & 10.

criminal history category of only I.[5]

Additionally, there is every reason to expect that the social science underlying the NADCP Best Practices is applicable to human behavior and psychology generally and that it is not somehow specific to any particular judicial system. In other words, the attributes of drug court programming are not system dependent, but human-nature dependent. In the end, the BRIDGE Program, like its state-court corollaries, is simply a special docket for low level criminal defendants whose offenses are motivated by drug addiction. We should anticipate similar results and, indeed, have observed as much in over 6 years of operation.

(3) How the BRIDGE Program is Run

The BRIDGE Program is designed to retain flexibility with regard to the stage of judicial proceedings at which it is used. As already explained, it can accommodate "pre-trial" participants, "post-trial" participants, and hybrids of the two. Nevertheless, as a primarily "front-end" program, the majority of our participants are in the "pre-trial" stage, meaning that they have pled guilty and are awaiting sentencing.

At the risk of becoming too granular, it may be helpful to explain just *how* a defendant is selected for admission into the Program. Potential participants are referred by judges, defense attorneys, probation officers, AUSA(s), and members of the BRIDGE Team alike. This referral is done by way of a simple form. Probation

[5] *See* U.S. Sentencing Commission's 2010-2015 Sourcebooks of Federal Sentencing Statistics, table 37.

then screens the referred defendant, looking into their criminal history, concurrent state charges, mental health comorbidities, etc. Most importantly, the individual must have a documented substance abuse addiction problem *that motivated the criminal conduct in question*. If there is any doubt regarding the validity of the drug dependency at issue, the defendant will be referred for a thorough evaluation in order to confirm this requirement—a nexus between drug addiction and the offense of conviction.

Next, the presiding judge reviews the referral materials along with the supervising probation officer in light of the BRIDGE Program's eligibility criteria and determines if the defendant is a good candidate. The potential participant is provided with information that gives an overview of the Program, the goals and methods of its three phases, the system of incentives and sanctions, etc. The candidate is also required to observe one session of BRIDGE Court in order to complete their application. If the presiding judge agrees to accept the defendant into the program, the supervising probation officer seeks approval from both the AUSA and District Judge assigned to the case.

If ultimately approved, the defendant must sign the BRIDGE Program Participation Agreement acknowledging and consenting to all of the supervisory and treatment measures he/she will be required to undergo. In full candor, these measures are quite intrusive and are designed to introduce a disciplined lifestyle from the very beginning of the Program. BRIDGE participants are supervised by a probation officer to ensure that they comply with Program requirements, including: (1)

participation in substance abuse treatment and, if needed, cognitive behavioral therapy; (2) seeking and maintaining employment or full-time education; (3) abstinence from drugs and alcohol and submission to random urinalysis testing; (4) attendance at self-help meetings such as Narcotics Anonymous; (5) maintaining relationship with a sponsor and getting involved in the recovery community; (6) compliance with other directives of the Court, such as avoidance of certain social settings or relationships which have been verified as relapse triggers; (7) complete transparency and constant contact with the supervising probation officer.

These requirements are not without precedent. Indeed, they are quite similar to those conditions commonly imposed by judges for pretrial supervision under 18 U.S.C. § 3142.[6] In other words, federal judges are already regulating defendants' lives in the ways contemplated by a drug court, but, in drug court, intensive treatment and supervision are enforced through regular judicial accountability. Thus, it might be said that drug courts like the BRIDGE Program are simply more of what the criminal code anticipates and what all judge's want—supervision and safety. To be clear, the BRIDGE Program is not, as some drug court critics might suggest, a misguided attempt at social work conducted by the judiciary. Rather, it is a court-driven program, and we marshal the necessary operational resources through the lens of Section 3142.

Lastly, I will provide a brief description of the U.S. Probation Office's supervision of BRIDGE participants and the mechanics of staffing and court

[6] *See* 18 U.S.C. § 3142(c)(B)(ii, iii, iv, vi, vii, ix, x, xii, and xiv)

sessions. We have found that selecting a supervisory probation officer who sincerely believes in the mission and methods of drug courts is perhaps the lynchpin to success at any particular Court location. The probation officers we have assigned to BRIDGE are *extremely* thorough in monitoring participants' drug testing, housing, N.A. attendance, substance abuse and mental health treatment, financial planning, employment and vocational training, continuing education, family and social relationships, and the list could go on. Again, these functions of the probation officer are quite similar to those functions routinely performed pursuant to Section 3142, but with a higher emphasis on treatment as it relates to drug addiction and greater latitude to intrusively monitor participants' relational and environmental circumstances in order to provide effective advice to the presiding judge regarding case-specific methods and goals. Participants are encouraged, indeed required, to take affirmative steps to maintain honesty and transparency at all times. Of course, this greater degree of intrusion and policy of "self-reporting" can sometimes raise concerns about self-incrimination, but its utility in achieving lasting results is unmatched, and its implementation is justified by participants' knowing, intelligent, and voluntary consent, which is a condition precedent to admission to the Program.

Before each session of BRIDGE Court, which meets biweekly, we have a staffing meeting where the presiding judge receives input from the supervising probation officer, the AUSA(s), defense counsel, and treatment providers in order to preview the status of each case and brainstorm solutions to any issues that have

arisen. In the drug court sessions themselves, each participant is required to answer truthfully whether they have used any drugs or alcohol, provide proof of attendance at recovery meetings, proof of hours at work or attendance at school, and verify progress on any other matters the Court has required of them. The empirical research behind drug courts shows that a graduated system of small, but immediate and ultimately increasing, rewards and sanctions has an amplified impact in ensuring compliance with Program requirements. The presiding judge has a large toolbox of options at his or her disposal when deciding how to proceed in any given case.

(4) BRIDGE Program Participant Data

The following numbers represent participant data from the BRIDGE Program from its inception until the present, and across four South Carolina Divisions (Charleston, Greenville, Florence, Columbia):

Total participants:	109
Graduates:	43
Active participants:	30
Terminated:	20
Voluntarily withdrawn:	15
Deceased:	1

(5) How the BRIDGE Program Measures Success

The BRIDGE Program measures success in terms of two main metrics: (1) cost savings, and (2) recidivism reduction. However, it must be said that these

quantitative values do not fully account for qualitative impacts in the lives of our graduates and even those who do not complete the program, nor do they account for the secondary and tertiary effects on families, communities, and beyond. Admittedly, these more remote effects are difficult to measure but, as will be discussed, such effects will be the subject of research we have recently associated with our program in conjunction with Clemson University.

First, a disclaimer is in order. We are not social scientists and we do not pretend to be. Nevertheless, with an eye toward holding ourselves accountable, the BRIDGE Team has done its best to track cost savings in terms of dollars saved per dollars invested, and recidivism reduction in terms of subsequent criminal conduct by BRIDGE graduates.

With respect to cost savings, the results of our own calculations are very encouraging. We have explained our methodology for calculating cost savings at length in a separate memorandum, including analysis based upon the marginal cost of incarceration and analysis that incorporated fixed costs as well. For purposes of these remarks, it should suffice to say that, with fixed costs incorporated, the BRIDGE Program saves approximately $7 in resources for every $1 spent. Under this rubric, the total savings for the Program are approximately $3.5 million. It should be emphasized that the numbers we compiled in our memorandum report were all generated with a conservative eye toward the information inputs. In other words, if there was any question regarding the accuracy of claiming particular savings, we

consistently erred on the side of not claiming those savings (e.g. many of the costs attributed to the Program would almost certainly have been incurred by U.S. Probation in providing pre-trial drug treatment to the participants had they not been enrolled in drug court, but no effort was made to disaggregate these "expenses").

With respect to recidivism reduction, we have knowledge of the following subsequent criminal conduct by BRIDGE graduates. Out of 43 graduates: 2 have incurred state DUI charges; 1 committed a series of supervised release violations (having received a time-served sentence) involving drug possession and use, DUI, and failure to notify Probation of police contact regarding a hit and run incident, and her supervised release was revoked for 9 months with no term of supervised release to follow; 1 reoffended by selling illegal drugs, was readmitted to the Program, and successfully completed it for a second time; and 1 tested positive during supervision, admitted to use, was readmitted to the Program, and is a current participant. The BRIDGE Team makes substantial effort to keep in touch with our graduates, and we have somewhat of a luxury in this respect due to the relatively small size of our participant population. Of course, we have official information about any of our graduates who remain under our supervision. We have no formal evaluation of the aforementioned *qualitative* impacts on our graduates' lives, families, and communities, but our informal appraisal of these impacts is overwhelmingly positive.

One invaluable resource that has allowed us to maintain continual involvement in our graduates' lives is our BRIDGE mentor program, run in partnership with the

Federal Bar Association. These FBA mentors are linked with participants during the course of the Program. They assist participants with career counseling, community integration, and other related matters, and they tend to keep up relationship with our graduates long after they have completed the Program. In addition, the BRIDGE Program recently began a partnership with the local Drug Enforcement Agency field office, whereby BRIDGE graduates go to local schools with DEA officers and speak to students about the dangers of addiction. We are encouraged by this development, as we believe it is a sign that Program graduates are beginning to serve as real catalysts for change within their communities.

As the BRIDGE Program has grown and matured, we have recognized the need to substantiate our own internal research with the expertise and impartiality of true social scientists. Accordingly, in October 2016 we began a research partnership with Clemson University and Greenville Hospital System. The first stage of this partnership is for an independent, third-party, retrospective evaluation of the BRIDGE Program's basic metrics in recidivism and cost savings. This research is currently underway. The second stage of the partnership, currently only conceptual in nature, would be a prospective and thorough evaluation, however imagined, of all the qualitative and quantitative attributes of the program in system, societal, and individual impacts. Such an evaluation might reasonably include an examination of the efficacy of any or all of the systems and programming used by the BRIDGE Program. Finally, it is our sincere hope that the Commission, with its unique research

capabilities, might bring additional resources to the table should it take an interest in understanding, validating, and quantifying the efficacy of the BRIDGE Program.

(6) Sentencing BRIDGE Program Graduates

Another common question directed toward the BRIDGE Program concerns how graduates are sentenced and what role the sentencing guidelines play in the sentencing process. To this point, all BRIDGE graduates have received a non-custodial outcome—probation, a time-served sentence, or, less commonly, full dismissal of their charges.

This is not to say that the sentencing guidelines play no role in BRIDGE participants' resultant sentences. Indeed, during the admissions process, the supervising BRIDGE Court judge, the original district judge, and the AUSA collectively consider whether they can tolerate moving from the anticipated guidelines range to a non-custodial outcome. In other words, the breadth of disparity between the applicable guidelines range and a non-incarceratory sentence is weighed on the front end, and potential participants are only admitted to the Program if a probationary or time-served sentence would be satisfactory to the Court and to the prosecution.

That said, participants are expressly and repeatedly informed, and required to acknowledge, that neither the BRIDGE Program nor any of its personnel make any promise as to the sentencing outcome of their case should the participant successfully complete the Program. As a whole, BRIDGE Program policies and procedures are

designed to evaluate each candidate individually and ask whether they are the type of defendant for which a non-custodial sentence would be appropriate. This point highlights a principle already discussed in the first section of these remarks: that the impetus for creating the BRIDGE Program was to provide South Carolina Judges with additional sentencing tools which they felt they lacked for a certain subset of non-violent drug and property offenders.

I suppose it can be extrapolated that BRIDGE sentencing practices place a rather large emphasis on Section 3553(a)(1), which requires the Court, in imposing a sentence sufficient but not greater than necessary, to consider the nature and circumstances of the offense and the history and characteristics of the defendant. In the course of the admissions process, the BRIDGE Program, through screening and evaluation, *requires* that the offense in question be more directly related to substance abuse and/or addiction than to some independent criminal motivation or intent.

One criticism that is often directed at drug courts is the notion that they have the adverse effect of imposing "sentencing cliffs" on a system in which it is already difficult to maintain a satisfactory degree of sentence regularity and consistency. Put more simply, "Don't drug courts create sentencing disparities between similarly situated defendants where they would not otherwise exist?" The answer to this objection is that, where drug courts are operated properly, eligible defendants are actually *not similarly situated* to their counterparts who are not eligible, even though their offense(s) of conviction and guideline range may appear to be similar. But, the

proper distinction, between eligible and non-eligible defendants can really only be made to the extent that the drug court team is able to associate the criminal conduct in question with a clinical diagnosis. To this end, the BRIDGE Program attempts, as much as possible, to drill down on the nexus between the defendant's conduct and the defendant's addiction, which requires an in-depth look at both the relevant criminal history and the substance abuse history. Respectfully, to the extent criminal activity is established to be motivated by a clinically diagnosed substance addiction, drug court programming necessarily recognizes that such defendants are differently situated from others committing similar conduct, but for different criminogenic factors, thereby justifying the disparity in sentencing outcome.

The sentencing of BRIDGE graduates balances two important considerations, which are sometimes in tension. The original and sentencing district judge, and not the BRIDGE supervisory judge or the BRIDGE Team, always retains discretion over the sentencing outcome. But, the exercise of such discretion is always informed by the important best-practices precept that it does not make sense to have participants stabilize their entire lives and establish a strong recovery network only to *then* incarcerate them once they have done so. In this context, the reasonable approach has been to informally ask, at the outset, whether the sentencing judge can anticipate tolerating a non-custodial sentence for any particular defendant.

(7) Tracking BRIDGE Program Graduates

The BRIDGE Program includes a three-month aftercare process, whereby

graduates are required to maintain a certain degree of contact and accountability with the supervising probation officer, and to attend at least three sessions of BRIDGE Court as an observer. Judicial accountability, however, is absent in the aftercare phase. Some graduates continue to be under ongoing supervision due to a probationary sentence. Additionally, as already mentioned the Program is still small enough that BRIDGE personnel and mentors stay in touch with many of our graduates out of interest for their welfare. Other graduates voluntarily appear at sessions of BRIDGE Court to encourage active participants, to express loyalty and gratitude, and for continuity with their community of recovery.

In terms of formal tracking and analysis, the BRIDGE Program is in the beginning phases of such research in partnership with Clemson University and Greenville Hospital Systems. As an emissary for the BRIDGE Program, I welcome any additional resources that the Commission may be able to provide for this simple reason—we want to know the Program's unvarnished results because we want it to be as effective as possible.

Respectfully submitted,

Bruce H. Hendricks

Bruce Howe Hendricks
United States District Judge

United States District Court for the District of South Carolina

Interim Report on the Bridge Drug Court Program

The Honorable Bruce Howe Hendricks
United States District Judge

August 2016

The Drug Court for the United States District Court for the District of South Carolina, known as the Bridge Program (the "Program"), is a supervision and rehabilitation program for defendants whose criminal conduct appears to be motivated, in significant part, by substance abuse and addiction. Often disqualified from participating in Pre-Trial Diversion, or quickly failing out because of their drug problems, these individuals return to court, time and time again, a frustration to themselves and the criminal justice system. Drug courts are a proven and effective approach to ending this cycle. Since the Bridge Program began on November 29, 2010, approximately one hundred and three (103) participants have entered the Program, approximately twenty-nine (29) participants are currently in it, and forty-one (41) have successfully graduated.[1] This memorandum reviews the evidence for the drug court model, argues for the adoption of such programs in the federal system, and describes the costs and savings associated with the Bridge Program.

[1] The remaining participants were either involuntarily terminated from the program or withdrew. One participant passed away.

I. BACKGROUND

The term "drug court" typically refers to a special docket for low-level criminal defendants whose offenses are fueled by substance addiction. Through a team-based, interdisciplinary approach that emphasizes treatment over punishment and provides accountability through regular drug testing and court appearances, drug courts help participants overcome addiction and break comorbid cycles of crime, incarceration, and recidivism. Participants who successfully complete such programs are often eligible to have their charges dismissed or to receive a non-custodial sentence. Judge Charles B. Simmons, who runs a state drug court in Greenville, South Carolina, and has served as the chairman of the board for the National Association of Drug Court Professionals, described the drug court model as follows:

> Drug courts strike the balance between protecting public safety and improving public health. Participants receive the treatment they need, are regularly tested for drug use and appear frequently before a judge to review their progress. They receive rewards for doing well and sanctions for not living up to their obligations, including lengthy prison terms for those unwilling to make the necessary changes.[2]

Common rewards "include praise and small tokens such as sweets and gift tokens," while "[s]anctions can range from chastisement to a brief stay in jail."[3]

The first drug court began in Florida in 1989 when the Dade County Circuit Court "developed an intensive, community-based, treatment, rehabilitation, and supervision program for felony drug defendants to address rapidly increasing recidivism rates."[4] By May of 2014, there were over 2,800 similar programs operating in jurisdictions throughout the United States.[5] The State of South Carolina has used drug courts since at least 1998.[6]

---

[2] Charles B. Simmons, Jr. "Drug Courts Save Lives, Money, Reduce Crime." THE STATE, August 10, 2008.
[3] *Drug Courts: Stay Out of Jail Clean*, THE ECONOMIST, February 24, 2011.
[4] Office of National Drug Control Policy: Drug Courts *available at* http://www.whitehousedrugpolicy.gov/enforce/drugcourt.html.
[5] *Drug Courts,* National Criminal Justice Reference Service, https://www.ncjrs.gov/pdffiles1/nij/238527.pdf
[6] Simmons, *supra* note 2.

Drug courts developed against a backdrop of growing incarceration rates in the United States. In 1972, the United States imprisonment rate, which stood at 93 per 100,000,[7] began a period of prolonged and steep growth, increasing annually by six to eight percent through 2000.[8] When the rate peaked in 2007, it was 506 per 100,000.[9] The 2012 rate of 471 per 100,000 is "4.3 times the historical average of 110 per 100,000."[10] As a result, the United States is unparalleled in the proportion of its population that it incarcerates, making up 25% of the world's prisoners, but only 5% of its population.[11] Increased incarceration has come at a substantial cost to taxpayers. The $68 billion spent on corrections in 2010 represents a 300% increase over 25 years.[12]

Despite substantial spending on corrections, approximately two-thirds (67.8%) of inmates are rearrested for a new crime within three years of their release, and three-quarters (76.6%) of them are arrested within five years of release.[13] The recidivism numbers are even worse for those imprisoned for property and drug crimes, the population typically eligible for drug court. Within a single year of release, 50.3% of inmates incarcerated for property offenses and 42.3% of those incarcerated for drug offenses will be rearrested.[14] The five-year rates are 82.1% for property offenders and 76.9% for drug offenders. Drug courts seek to break this cycle by treating the addictions that drive it.

---

[7] CHET BOWIE, U.S. DEPT. OF JUSTICE, BUREAU OF JUSTICE STATISTICS, PRISONERS, 1925-81 2 (1982).
[8] NATIONAL RESEARCH COUNCIL, THE GROWTH OF INCARCERATION IN THE UNITED STATES: EXPLORING CAUSES AND CONSEQUENCES 34 (Jeremy Travis et al. eds. 2014).
[9] *Id.*
[10] *Id.*
[11] Jeffrey Rosen, *Could Keeping Convicts from Violating Probation or Their Terms of Release be the Answer to Prison Overcrowding*, THE NEW YORK TIMES MAGAZINE, Jan. 10, 2010, at 38.
[12] Newt Gingrich and Pat Nolan, Op-Ed., *Prison Reform: A Smart Way for States to Save Money and Lives*, Wash. Post, Jan. 7, 2011.
[13] MATTHEW R. DUROSE, ALEXIA D. COOPER & HOWARD N. SNYDER, U.S. DEPT. OF JUSTICE, BUREAU OF JUSTICE STATISTICS, RECIDIVISM OF PRISONERS RELEASED IN 30 STATES IN 2005: PATTERNS FROM 2005 TO 2010 14 (2014).
[14] *Id.* at 8.

II. THE EVIDENCE FOR THE DRUG COURT MODEL

In the 25 years since their development, scholars have had significant opportunities to study the effectiveness of drug courts, and the evidence they have gathered indicates that drug courts significantly reduce both substance abuse and recidivism and save taxpayers money. "A statewide study in Georgia found the two-year recidivism rate among drug-court participants was 7%, compared with 15% for those on probation alone and 29% for drug-users who served time in state prison."[15] "The consensus reflected in three recent reviews of more than 60 recidivism studies is that adult drug courts reduce recidivism by an average of 8 to 13 percentage points."[16] *See also*, United States v. Baccam, 414 F.3d 885 (8th Cir. 2005) (Lay, J., concurring) ("Evidence shows that the flexible and pro-active approach of drug courts reduces recidivism rates to less than half of the recidivism rate of those offenders who are simply imprisoned for their drug crimes."). Proponents argue that the best programs have "reduced crime by as much as 45 percent over other dispositions."[17]

The positive impact of drug courts has been shown to be significant even where researchers have controlled for a range of variables including enrollment in drug treatment programs. In 2011, the National Institute of Justice (NIJ) and researchers from the Urban Institute, RTI International, and the Center for Court Innovation concluded a five-year longitudinal study of adult drug courts entitled the Multisite Adult Drug Court Evaluation (MADCE). The study examined outcomes for 1,157 participants in 23 drug court programs and compared them to outcomes for 627 offenders at six comparison sites that operated a range of other programs for

---

[15] THE ECONOMIST, *supra* note 3.
[16] Michael Rempel, et al., *Multi-Site Evaluation Demonstrates Effectiveness of Adult Drug Courts*, 95 JUDICATURE, No. 4, at 154 (January/February 2012).
[17] WEST HUDDLESTON & DOUGLAS B. MARLOWE, NATIONAL DRUG COURT INSTITUTE, PAINTING THE CURRENT PICTURE: A NATIONAL REPORT ON DRUG COURTS AND OTHER PROBLEM-SOLVING COURT PROGRAMS IN THE UNITED STATES 9 (2011).

drug-involved offenders.[18] The comparison offenders were "carefully matched to the Drug Court participants on a range of variables that influenced outcomes." Drug court participants reported less criminal activity (40% vs. 53%), were arrested less frequently (52% vs. 62%), reported less drug use (56% vs. 76%) and were less likely to test positive for drugs (26% vs. 46%).[19] The study also found that 18 months after the program, drug court participants were significantly more likely to be employed and reported less family conflict than the comparison offenders.

The use of drug courts also results in substantial savings for taxpayers and increased productivity for society. A three-year study in New York estimated that the state court system saved $254 million by diverting 18,000 non-violent drug offenders from prison to drug court.[20] "In Georgia, a drug-court sentence costs over $10,000 less than a prison sentence–no small number in a state that operates the fifth-largest prison system in the country, spending one in every 17 of its budgetary dollars on incarceration and parole."[21] A meta-analysis conducted by The Urban Institute found that drug courts produced an average of $2.21 in direct benefits to the criminal justice system for every $1 invested.[22] When community savings are added (such as a reduction in emergency room episodes, reduction in the number of victims, and reduction in dependence on foster care), the savings increased up to $27 for every $1 invested.[23]

In summary, the evidence from 25 years of experience shows that drug courts reduce drug use, reduce recidivism, and save taxpayers money. A matched study shows that drug courts are more effective than other types of criminal interventions even when coupled with drug treatment.

---

[18] SHELLI B. ROSSMAN & JANINE M. ZWEIG, THE MULTISTATE ADULT DRUG COURT EVALUATION 1 (2012).
[19] SHELLI B. ROSSMAN, JOHN K. ROMAN, JANINE M. ZWEIG, MICHAEL REMPEL, CHRISTINE H. LINDQUIST, THE MULTI-SITE ADULT DRUG COURT EVALUATION: EXECUTIVE SUMMARY 5 (2011) [hereinafter MADCE EXECUTIVE SUMMARY].
[20] HUDDLESTON & MARLOWE, *supra* note 17, at 17.
[21] THE ECONOMIST, *supra* note 3.
[22] HUDDLESTON & MARLOWE, *supra* note 17, at 10. *See also* Rempel, et al., *supra* note 16 at 156. (A cost benefit analysis conducted as part of the MADCE estimated that, on average, drug courts saved $5,680 to $6,208 per participant.).
[23] HUDDLESTON & MARLOWE, *supra* note 17, at 10.

While not every drug-dependent defendant is a candidate for drug court, and while not every drug court participant will complete their programs, 75% of those who do graduate "will never see another set of handcuffs."[24] In short, drug courts work where other interventions have failed.

III. THE CASE FOR DRUG COURT'S IN THE FEDERAL SYSTEM

At its inception, the Bridge Program mainly treated addicted defendants who had committed property crimes that fell under the jurisdiction of federal authorities, for example, theft and receipt of stolen mail, counterfeiting, conspiracy to defraud the United States, and other types of fraud. As the Program experienced success with these participants, it expanded its eligibility criteria to accept non-violent drug offenders who were dealing drugs to support addiction. The Bridge Program not only found that it could effectively treat such offenders, but that in doing so, there was a substantial opportunity to save resources and improve the lives of the participants, their families, and the community.

Our experience with the Bridge Program combined with basic facts about the federal criminal justice system leads us to believe that drug courts are a feasible and sensible alternative to incarceration for some federal defendants. As in the state system, the growth of federal prisons has created a serious financial and logistical problem. Making drug courts available to federal defendants has the potential to ease some of the burden on the Bureau of Prisons (BOP) and produce relative efficiencies beyond those achieved at the state level. Finally, despite claims to the contrary, a significant number of federal defendants are suitable candidates for drug court.

A. Growth of Federal Prisons has Created a Financial and Logistical Burden

In 2013, there were 215,900 people serving time in federal prisons,[25] representing nearly a tenfold increase in the number of federal inmates incarcerated in 1980.[26] As a result of this growth,

[24] West Huddleston, Interview on C-SPAN, August 6, 2011.
[25] E. ANN CARSON, U.S. DEPT. OF JUSTICE, BUREAU OF JUSTICE STATISTICS, PRISONERS IN 2013 2 (2014).

federal prisons are operating at 35-40% above their rated capacity, and without new policy changes, are estimated to be operating at 55% above their rated capacity by 2023.[27] A BOP study has concluded that there is "a significant positive relationship" between overcrowded prisons and inmate misconduct.[28] The growth of federal prisons has resulted in increasing costs (35.6% from FY2000 to FY2013) such that the BOP now consumes more than 25% of DOJ's budget.[29]

Drug convictions have driven the growth of federal prisons. Between 1998 and 2010, the number of convicted offenders serving time in federal prison increased 77% from 104,413 to 184,809. An analysis by the Urban Institute Justice and Policy Center found that the increased time to be served by drug offenders was "the single greatest contributor" to growth of the federal prison populations during that period."[30] "There were 34,043 more prisoners serving time for drug offenses in 2010 than in 1998," which "account[s] for 42% of the total growth in the prison population and represents a 57% increase over the number of drug offenders in 1998."[31] As of 2010, a majority of those in federal prison (52%) were there for a drug conviction.[32]

The Program is under no illusions that introducing drug courts in the federal system will magically reverse mass incarceration or relieve overcrowded prisons. However, in conjunction with other policy changes, the adoption of federal drug courts could make a significant difference over time. Furthermore, it is possible that introducing drug courts in the federal system will result in an even higher payoff than observed in the states.

---

[26] NANCY LA VIGNE & JULIE SAMUELS, URBAN INSTITUTE JUSTICE POLICY CENTER, THE GROWTH & INCREASING COST OF THE FEDERAL PRISON SYSTEM: DRIVERS AND POTENTIAL SOLUTIONS 1 (2012).
[27] JULIE SAMUELS, NANCY LA VIGNE & SAMUEL TAXY URBAN INSTITUTE JUSTICE, STEMMING THE TIDE: STRATEGIES TO REDUCE THE GROWTH AND CUT THE COST OF THE FEDERAL PRISON SYSTEM 1 (2013).
[28] NATHAN JAMES, CONGRESSIONAL RESEARCH SERVICE, THE FEDERAL PRISON POPULATION BUILDUP: OVERVIEW, POLICY CHANGES, ISSUES, AND OPTIONS 23 (2014).
[29] LA VIGNE & SAMUELS, *supra* note 26, at 2.
[30] KAMALA MALLIK-KANE, BARBARA PARTHASARATHY & WILLIAM ADAMS, URBAN INSTITUTE JUSTICE POLICY CENTER, EXAMINING GROWTH IN THE FEDERAL PRISON POPULATION 1998 TO 2010 3 (2012).
[31] *Id.* at 4.
[32] MARK MOTIVANS, U.S. DEPT. OF JUSTICE, BUREAU OF JUSTICE STATISTICS, FEDERAL JUSTICE STATISTICS, 2010 23 (2013).

B. Drug Courts May Have a Relatively Higher Payoff in the Federal System

While the savings and benefits obtained through the use of drug courts in state systems have been significant, the potential to maximize these benefits lies in the federal system for several reasons. First, drug convictions account for a much larger portion of the federal prison population than they do in state systems. Second, federal sentences are, on average, much longer than comparable state sentences, and a much higher percentage of federal defendants receive custodial sentences. Finally, at least in some jurisdictions, federal incarceration is more expensive than it is in the corresponding state system.

The state prison systems dwarf the federal system in terms of the total number of people incarcerated. As of December 31, 2013, there were 1,321,781 sentenced prisoners under the jurisdiction of state authorities compared to only 195,098 sentenced prisoners under the control of federal authorities.[33] However, only 16% (210,200) of the inmates in state prison are serving sentences for drug convictions.[34] By contrast, 51% (98,200) of federal inmates are serving sentences for drug offenses.[35] In other words, although federal inmates make up less than 13% of the sentenced prison population in the United States, they make up almost a third (31.82%) of those serving time for drug crimes.

The potential savings are increased by not only the number of drug offenders who enter the federal system, but also by the type and length of the sentences they receive. As an initial matter, federal drug defendants are far more likely to receive a custodial sentence than state drug defendants. Of the 25,416 drug convictions secured by U.S. Attorneys' Offices in 2010, 91% of them resulted in custodial sentences.[36] The rates in state systems are much lower. As would be

[33] CARSON, *supra* note 25, at 4.
[34] *Id.* at 15.
[35] *Id.* at 16.
[36] MOTIVANS, *supra* note 32, at 22.

expected, the median federal sentence (30 months as of 2010)[37] is substantially longer than the median state sentence (17 months as of 2006). However, this difference is even more pronounced with regard to those convicted for drug offenses. The median term of incarceration imposed on those convicted of drug offenses in federal court was 60 months,[38] whereas the median time served by those convicted of felony drug offenders in state court was 13-14 months.[39] Assuming that all federal convicts received "good time" and served only 87% of their sentences, the median time served by federal drug offenders would still be over three times the length of the median time served by drug offenders in the state systems.

In some instances, the cost of incarceration in federal prison is higher than it is in state prisons. For example, in 2014, the average cost of incarcerating an inmate in South Carolina was $19,137,[40] approximately $10,000 less than the cost of incarcerating a federal inmate. It should be noted, however, that this is not true of all jurisdictions.

C. A Significant Number of Federal Defendants are Suitable Candidates for Drug Court

None of the figures discussed above are meaningful if federal defendants generally, and federal drug defendants in particular, are categorically ill-suited for drug court programs. This was one of the conclusions reached by the Department of Justice in a 2006 memo that argued against the need for drug courts in the federal system.[41] The memo argued that (1) substantial programs already exist to help federal defendants with drug problems, (2) most federal drug offenders have committed serious drug offenses and are not good candidates for drug courts, and (3) the resources

---

[37] *Id.* at 2.
[38] *Id.* at 22.
[39] CARSON, *supra* note 25, at 18.
[40] SOUTH CAROLINA DEPARTMENT OF CORRECTIONS, COST PER INMATE FISCAL YEARS 1988-2014 (2014) *available at* http://www.doc.sc.gov/pubweb/research/BudgetAndExpenditures/PerInmateCost1988-2014.pdf.
[41] U.S. DEPT. OF JUSTICE, REPORT TO CONGRESS ON THE FEASIBILITY OF FEDERAL DRUG COURTS 4 (2006) [hereinafter, 2006 DOJ Memo].

required to run drug courts in the federal system would divert funds from state drug courts and federal drug enforcement initiatives.[42]

Under the leadership of Attorney General Eric Holder, DOJ altered its position and concluded that the time had come to give (pre-trial[43]) drug courts a chance in the federal system. Since 2010, drug courts have been started in several federal districts. In March of 2014, Attorney General Holder visited Charleston to observe a session of the Bridge Program. In his remarks following the visit, the Attorney General praised the Program as one that he would like to see replicated.[44] While the reasons provided in opposition to federal drug courts in the 2006 DOJ Memo no longer represent DOJ policy, they warrant some discussion because they represent intuitive questions or objections that are commonly raised in discussions of expanding drug courts to the federal system.

1. Substantial programs already exist to help federal defendants with drug problems.

Federal defendants are provided access to drug counseling, both within the Bureau of Prisons and as a component of supervision by the United States Probation Office. We are certainly not opposed to these programs and believe that they are beneficial and necessary. However, the fact that these programs exist does not mean that they are an affordable or effective way to treat all federal defendants or that drug courts are redundant or unnecessary in the federal system. It is inefficient to incarcerate low-level defendants if an addiction is motivating their offenses and can be

---

[42] *Id.*

[43] It should be noted that reentry courts, which are based on the drug court model, have existed in the federal system for some time. The primary difference between the Bridge Program and these reentry courts is that the Bridge Program is principally a pre-trial program that focuses on participants who are eligible to have their charges dismissed or receive a non-custodial sentence if they successfully complete the program. Reentry courts, on the other hand, provide similar accountability for federal offenders who have already served a custodial sentence. These released inmates may be offered a reduction in their term of supervision in return for successful completion of the program. The District of South Carolina has recently developed its own Reentry Court (REAL Court), which is separate from the Bridge Program.

[44] Ryan J. Reilly, *America's Top Cop Wages a Long Battle to Dial Back the Drug War*, HUFFINGTON POST, May 20, 2014.

effectively treated through a legally supervised process that is less expensive than incarceration and less harmful to the defendant and his or her family and community.

Additionally, the growth of the federal prison population has overburdened BOP's drug treatments programs. A 2012 USA Today report regarding the availability of drug treatment in federal prisons had this to say: "Waiting lists were so long for the bureau's Residential Drug Abuse Program, which provides sentence reductions of one year for inmates who complete it, that only 25% of graduates gained entry with at least a year left on their prison terms to fully benefit from the reduced sentence."[45] A 2012 Government Accountability Office (GAO) report entitled, "Bureau of Prisons: Growing Inmate Crowding Negatively Affects Inmates, Staff, and Infrastructure," provides details regarding the number of federal inmates waiting for drug treatment. The report showed long waiting periods for drug education programs, nonresidential drug treatment programs, and residential drug treatment programs across every security level. For example, in 2011, the average waiting period for residential drug treatment for a medium security inmate was 92.8 days, down from 242.3 days in 2006.[46] These numbers are typical across program types and security levels.[47] While waiting periods have been reduced somewhat in recent years, as of 2011 there were far more federal inmates on waiting lists for basic drug education programs (over 51,000) than were enrolled (31,803).

Aspects that are unique to the drug court model are significant in helping participants to succeed. The central feature of drug court is the combination of evidence-based treatment and regular judicial accountability. The scholars who conducted the MADCE concluded that "the primary mechanism by which drug courts reduce substance use and crime is through the judge."[48]

---

[45] Kevin Johnson, *Prisoners Face Long Wait For Drug-Rehab Services*, USA TODAY, Dec. 4, 2012.
[46] UNITED STATES GOVERNMENT ACCOUNTABILITY OFFICE, BUREAU OF PRISONS: GROWING INMATE CROWDING NEGATIVELY AFFECTS INMATES, STAFF, AND INFRASTRUCTURE 71-73 (2012).
[47] *Id.*
[48] MADCE EXECUTIVE SUMMARY, *supra* note 19, at 7.

The researchers found that "[d]rug [c]ourt offenders believe that their judge treated them more fairly than the comparison group, including demonstrating greater respect and interest in them as individuals" and affording them greater opportunities to express themselves during the proceedings.[49] Such perceptions of the judge are correlated with better outcomes across all offender subgroups, including "demographics, drug use history, criminality, and mental health."[50] A separate analysis of structured observations by the research team found that drug courts whose judges were observed to have a positive judicial demeanor produced the most positive outcomes.[51] The central role of judicial accountability in making drug courts work is consistent with evidence suggesting that small sanctions immediately and consistently applied have a stronger deterrent effect than the threat of larger sanctions that are delayed or uncertain.[52] A final advantage of the drug court model is that it allows participants to battle and overcome their addictions in the real world setting to which they would ultimately return were they incarcerated. Thus, while the drug treatment programs provided by the Bureau of Prisons and United States Probation are important components of the federal correctional system, they do not render drug courts superfluous or unnecessary.

2. Federal defendants are not good candidates for drug courts.

Another argument that is sometimes raised against the use of drug courts in the federal system is the belief that most federal drug offenders have committed serious drug offenses and are not good candidates for drug courts. It should be emphasized that drug offenders are not the only category of federal defendants who are served by federal drug courts.[53] Nevertheless, the inclusion

---

[49] *Id.*
[50] *Id.*
[51] *Id.*
[52] Rosen, *supra* note 11, at 38 (describing Hawaii's HOPE program, which reduced positive drug tests by 93% by implementing small but immediate sanctions for violations).
[53] Indeed, a substantial number of the Bridge Program's participants have been defendants who have committed fraud, counterfeiting, and other similar offenses to obtain money to feed an addiction. As the Huffington Post wrote of the Bridge Program following Attorney General Holder's visit, "Not all the participants that day in April had even been charged in drug cases. One was recruited by a pawn shop owner to steal a Dyson vacuum cleaner from Lowe's store and was charged in a federal conspiracy case. Another was facing federal charges because he tried to pay of liquor store

of federal drug offenders does increase the cost-effectiveness of such programs. The argument that such offenders are not good candidates for drug courts is based on questionable assumptions about the motivations of those charged with drug trafficking, as illustrated in the 2006 DOJ Memo:

> There is a dramatic difference between the behavior and motivations of a simple substance abuser and a drug trafficker, whether violent or nonviolent. The abuser commits crimes in support of, or because of, his or her drug habit. The trafficker, on the other hand, is motivated by the desire for financial gain or the desire for power. Drug court programs are only designed to change the attitudes and behavior of the substance abuser. They are not designed or equipped to change the quite different attitudes and behavior of the drug trafficker or violent felon. . . . Given the completely different motivations and behaviors of drug traffickers it is highly unlikely that a drug-court-type program would have any success in reducing recidivism. [54]

Our experience suggests that drug offenders cannot be so easily divided into these categories. One of the prerequisites for entry into the Bridge Program is a finding that addiction is a substantial motivator or contributor to the individual's criminal conduct, and observing this requirement has not left the Program without eligible participants. We have found that drug addicts are rarely as discriminating in what they will or will not do to feed a drug habit as the argument above suggests.[55]

Moreover, the perception that all or even most federal drug defendants are hardened or violent criminals is simply inaccurate. Half of those sentenced for drug offenses in FY2010 were in the lowest criminal history category.[56] Additionally, 84% of sentenced drug offenders had "no weapon involvement."[57] Citing similar figures, Judge John Gleeson, who helps to run a drug court program in the Eastern District of New York, concluded, "anyone who believes that the federal

---

with a counterfeit $20 bill his friends had made using printer-scanner-copier." Reilly, *supra* note 44. While the guidelines range for such offenders are often low, as discussed elsewhere, offenders who commit property offenses tend to recidivate at the highest levels, placing a strain on law enforcement and courts if not the prisons.

[54] 2006 DOJ MEMO *supra* note 41, at 4.

[55] Bridge Program participants have given harrowing accounts of the lengths to which they have gone to obtain drugs. One participant, who subsequently graduated from the program, explained to the Court how he would dig through dumpsters looking for discarded medications, and would take virtually anything he found regardless of whether it would get him high or not. Other defendants have been so desperate that they have committed offenses that are so obvious that there is no way they could expect that they would not be caught.

[56] LA VIGNE & SAMUELS, *supra* note 26, at 4.

[57] SAMUELS, LA VIGNE & TAXY, *supra* note 27, at 11.

system deals only with 'the most serious drug and violent' offenders isn't familiar with the federal criminal docket."[58]

Most of the drug offenders enrolled in the Bridge Program are poor, non-violent defendants who sold or transported drugs to feed an addiction and were charged as part of a larger conspiracy.[59] As the Huffington Post observed, "Participants in the Bridge Program are far from drug kingpins. Most, if not all, of them don't have the financial resources to afford their own lawyers and are represented by federal public defenders or court-appointed counselors."[60]

Furthermore, the research that has been conducted on drug courts suggests that more serious offenders may actually do better in drug courts than those who have committed minor offenses. The MADCE researchers found "that high-risk offenders—those who initially pose the greatest risk of criminal re-offending as well as the greatest need for treatment—are especially likely to benefit from drug court participation."[61] While there were very few subgroups within the MADCE study that "experienced a differential effect," a notable exception was that "[o]ffenders with violent histories showed a greater reduction in crime than others at follow-up."[62] The MADCE researchers also found that participants who "perceive more severe consequences of program failure . . . perform better."[63]

Our experience with the Bridge Program supports the perception that defendants with more serious charges often seem more motivated to complete the Program and change their lives. Conversely, several former Bridge participants who have elected to drop out of the program have explained that the Program's stringent requirements and restrictions were not worth the effort they

[58] *United States v. Leitch*, No. 11-CR-00039 JG, 2013 WL 753445, at *10 (E.D.N.Y. Feb. 28, 2013).
[59] As Judge Gleeson has noted, many of the long sentences imposed in the federal system are" triggered . . . by drug type and quantity" rather than by the defendant's role in a drug trafficking organization or conspiracy. *United States v. Diaz*, No. 11-CR-00821-2 JG, 2013 WL 322243, at *12 (E.D.N.Y. Jan. 28, 2013).
[60] Reilly, *supra* note 44.
[61] Rempel, et al., *supra* note 16, at 156.
[62] MADCE EXECUTIVE SUMMARY, *supra* note 19, at 7.
[63] Michael Rempel, et al., *supra* note 16, at 156.

required given the light sentences that some of the participants were likely to receive even after dropping out of the Program. If anything, this Court has struggled with participants whose offenses were too minor, not too serious.

Another related argument against federal drug courts is the claim that federal prosecutors should simply decline to charge the type of offenders who would qualify for drug courts. Of course, in some instances, such offenders are an important component of the government's case. Furthermore, the facts simply do not support the conclusion that federal prosecutors are routinely dismissing drug matters that they open after concluding that the offense is not sufficiently serious. To the contrary, drug cases have the highest prosecution rate of all federal matters, surpassing weapons charges, sex offenses, violent offenses, and other crimes as the federal felony matters that prosecutors are least likely to decline to prosecute.[64]

3. There are concerns about the costs of drug courts.

A final argument against adopting drug courts in the federal system involves concerns over cost. As the analysis in Part IV will show, drug courts can be successful on a limited budget, particularly if the program forges effective partnerships with the community. While the Bridge Program could certainly benefit from additional resources – for example, a dedicated drug court coordinator for the district – the Program has been successful with minimal expenditures. Our analysis, discussed in more detail infra, shows that the Program has paid for itself and saved taxpayers money in addition to the positive intangible results it has produced.

In summary, the perception that federal defendants are categorically ill-suited for drug courts is based on assumptions that are not supported by the facts. The evidence from state court and our own experience suggests that defendants facing relatively more serious charges often succeed in drug

[64] MOTIVANS, *supra* note 32, at 13.

courts, and as the following analysis will show, it is the success of such defendants that results in the greatest savings for the taxpayer.

IV. A COST ANALYSIS OF THE BRIDGE PROGRAM

Measuring the cost effectiveness of the Bridge Program is complicated by the fact that both the Bridge Program and the alternative to which it is compared – incarceration followed by a period of supervised release – rely heavily on resources that are fixed costs. The additional expense to the taxpayer for the Bureau of Prisons to incarcerate one additional inmate (the "marginal cost") is, on average, only $10,363;[65] however, when fixed costs are factored in, that figure jumps to $29,027.[66] Likewise, the Bridge Program operates primarily by using resources that are fixed. All of the court staff and many of the attorneys involved in the program are paid an annual salary, which is unaffected by their participation or non-participation in the Bridge Program. Consequently, the cost to the taxpayer to run the Bridge Program is very small.[67] However, an analysis would be incomplete if it did not at least attempt to account for the increased labor required to operate the Bridge Program.

To evaluate the costs and savings associated with the Bridge Program, we therefore believe that at least two comparisons are needed. The first calculation seeks to measure the cost and savings for the taxpayer, comparing actual Bridge expenditures for each participant with the marginal cost of incarceration and supervision based on the participant's guideline range. The second comparison

---

[65] SAMUELS, LA VIGNE & TAXY, *supra* note 27, at 2.

[66] JAMES, *supra* note 28, at 15. The average per capita costs actually increased to $29,291 in fiscal year 2013; however, the 2012 figure is used because it corresponds with the marginal cost calculation.

[67] The Bridge Program began at a time when federal agencies were experiencing tremendous financial pressure. Budgets were frozen and there was virtually no money for new programs. As a result, the Bridge Program was forced to operate using existing resources and to reject any proposal that would meaningfully increase its costs. The program is proud of what has been accomplished using these limited resources and is grateful to the federal employees and members of the local community who have given their time, talents, and resources to start and maintain the Program. That being said, the Program would unquestionably benefit from additional resources.

seeks to measure total savings by adding a measure of fixed costs to both the Bridge Program and the alternative custodial sentences.

A. Taxpayer Savings

In performing these calculations, we include in our actual expenditures any money that the program spends for treatment or any service provided to participants. To calculate the marginal cost of incarceration, we assume that each participant would receive a sentence that is the average of the high and low range under the applicable Federal Sentencing Guidelines and the average of the high and low recommended term of supervision. We further assume that Bridge participants who fail to complete the Program will receive the same sentence (guidelines average) that they would have received had they not participated in the program. Any money that the Program spends on services for the participant is recorded as an expense associated with the Program, regardless of whether the participant benefitted from the services or would have received similar services as a part of pre-trial supervision by United States Probation. Additionally, no effort is made to account for money that the Program may save United States Probation in reduced pre-trial services for Program participants. It is important to note that this omission may result in a substantial underestimation of the savings the Bridge Program has produced.

We also assume that participants who successfully complete the Program and graduate will not receive a custodial sentence.[68] Where a term of supervision is imposed following completion of the Bridge Program, the cost of the supervision is subtracted from the savings associated with that participant. It is also important to note that this measure may not account for savings that could be realized if programs such as the Bridge Program were to be become widespread. This is because long-term marginal costs tend to be higher than short-term marginal costs. If the use of federal drug

[68] This assumption is supported by the Court's practice. To date, all graduates have received non-custodial outcomes, either a sentence of time served or complete dismissal of their charges.

courts were to meaningfully reduce the number of defendants being sentenced to prison, BOP could, over time, adjust its expectations of future incarceration, leading to larger savings.

To demonstrate how this calculation is performed, consider the case of Kelly Shea. Prior to entering the Bridge Program, Ms. Shea pled guilty to conspiring to possess with intent to distribute a quantity of cocaine and cocaine base (21 U.S.C. § 841(a) and § 841(b)(1)(C) and 846). For this offense, Ms. Shea faced a guideline range of 18-24 months followed by a term of supervised release. The cost to the taxpayer to impose this sentence upon Ms. Shea would include between $15,544.44 and $20,725.92 (for an average cost of $18,135.18) for her incarceration and $10,300.11 for her supervision. Thus, the total cost to the taxpayer, assuming that Ms. Shea received the average period of incarceration, would be $28,435.29. The Program spent $6,811.85 on expenses for Ms. Shea, and when she graduated after 12 months in the Bridge Program, her charges were dismissed. Consequently, the total savings for the taxpayer on her case was **$21,623.44**. Using this same process to calculate all the taxpayer savings for the 38 graduates counted in this analysis and then subtracting the costs the Program paid for participants who failed to graduate and are no longer in the Program yields a total taxpayer savings of **$1,455,602.61**, for an average taxpayer savings of **$14,132.06** per *participant* (not per graduate).

B. <u>Total Savings</u>

The second comparison adds to the calculations above a measure of the fixed costs associated with participation in drug court or a custodial sentence followed by a term of supervised release. The same assumptions are made regarding the length of sentences and supervision and the expenditures on participants who fail to graduate as are made above in the taxpayer savings calculation. The total cost of drug court is estimated by adding to the actual expenditures an estimation of the time spent by essential drug court personnel expressed as a portion of their salaries. The Bridge Program is assumed to meet every other week for a staff meeting and a court

session. "Essential drug court personnel" are assumed to include a judge with an estimated yearly salary of $200,000; an AUSA with an estimated yearly salary of $110,000; a public defender with an estimated yearly salary of $110,000; a probation officer with an estimated yearly salary of $70,000; and a courtroom deputy with an estimated yearly salary of $50,000.[69] We believe that a qualified, substance abuse counselor is also an indispensable member of the team, and we have been fortunate to secure a commitment from the Center for Behavioral Health, which provides treatment for many of our participants, to send their counselor to court at no additional cost to the Program.[70] Over the long term, this savings will be significant and will ensure that more of the funds expended by the Program go directly towards treatment.

The calculations assume that the judge spends an average of six (6) hours for each hearing, that the AUSA and FPD each spend an average of three (3) hours for each hearing, that the courtroom deputy spends an average of two (2) hours for each hearing, and that the United States Probation Officer assigned to the program spends 85% of her time on the Program.[71] Assuming a forty (40) hour workweek, we then calculate the percentage of each person's work time that the Program consumes and multiply that number by the person's salary. The total yearly cost of by this measure is estimated to be around $80,000.

It should be noted that a much larger team of people have volunteered their time and expertise to help develop the Program, to provide advice and assistance to the presiding judge, and to encourage the participants both in and out of court.[72] Without these volunteers, the Program

[69] These estimates may be higher or lower than the salaries of the actual individuals involved, but represent a reasonable estimation of the salary that would be received by a an employee with a similar level of experience.
[70] In addition, the rates charged by Center for Behavioral Health are lower than rates charged by other vendors previously used.
[71] These estimates may overstate the additional time that the Program costs the USAO, FPD, and the Court because no attempt is made to account for the possibility that some Bridge Program participants would have elected to go to trial had they not been given the opportunity to enter the Program.
[72] Participants' attorneys have appeared in court even though they are not typically required (or paid) to be present, experts from the Medical University of South Carolina and other institutions have given presentations and consulted with the court, other federal judges have encouraged their law clerks to volunteer time with the Program and have made

would not be what it is. However, our measure of essential personnel assumes a program that is up and running and calculates costs for those whose presence in the courtroom and at staffing meetings is absolutely required for a session of court to occur.

No attempt is made to divide the cost of essential personnel among the various participants. Rather, the estimates are multiplied by the time the program has been in existence (approximately 68 months) and subtracted from the savings gained by graduates who have avoided custodial sentences. The total cost of a custodial sentence is estimated by multiplying the average guidelines range sentence by the average monthly cost of incarceration, which is drawn from 2012 BOP figures ($29,027.00 annually or $2,418.92 monthly). When fixed resources are accounted for, the total savings for the Program is **$3,428,429.14**, for an average total savings of **$33,285.71** per participant.

There are several facts that are important to keep in mind with regard to these figures. First, these estimates are conservative. As noted, many of the costs attributed to the Program may have been incurred by United States Probation in providing pre-trial drug treatment to the participants had they not been enrolled in drug court. Some of the participants may have elected to go to trial had they not enrolled in the Program, which would have created additional work for the prosecutor and defense attorney. These calculations do not account for such possibilities. Second, when the Program started, there were only seven (7) participants, and the first participant did not graduate from the Program until January of 2012. Thus the rate at which the Program is saving money is likely to be higher now that the program is up and running full scale. Finally, the savings calculated here do not measure the significant future financial benefits that are associated with breaking the cycle of addiction, crime, and recidivism. Evaluation of such costs would likely require a larger sample size than is currently available and assistance from professional researchers. Still there are

---

themselves available to speak at graduations and encourage the participants, the Federal Bar Association has developed a mentoring program that helps participants make professional and community contacts, and a wide range of people from local religious and community leaders to family and friends have showed up to provide support and accountability for the participants.

substantial reasons to expect that these benefits will be significant. With a few minor exceptions, most of those who have graduated from the Program have not only avoided subsequent problems with the law, but many are gainfully employed and giving back to their communities. We expect that in most instances, a participant's graduation from the Program marks the beginning of the real savings, not the end.

C. Intangible and Indirect Savings

While this memorandum has attempted to measure some of the financial savings that result from the Bridge Program, many of the benefits are not easily reduced to a dollar figure. As noted previously, researchers have estimated that the direct-cost savings of $2.21 for every $1 invested in drug courts increase to $27 for every $1 invested in drug courts when indirect cost-offsets are accounted for, although it is ultimately impossible to accurately measure such costs.

As longtime drug court judge Peggy Fulton Hora explained in a recent law review article:

> The defendant is not the sole beneficiary of the drug treatment court process. A recent California study estimated that drug courts save taxpayers ninety million dollars annually. Additionally, the community experiences a reduction in crime, with an estimated monetary value of as much as twenty-four thousand dollars per drug court participant due to reduced future court costs and victim impact costs. This value may actually underestimate the financial benefit to society because it does not take into account the ability of the newly sober drug treatment court graduate to work, effectively parent, pay taxes, participate in commerce, and perhaps lead a healthier lifestyle, all of which would result in savings of future medical costs, including the costs of substance-exposed infants.[73]

A few examples from the Bridge Program serve to illustrate the nature of the benefits realized. When graduate Katherine ("Katie") Swiatocha joined the Program, she was a young, single mother who had serious issues with substance abuse. Although she had no record aside from a motor vehicle violation, Ms. Swiatocha faced federal charges for conspiracy and possession with intent to distribute and distribution of oxycodone and cocaine. She worked in a bar, lacked coping

[73] The Honorable Peggy Fulton Hora & Theodore Stalcup, *Drug Treatment Courts in the Twenty-First Century: The Evolution of the Revolution in Problem-Solving Courts*, 42 GA. L. REV. 717, 802 (2008).

skills and a sober support network, and could not identify any of her own strengths. On the first day she reported for drug court, she tested positive for marijuana and was enrolled in drug treatment. As she committed herself to the Bridge Program, her life began to turn around. She married her boyfriend and began to settle into a family routine. As required by the Program, she left her bar job and took a job at a retail store, where she continues to work today. She developed coping skills and self-confidence, learned to manage her time and keep her commitments, and completed her GED. She is pursuing a college education and recently gave birth to healthy baby. Katie easily could have delivered a drug-dependent baby that would have required extensive medical treatment and lost custody of both of her children.[74] Instead she delivered a healthy, drug-free baby and has developed into an attentive and capable mother. The likely intangible/indirect savings with respect to Katie include decreased medical costs, decreased costs for foster care, and a host of other benefits that emerge from the development of a more self-sufficient family unit.

Ryan Stumpf graduated from Cane Bay High School in May of 2011. Both Ryan and his mother stated that they believed that he would not have completed his senior year without the support of the Bridge Program. Ryan's successful completion of the Program earned him more than simply the opportunity to graduate from high school: he has received a second chance for a future without a felony record, a benefit that, if maintained, will afford him better educational and job opportunities over the course of his entire life. For Jaison Hrobar, the Program gave him the opportunity to be reunited with his family and have the chance to "be a dad again." Jaison not only graduated from the Program, but is now looking for ways to give back to others suffering with

[74] "Various sources estimate that babies born prematurely due to poor maternal health . . . require care which costs between $2,500 to $5,000 per day." The Honorable Peggy Fulton Hora et. al., *Therapeutic Jurisprudence and the Drug Treatment Court Movement: Revolutionizing the Criminal Justice System's Response to Drug Abuse and Crime in America*, 74 NOTRE DAME L. REV. 439, 503 (1999).

addiction through a non-profit he formed with a friend. At his graduation on January 3, 2012, Jaison said that before he walked into this Program he was a "dead man" and that now he has his life back.

A final example is Shaun Dubis, whose story was described in a May 2014 Huffington Post Article that covered Attorney General Holder's visit to the Bridge Program (a copy of the article is attached as Exhibit A). In his early thirties, Shaun had been addicted to heroin for more than half of his life. He had been in and out of drug treatment for over a decade without success and had failed out time and time again. He was quite literally dragged from the edge of death – having been resuscitated after overdosing. The consensus among several of the professionals who work with the Program was that Shaun was the worst heroin addict they had ever seen. His father choked with emotion as he described how he and Shaun's mother lived dreading the knock at the door that would bring them the inevitable news that Shaun was dead.

Instead, Shaun was arrested on federal drug charges and referred to the Bridge Program. With the accountability provided by the Program, Shaun completed a residential drug treatment program, got a job installing custom shutters with his brother, and began to fight for the life he had come so close to losing. When he broke his hand, he continued to work without pain medication so as not to compromise his recovery. He developed into a role model for younger participants in the Program and began to encourage others on the path to sobriety. When he stood before the Court in November of 2014 for his graduation, he was barely recognizable as the man who had been brought in on drug charges more than two years earlier. Never one to waste words, Shaun's message was simple and heartfelt – "thank you, thank you for giving me this chance."

V. CONCLUSION

Although less than four years old, the Bridge Program has already been efficient to significant result. The research conducted on drug courts in the state systems indicates that these

programs save money and improve outcomes for participants. There are good reasons to believe that these results could be replicated and even improved were such courts encouraged in the federal system. Despite arguments to the contrary, many federal defendants are excellent candidates for drug courts. While we believe the research supporting drug courts is persuasive and our financial analysis is encouraging, there is no stronger endorsement for drug courts than the accounts of our graduates who have avoided incarceration and begun the important process of recovering from their addictions and rebuilding their lives.

Honorable Leo Sorokin
United States District Court Judge
District of Massachusetts

Judge Sorokin is a United States District Judge for the United States District Court for the District of Massachusetts. Prior to being elevated, he served as a Magistrate Judge from 2005 through 2014. While serving as a Magistrate Judge, Judge Sorokin presided over the Court Assisted Recovery Effort ("CARE") court, the District of Massachusetts' reentry program, from its inception, in 2006, until 2014. Judge Sorokin was instrumental in the development of the Repair, Invest, Succeed, Emerge ("RISE") program, the District's pretrial alternative court that is currently in its second year of a three-year pilot. Judge Sorokin continues to participate in the RISE program as a Committee member.

He received his Bachelor of Arts from Yale College, *cum laude*, in 1983, and his J.D. from Columbia Law School, in 1991. Following law school, Judge Sorokin served as a law clerk to the Honorable Rya W. Zobel of the United States District Court for the District of Massachusetts from 1991 to 1992.

Statement Submitted by Judge Leo T. Sorokin, District of Massachusetts
to United States Sentencing Commission in Advance of Testimony on March 15, 2017

Thank you, Commissioners, for the opportunity to testify today, and for the Commission's ongoing interest in alternatives to incarceration.[1] Having reviewed Judge Hendricks's comprehensive and thoughtful statement, I agree with her points. My comments will explain the particular implementation in the District of Massachusetts of our presentence intensive supervision program called Repair, Invest, Succeed, Emerge, or "RISE" – a program which is fully consistent with the Guidelines. For each RISE defendant, no promises are made and no benefit accorded for successful completion of the RISE program. Participants do obtain a twelve-month delay in sentencing, during which they participate in RISE. Thereafter, Probation and then the Court, after consideration of any objections from the parties, calculate the Guidelines in the ordinary course, determine the application of any departures, and finally apply the § 3553 factors.

Before answering the specific questions posed regarding RISE, I wish to make three suggestions for the Commission's consideration. These suggestions relate to the broader topic of alternatives of incarceration and, like the RISE program, are fully consistent with the Guidelines. First, a thoughtful approach to selecting a defendant's sentencing date is a powerful tool courts can use to develop better information for our sentencing decisions and thereby promote public safety. In one form or another, RISE, BRIDGE, and CASA use that tool by delaying sentencing for a year, when appropriate, during which time Probation closely monitors the defendant's behavior. The impending, rather than immediate, sentencing operates both as a powerful

[1] This statement represents my own views and is not a statement on behalf of my colleagues or the District of Massachusetts.

motivator and a difficult test for the defendant, because the weight of the consequences of his past and present actions are vividly in front of him. I believe Judges should use this tool, not in every case, but in appropriate cases. During this extended presentencing period, some defendants will demonstrate that probation or time served is the proper sentence under the law. Others will not. Public safety is best served when we use every tool available to us to do the best job we can do in determining the proper sentence for each individual defendant's circumstances. The more we know about the defendant, the better we are able to serve that function. Our experience with RISE to date also has shown us that participants in RISE are extremely motivated to make amends for their wrongs and to rehabilitate themselves by becoming sober, employed, educated, and law-abiding. This is itself a valuable aspect of sentencing. The Commission could promote this aim by permitting Courts to assess in sentencing, with a Guideline adjustment, the significance of participation in a presentencing supervision program.

Second, the phrase "*alternatives* to incarceration" implies two separate universes. I suggest to you that we can promote public safety most effectively by taking a more holistic view. Under such a view, what happens in the Bureau of Prisons should relate seamlessly to what happened during the pretrial and sentencing phases, and also to what will happen during post-prison supervision by Probation. Sentencing is the appropriate, and probably ideal, time to identify treatment needs that bear on public safety. In Massachusetts, we have taken a major step toward working with the Bureau of Prisons to achieve this sort of holistic approach. We prescreen defendants for the BOP's Residential Drug Abuse Program, or "RDAP." As part of a pilot program with the BOP, RDAP-eligible defendants may, upon completion of RDAP, transition to a residential working treatment program in Boston (subject to electronic monitoring), rather than to the BOP Residential Reentry Center ("RRC") in Boston. Once the

defendant concludes his BOP sentence, he commences supervised release and the Court Assisted Recovery Effort, or "CARE," our reentry drug court.

This treatment continuum maximizes the value of BOP's investment in a defendant. As a general matter, the benefits of in-patient drug treatment – which is what RDAP is – are promoted and maximized when an individual is stepped down to a working drug treatment home (rather than removed from a treatment environment completely). Placement of these defendants in a residential treatment home costs about the same per day as placement in the RRC – in other words, this approach carries with it no additional cost, while providing enhanced treatment and rehabilitative benefits. These residential treatment stays are then followed by intensive supervision coupled with outpatient treatment, i.e., CARE. A similar continuum ought to provide cognitive behavioral therapy ("CBT") in a similar manner for offenders without substance abuse problems, but who otherwise present a high risk of recidivism. The value of a CBT program for these offenders has been shown by Judge Casey Rodgers's work in the Northern District of Florida. The Commission could promote this collaboration by permitting Courts to assess in sentencing, with a Guideline adjustment, the significance of participation in a combined BOP-Court program.

Third, the recent rapid rise in deaths from opiate overdoses highlights an important point about controlled substances, especially heroin, cocaine, and methamphetamine. Unfortunately, despite sustained law enforcement efforts, large amounts of these drugs are purchased and consumed every day by individuals in the United States. A drug treatment provider in Boston once told me about a day when her clinic experienced a large spike in both new admissions to treatment and overdoses. This spike, she said, arose the same day as a large joint task force sweep resulted in the arrest of many drug dealers. According to this provider, the mere fact of

the arrests caused some users to seek treatment, and led others to overdose after obtaining drugs from a new dealer. Identifying information for some of these users was within the evidence gathered during the criminal investigation. Best practices suggest that when law enforcement has information that a person is using or abusing controlled substances, as occurs in some federal cases, the officers privy to such information should do something with it. For example, law enforcement officers aware of the identity of a drug abuser could provide the information to a treatment provider, or knock on the person's door to provide treatment information. In a recent federal case in Massachusetts, law enforcement did exactly that. And in at least one community outside of Boston, such action occurs at the end of every drug investigation. See http://www.arlingtonma.gov/departments/police/opiate-outreach-initiative; see also http://www.paariusa.org.

Presently, the Guidelines acknowledge the possible importance of a defendant assisting in the prosecution of another, but not the possible importance of a defendant assisting in the saving of the life of another by assisting the government in arranging treatment for a person abusing controlled substances. Therefore, I suggest you amend U.S.S.G. § 5K1.1 with the italicized language shown below:

> Upon motion of the government stating that the defendant has provided substantial assistance *in (1)* the investigation or prosecution of another person who has committed an offense *or (2) identifying and/or assisting into treatment one or more persons addicted to or regularly abusing controlled substances*

* * *

Turning to the District of Massachusetts's RISE program, below are my answers to each of the various issues your staff suggested I address.

(1) Why Massachusetts Created RISE

In 2006, our District created one of the first federal reentry drug courts, called CARE. This is a public safety program. It combines intensive supervision (e.g., more frequent drug testing, more frequent meetings between the offender and the Probation Officer, and closer oversight) with swift, certain sanctions for all failures to comply with any requirements of supervision. These sanctions include, depending upon the violation, immediate incarceration. The program is overseen by a federal magistrate judge, and participants appear for frequent judicial status conferences. The US Attorney's Office supported the creation of CARE in 2006, continues to support the program, and participates in all aspects of it. This program is only appropriate for, and available to, offenders with serious histories of abuse of drugs or alcohol. Offenders without sufficiently serious drug problems are not accepted into CARE.

We have been very pleased with the results of more than a decade of our efforts. Offenders generally do better during their supervision in CARE than on regular supervision; they are more likely to remain sober, employed, and law-abiding in CARE than on regular supervision; and they appear to recidivate at lower levels than offenders on regular supervision. These effects were documented in a study conducted by an outside researcher from Northeastern University. The results of that study are unsurprising. Numerous research studies have shown that drug courts save money, reduce recidivism, and create many collateral benefits, such as improved employment and renewed family relationships.

Three further points bear mention with respect to CARE. First, like the BRIDGE Program in South Carolina, we built our program upon – and continually strive to comply with – the key components of drug courts established by the National Association of Drug Court Professionals ("NADCP") and based upon years of research. Second, the drug court approach

works with federal offenders. I initiated CARE and presided over it every week for eight years. I witnessed it working firsthand. So, both the research and my experience show it works. I am unaware of any study showing that there is something about federal court or federal offenders that makes this approach inapplicable or improper.[2] Third, neither CARE nor RISE are social work.[3] At court sessions, the presiding judicial officer imposes sanctions, identifies compliance with prior court directions, issues orders and less formal directives as to how the offender ought achieve compliance, and reprimands actions not warranting formal sanctions. In other words, the court functions as a court. In some cases, closer involvement of a judicial officer promotes the objectives of the governing rules and statutes. This is a regular feature of federal court. Cf. Fed. R. Civ. P. 16 (empowering courts to hold multiple conferences to establish and maintain control of proceedings).

CARE's success caused many judges, including me, to believe that the same approach would benefit some offenders on pretrial release and improve the quality of our sentencing decisions, and so we created RISE. In particular, we thought that, in certain cases, both the court and the offender might benefit from a period of time during which the offender's behavior and compliance could be observed, after a plea but before imposition of sentence. We believed that allowing such a period of time would provide us with the information necessary in some close cases to determine whether non-incarcerative sentences might be appropriate, or to discern how

[2] The FJC Reentry Study is not such a study. It does not purport to examine whether something about federal court or federal offenders affects the application of research data acquired in studying programs in other settings. Indeed, it does not ever discuss, address, or consider such studies. It suffers from other methodological and conceptual problems which are beyond the scope of this statement, but which I explained in a letter to the Criminal Law Committee.

[3] Of course, if this activity, which is lawful and within the scope of our responsibilities, helps prevent a felon from victimizing another person or transforms a male into a responsible father, then I, for one, think we should perform it even if it is deemed "social work," given our obligations as public servants.

long a sentence of imprisonment need be. The same underlying principles driving the creation of the BRIDGE program in South Carolina drove our creation of RISE: to provide an alternative sentencing tool and promote public safety through parsimonious use of scarce public funds. RISE also requires more meaningful and significant acceptance of responsibility than the Guidelines require. In this way, it differs from most federal front-end programs.

(2) How Massachusetts Developed RISE

In 2014, we formed a committee consisting of several district and magistrate judges, several United States Probation Officers including our Chief, a representative of the United States Attorney's Office, a representative of the Federal Public Defender's Office, and the Chair of our Criminal Justice Act Panel. This "RISE Committee" reviewed the documents regarding most of the other so-called front-end or alternative court programs operating in the federal system at the time, and spoke with our counterparts in other districts. The Committee also observed both Judge Laplante's "LASER" Docket in the District of New Hampshire and then-Judge Gleeson's "Alternatives to Incarceration" program in the Eastern District of New York. We drew upon our experience and research with CARE and our reentry court program for high risk offenders. Finally, to guide us in data collection and related study considerations, we consulted with a former high-ranking official from the Office of Management and Budget who has had years of experience conducting program evaluations.

Ultimately, the RISE Committee developed a proposal supported by all of its members and their constituent organizations, and the Court adopted the proposal as a three-year pilot. RISE expires at the end of the three years unless expressly renewed by the Court. We selected three years to provide sufficient time to evaluate all aspects of the program.

(3) What is RISE and How Does it Operate

A defendant may participate in RISE only if: (a) he is eligible, pursuant to criteria I will explain below; (b) his district judge approves his participation after considering a non-binding recommendation from the RISE Committee; and (c) he enters an early plea of guilty. Neither participation nor successful completion of RISE confers any sentencing benefit on a defendant beyond the sentencing judge's consideration at sentencing of the defendant's conduct (good or bad) during RISE. Participation typically lasts twelve months.

A focus on accepting responsibility distinguishes RISE from most other alternative programs and, frankly, from the Guidelines as well. Everyone in RISE must participate in our restorative justice program, which requires: (a) an informational meeting with our restorative-justice-trained Probation Officer; and (b) a two-day workshop with other RISE participants, several Probation Officer facilitators, and several community members, including two mothers whose sons were killed in, or as a result of, the drug trade. In addition, we invite each defendant to conduct an individual restorative justice project after the workshop. We want the defendants in RISE to appreciate the real human harm caused by the criminal acts they committed and, ideally, to engage in some activity to repair at least some of that harm. To date, we have held two restorative justice workshops, with a third scheduled later this month. Although our pilot program is new and small, we are extremely pleased with the early results. In developing this aspect of RISE, we have drawn upon restorative justice programs operating in the Massachusetts and California state prisons, and Bridges to Life, a faith-based restorative justice program in which, I understand, more than 25,000 inmates in the Texas Department of Corrections have participated.

RISE is a voluntary program. Eligibility is determined as follows. Only defendants on pretrial release may apply for participation in RISE. It is not available to detained defendants, and it is not a basis for obtaining release. Among released defendants, two types of offenders may participate: (a) those defendants with a "serious history of substance abuse or addiction" which "substantially contributed to the commission of the charged offense," or (b) those defendants whose history reflects "significant deficiencies in full-time productive activity, decision making, or pro-social peer networks, as a result of which the defendant would benefit substantially from a structured pretrial program."

The RISE Committee reviews an applicant's relevant paperwork (e.g., bail report, Indictment, criminal record, release conditions, supervision information, and sometimes a letter from defense counsel) as well as the results of two screening tools administered to all RISE applicants (the Texas Christian University Drug Screen, or "TCUDS," and the Post Conviction Risk Assessment, or "PCRA") and makes a consensus recommendation to the district judge presiding over the case. The Committee's recommendation is based upon whether the defendant satisfies one of the foregoing two categories, and whether there is anything known to the Committee that suggests the defendant should not participate.[4]

Probation, working with the RISE Committee, prepares an individualized list of goals or objectives for each participant. Every participant appears monthly before the magistrate judge presiding over RISE. These hearings follow the CARE model described above. We now have two RISE sessions – one in Boston, and another in Worcester.

[4] Although consensus is not required by the document creating RISE, the RISE Committee has operated by consensus in each case it has considered to date. Similarly, the final decision for CARE participation rests with the Court, but the program operates on a consensus basis, and every acceptance since 2006 has been a consensus decision.

Attached to this statement is the description of RISE, as approved by the Court, along with a sample set of objectives for a participant.

(4) RISE Program Participant Data

Below is the relevant data as of February 28, 2017:

- 46 individuals have applied to RISE since the pilot began in August 2015.
- 19 individuals became participants.
- To date, 2 participants were terminated, 6 completed RISE and have been sentenced, and 11 remain active participants.
- 9 participants are female and 10 male.
- 2 individuals are pending acceptance by their assigned district judge.
- 4 applications are pending before the Committee.
- Most of the participants (15) faced drug distribution charges.

(5) How We Measure Success and Sentencing RISE Defendants

We are tracking and evaluating RISE on an operational basis; that is, we evaluate it to determine whether it is meeting the goals we have established, whether it is a wise use of resources, and whether we can improve it. Although we are still early in the program, and most participants have not yet completed it, we are looking at the following types of measures. First, we evaluate how the defendants are doing in RISE – i.e., compliance with supervision, accomplishment of the initial objectives, and general demonstration of sober, employed, law-abiding, and responsible behavior.

Second, we are evaluating whether the program is making a meaningful difference at sentencing. At sentencing, the Court considers the defendant's performance in RISE to the extent relevant to the selection of the Guideline sentence, including any departures (most likely for extraordinary acceptance of responsibility or post-offense rehabilitation) or a variance under § 3553(a). We promise no benefit to the defendant. As I said at the start, RISE is fully consistent with the Sentencing Guidelines. Sentencing of a RISE defendant is no different than the sentencing of any other defendant, except, perhaps, in the sense that the sentencing judge has more information about the defendant than she otherwise would. All relevant facts are considered, the Guidelines calculated, departures considered, § 3553 factors evaluated, and then a sentence imposed.

As a practical matter, we do anticipate that most defendants accepted into RISE, if fully successful, likely (but not always) will receive a non-incarcerative sentence as a permissible application of the Guidelines and/or § 3553. Of the six defendants sentenced after successful completion of RISE five have received either probation or a time-served sentence, and one received an additional month of custody beyond time already served. This is so because most of the defendants selected for RISE either are eligible for such a sentence under the Guidelines, or do not face a lengthy Guideline sentence. For the latter group, successful performance in RISE may warrant departures or variances as noted above resulting in sentences of probation, time served, or a brief further period of incarceration.

We do consider accepting defendants into RISE who, even with success, are likely to receive a sentence of incarceration. No such defendant has completed RISE yet. While there are good reasons to accept such persons into RISE – e.g., treatment is best begun immediately, it will promote better behavior in prison, and successful participation may result in an appropriately

shorter prison sentence – some are concerned by the prospect of the Court encouraging such a defendant over an extended period of time to develop a sober, employed, law-abiding life, only to then have the Court interrupt progress in those areas by sending the defendant to prison. We continue to examine this issue.

We also intend to track post-RISE recidivism data. However, to date, only a handful of defendants have completed the program, so we have no such data to report at this time.

(6) Tracking Defendants After RISE

The defendants that have completed RISE to date all remain under supervision of the Probation Office. Each is tracked.

* * *

I would be happy to provide further information on any matter of interest to the Commission. Thank you again for your consideration of my submission.

UNITED STATES SENTENCING COMMISSION
ONE COLUMBUS CIRCLE, NE
SUITE 2-500, SOUTH LOBBY
WASHINGTON, DC 20002-8002
(202) 502-4500
FAX (202) 502-4699

March 10, 2017

MEMORANDUM

TO: Acting Chair Pryor
Commissioners
Ken Cohen, Staff Director

FROM: Drug Policy Team[1]

SUBJECT: March 15, 2017 Public Hearing on Controlled Substances

I. INTRODUCTION

At the March 15, 2017, public hearing the Commission will hear testimony from witnesses[2] concerning the Commission's study of offenses involving MDMA/Ecstasy, synthetic cannabinoids (such as JWH-018 and AM-2201), and synthetic cathinones (such as Methylone, MDPV, and Mephedrone).[3] Public comment from a variety of stakeholders led the Commission to add this multi-year study to its priorities for the current amendment cycle.[4] This memorandum

[1] Pete Madsen, James Parker, Charles Ray, Christina Stewart, Lou Reedt (Chair).

[2] The hearing agenda and witness testimony are included in this binder.

[3] *See* 81 FR 58004 (Aug. 24, 2016). In December 2016, the Commission published an issue for public comment on this study. *See* 81 FR 92021 (Dec. 19, 2016). This *Federal Register* notice is attached to this memorandum.

[4] *See* Letter from Jonathan J. Wroblewski, Director, Office of Policy and Legislation, Criminal Division, United States Department of Justice, to the Honorable Patti B. Saris, Chair, United States Sentencing Commission, at 14-15, 21 (July 24, 2015); Letter from Michelle Morales, Acting Director, Office of Policy and Legislation, Criminal Division, United States Department of Justice, to the Honorable Patti B. Saris, Chair, United States Sentencing Commission, at 6 (July 19, 2016); Letter from Marjorie Meyers, Chair, Federal Defender Sentencing Guidelines Committee, to the Honorable Patti B. Saris, Chair, United States Sentencing Commission, at 8-11 (July 25, 2016); Letter from the Probation Officers Advisory Group to the Honorable Patti B. Saris, Chair, United States Sentencing Commission, at 7 (July 22, 2016).

briefly discusses some of the issues more fully examined in the team's previous memoranda to assist the commissioners in their preparation for the hearing.

II. STUDY OF CONTROLLED SUBSTANCES

The Commission's study concerns offenses involving certain synthetic cathinones and synthetic cannabinoids, which are schedule I controlled substances not referenced at §2D1.1 (Unlawful Manufacturing, Importing, Exporting, or Trafficking (Including Possession with Intent to Commit These Offenses); Attempt or Conspiracy). The Commission also included MDMA, a schedule I controlled substance that is referenced at §2D1.1 in the study. The specific controlled substances under consideration are as follows:

Synthetic Cathinones

- MDPV (Methylenedioxypyrovalerone)
- Methylone (3,4-Methylenedioxy-N-methylcathinone)
- Mephedrone (4-Methylmethcathinone (4-MMC))

Synthetic Cannabinoids

- JWH-018 (1-Pentyl-1-3-1-(1-Naphthoyl)Indole)
- AM-2201 (1-(5-Fluoropenty1)-3-(1-Naphthoyl)Indole)

MDMA/Ecstasy (3,4-methylenedioxy-methamphetamine)

The following are brief descriptions of the controlled substances at issue in the study. Staff has also attached the National Institute on Drug Abuse's (NIDA) DrugFacts on synthetic cannabinoids, synthetic cathinones, and MDMA for your reference.

A. Synthetic Cannabinoids

According to NIDA, synthetic cannabinoids are man-made mind-altering chemicals that are either sprayed on dried, shredded plant material so they can be smoked (herbal incense) or sold as liquids to be vaporized and inhaled in e-cigarettes and other devices (liquid incense).[5] These chemicals are called cannabinoids because they are related to chemicals found in the marijuana plant. Because of this similarity, synthetic cannabinoids are sometimes misleadingly called "synthetic marijuana" (or "fake weed"). These substances are frequently sold under various brand names such as "K2" or "Spice", and are marketed as "safe," legal alternatives to marijuana. In fact, they may affect the brain much more powerfully than marijuana; their actual effects can be unpredictable and, in some cases, severe or even life-threatening.

[5] *See* National Institute on Drug Abuse, DrugFacts: Synthetic Cannabinoids (Revised November 2015) available at https://www.drugabuse.gov/publications/drugfacts/synthetic-cannabinoids. The DrugFacts is attached to this memorandum.

B. Synthetic Cathinones

NIDA describes synthetic cathinones as human-made drugs chemically related to cathinone, a stimulant found in the khat plant.[6] Khat is a shrub grown in East Africa and southern Arabia, and people sometimes chew its leaves for their mild stimulant effects. Synthetic variants of cathinone can be much stronger than the natural product and, in some cases, very dangerous. Synthetic cathinones, more commonly known as "bath salts," are marketed as cheap substitutes for other stimulants such as methamphetamine and cocaine. Additionally, products sold as "Molly" (a term generally applied to MDMA) often contain synthetic cathinones, especially methylone, instead.

C. MDMA/Ecstasy

According to NIDA, MDMA is a synthetic drug that alters the user's mood and perception of his or her surroundings, and is both a stimulant and hallucinogen.[7] MDMA is usually taken in a capsule or as a tablet, but can be swallowed as a liquid or "snorted" as a powder. The nickname "Molly" (slang for "molecular") may be used to refer to the powder form of MDMA, however, powder or capsules sold as Molly may contain other substances, such as synthetic cathinones.

III. §2D1.1, APPLICATION NOTE 6

With the exception of MDMA, these controlled substances being studied are not referenced in the Drug Quantity Table at §2D1.1(c). When a controlled substance is not specifically referenced in §2D1.1, Application Note 6 instructs the court to "determine the base offense level using the marijuana equivalency of the most closely related controlled substance referenced in [§2D1.1]."[8] The guidelines establish a three-step process for making this determination.[9] First, courts must determine the most closely related controlled substance referenced in §2D1.1. Application Note 6 provides:

> In determining the most closely related controlled substance, the court shall, to the extent practicable, consider the following:

---

[6] *See* National Institute on Drug Abuse, DrugFacts: Synthetic Cathinones ("Bath Salts"") (Revised January 2016) available at https://www.drugabuse.gov/publications/drugfacts/synthetic-cathinones-bath-salts. The DrugFacts is attached to this memorandum.

[7] *See* National Institute on Drug Abuse, DrugFacts: MDMA (Ecstasy/Molly) (Revised October 2016) available at https://www.drugabuse.gov/publications/drugfacts/mdma-ecstasymolly. The DrugFacts is attached to this memorandum.

[8] *See* USSG §2D1.1, comment. (n.6).

[9] *See* USSG §2D1.1, comment. (n.6); USSG §2D1.1, comment. (n.8).

(A) Whether the controlled substance not referenced in this guideline has a chemical structure that is substantially similar to a controlled substance referenced in this guideline.

(B) Whether the controlled substance not referenced in this guideline has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance referenced in this guideline.

(C) Whether a lesser or greater quantity of the controlled substance not referenced in this guideline is needed to produce a substantially similar effect on the central nervous system as a controlled substance referenced in this guideline.[10]

Once the most closely related controlled substance is determined, the next step is to refer to the marijuana equivalency from the Drug Equivalency Tables at §2D1.1(D) for the most closely related controlled substance to convert the quantity of controlled substance in the offense into its equivalent quantity of marijuana. The final step is to find the equivalent quantity of marijuana in the Drug Quantity Table at §2D1.1(c) and use the corresponding offense level as the base offense level of the controlled substance involved in the offense.[11]

Public comment suggested that questions regarding the most closely related controlled substance arise frequently in connection with the controlled substances being studied and require the courts to hold extensive hearings that require expert testimony on behalf of the government and the defendant.[12] Additionally, staff's analysis of fiscal year 2015 Commission data indicated that, at least in methylone cases, some courts adjust the marijuana equivalency to various different equivalencies, which causes disparate sentencing results.

IV. HEARING

A possible outcome of the Commission's study will be to establish marijuana equivalencies for the controlled substances that are not referenced at §2D1.1. Historically, the Commission has considered many factors when deciding whether to add a new substance to the Drug Equivalency Tables, including the following non-exhaustive list of factors discussed at previous meetings includes:

---

[10] *See* USSG §2D1.1, comment. (n.6).

[11] For example, if an offender is accountable for 50 grams of methylone and the marijuana equivalency is 1 gram methylone = 500 grams marijuana, the base offense level is determined by multiplying the 50 grams by the 500 grams of marijuana. The marijuana equivalency of 25,000 grams of marijuana results in a base offense level 16.

[12] *See* Wroblewski Letter, *supra* n.3, at 14-15; Morales Letter, *supra* n.3 at 6. Representatives of the Drug Enforcement Administration stated the same during the team's informal outreach in August.

- Legislative history(ies);
- Scheduling history;
- Commission data;
- Case law and scientific literature;
- International and national trafficking patterns;
- The "end product"; how it is sold and used;
- Pharmacological effects and health hazards associated with use of the controlled substance;
- Prevalence of use/abuse;
- Morbidity and mortality associated with use of the controlled substance; and,
- Public comment.

In 2001, the Commission amended the guidelines to increase the marijuana equivalency of 1 gm MDMA = 35 gm marijuana to 1 gm MDMA = 500 gm marijuana.[13] As the Commission explained, the marijuana equivalency was based on the aforementioned factors and the amendment's reason for amendment identified MDMA's pharmacological effects and health hazards, and the trafficking patterns associated with MDMA distribution, as particularly relevant to the Commission's action. The Commission included MDMA in the current study in light of its association with methylone and public comment suggesting that the guideline penalties for MDMA were set too high.

Staff reached out to find witnesses with broad experience and expertise for this introductory hearing to provide background on some of the referenced factors. Staff proposes that future hearings be more targeted, focusing on specific classes of controlled substances, and the specific controlled substances within those classes.

A. Panel I - General Introduction & Trafficking Patterns

The witnesses on Panel I will provide an introductory overview of the various controlled substances under study. The first witness is Dr. Eric Wish, Director of the Center for Substance Abuse Research (CESAR) at the University of Maryland, College Park. Dr. Wish will provide information on the topic of synthetic controlled substances and the unique issues that result from their use. Additionally, Shontal Linder, Section Chief of the DEA's Synthetic Drugs and Chemicals Section, will testify regarding the trafficking patterns for these controlled substances.

B. Panel II - Community Impact of Synthetic Cannabinoids and Supervised Release Issues

Panel II's witnesses will discuss the community impact of these controlled substances, local law enforcement responses, and the medical treatment of users, including the challenges posed by treating synthetic drug users in the emergency department setting. Specifically, Broward County, Florida, Captain Osvaldo "Ozzy" Tianga of the Sherriff's Department and Dr.

[13] *See* USSC, Report to the Congress: MDMA Drug Offenses, Explanation of Recent Guideline Amendments (May 2001); USSG App. Vol. III, amend. 609 (eff. May 1, 2001).

John Cunha, Director of Emergency Services, Holy Cross Hospital, in Broward County, will testify about their community's experiences.[14]

Additionally, the final Panel II witness, Dr. Lisa Rawlings of the Court Services and Offender Supervision Agency for the District of Columbia (CSOSA), will discuss issues related to monitoring and drug testing of persons on supervised release, particularly as compared to the traditional drugs.[15] For example, staff understands that one of the reasons individuals use synthetic cannabinoids and synthetic cathinones is that these substances are not detectable in standard urine tests, requiring a more expensive drug test to detect. Therefore, staff has invited Dr. Rawlings to give testimony about this issue and to discuss other concerns about supervising individuals who use these substances.

C. Panel III - Chemical Structure and Pharmacological Effects; Therapeutic uses of MDMA

Panel III will focus on two issues. First, the panelists will present the scientific testimony required by prongs (A) and (B) of §2D1.1, Application Note 6. Prongs (A) and (B) of Application Note 6 require the court to consider very detailed scientific data provided by multiple experts testifying on behalf of both the defendant and the government.[16] To help inform the Commission, staff invited two witnesses who have extensive experience testifying in court about the chemical structure and physical and psychoactive effects of these controlled substances.

The Commission will hear from Professor Gregory Dudley, Ph.D., an expert on the chemical structures of controlled substances who routinely testifies on behalf of the defense.[17] Additionally, Dr. Terrance Boos, Ph.D., of the Drug Enforcement Administration's Diversion Control Division, is also an expert on the chemical structures of controlled substances and the pharmacological effects of controlled substances.[18] Staff anticipates that Dr. Dudley's and Dr.

---

[14] *See, e.g.*, CBSMiami, [Broward Sherriff's Office], Drug Experts Concerned About Rise Of "Flakka" Drug In Broward (March 4, 2015), available at http://miami.cbslocal.com/2015/03/04/bso-drug-experts-concerned-about-rise-of-flakka-drug-in-broward/; Sun Sentinel, Civic leaders launch effort to fight flakka's 'deadly' threat (May 13, 2015), available at http://www.sun-sentinel.com/local/broward/fl-flakka-community-intervention-20150513-story.html; Channel 5 WPTV, Broward County Sheriff describes Flakka as the '$5 insanity drug' (May 13, 2015), available at http://www.wptv.com/news/state/flakka-broward-county-sheriff-describes-flakka-as-the-5-insanity-drug.

[15] The Court Services and Offender Supervision Agency for the District of Columbia is a Federal Executive Branch agency that provides supervision and support services to adult offenders on (1) probation, as ordered by the D.C. Superior Court; (2) parole, as granted by the United States Parole Commission; and, (3) supervised release, as determined by law and administered by the United States Parole Commission. Additional information regarding CSOSA is available on its webpage at http://www.csosa.gov/.

[16] Examples of this type of testimony was provided to the commissioners by Judge Thomas J. McAvoy (N.D.N.Y) in the case of *United States v. Marshall, et al.*, 14-CR-232 (TJM) (pending sentencing).

[17] A description of Professor Dudley's *bona fides* is in his witness biography included in this binder.

[18] See also the witness biographies in this binder for a full description of Dr. Boos' *bona fides*.

Boos' testimony will be fairly technical and include references to various chemical molecules, the ways individual molecules combine to form a given controlled substance, how chemical structures of various controlled substances differ from one another, and how these differences may be experienced by the users of these controlled substances.[19]

The second issue addressed by this panel relates to MDMA. The final witness will be Dr. Rick Doblin, Ph.D., founder and Director of the Multidisciplinary Association for Psychedelic Studies (MAPS), who will testify on the possible therapeutic uses of MDMA.[20] Staff expects that this testimony may inform consideration on whether the Commission should reconsider its 2001 decision setting MDMA penalties at their current level.

V. CONCLUSION

Staff looks forward to the March public hearing and further feedback from the Commission on proposed next steps for the continued study of these controlled substances.

[19] Staff explained to all witnesses that the March public hearing is intended as a broad introduction to the controlled substances under study and to conform their testimony appropriately.

[20] Currently, MAPS is raising funds for clinical trials that involve MDMA and patients suffering post-traumatic stress disorder (PTSD). *See* MAPS, MDMA-Assisted Psychotherapy, available at http://www.maps.org/research/mdma.

BAC 2210-40

UNITED STATES SENTENCING COMMISSION

Sentencing Guidelines for United States Courts

AGENCY: United States Sentencing Commission

ACTION: Request for public comment.

SUMMARY: In August 2016, the Commission indicated that one of its priorities would be the "[s]tudy of offenses involving MDMA/Ecstasy, synthetic cannabinoids (such as JWH-018 and AM-2201), and synthetic cathinones (such as Methylone, MDPV, and Mephedrone), and consideration of any amendments to the Guidelines Manual that may be appropriate in light of the information obtained from such study." See 81 FR 58004 (Aug. 24, 2016). As part of its statutory authority and responsibility to analyze sentencing issues, including operation of the federal sentencing guidelines, the United States Sentencing Commission is publishing this issue for comment to inform the Commission's consideration of the issues related to this policy priority. The issue for comment is set forth in the Supplementary Information portion of this notice.

DATES: Public comment regarding the issue for comment set forth in this notice should be received by the Commission not later than **March 10, 2017**.

ADDRESSES: All written comment should be sent to the Commission by electronic mail or regular mail. The email address for public comment is Public_Comment@ussc.gov. The regular mail address for public comment is United States Sentencing Commission, One Columbus Circle, N.E., Suite 2-500, Washington, D.C. 20002-8002, Attention: Public Affairs.

FOR FURTHER INFORMATION CONTACT: Christine Leonard, Director, Office of Legislative and Public Affairs, (202) 502-4500, pubaffairs@ussc.gov.

SUPPLEMENTARY INFORMATION: The United States Sentencing Commission is an independent agency in the judicial branch of the United States Government. The Commission promulgates sentencing guidelines and policy statements for federal courts pursuant to 28 U.S.C. 994(a). The Commission also periodically reviews and revises previously promulgated guidelines pursuant to 28 U.S.C. 994(o) and submits guideline amendments to the Congress not later than the first day of May each year pursuant to 28 U.S.C. 994(p).

In August 2016, the Commission indicated that one of its priorities would be the "[s]tudy of offenses involving MDMA/Ecstasy, synthetic cannabinoids (such as JWH-018 and AM-2201), and synthetic cathinones (such as Methylone, MDPV, and Mephedrone), and consideration of any amendments to the Guidelines Manual that may be appropriate in light of the information obtained from such study." See 81 FR 58004 (Aug. 24, 2016). The Commission intends that this study will be conducted over a two-year period and will solicit input, several times during this period, from experts and other members of the public. The Commission further intends that in the amendment cycle ending May 1, 2018, it may, if appropriate, publish a proposed amendment as a result of the study.

MDMA, Synthetic Cathinones, and Synthetic Cannabinoids.—As part of the study related to this policy priority, the Commission intends to examine offenses involving the following controlled substances:

Synthetic Cathinones

- MDPV (Methylenedioxypyrovalerone)
- Methylone (3,4-Methylenedioxy-N-Methylcathinone)
- Mephedrone (4-Methylmethcathinone (4-MMC))

Synthetic Cannabinoids

- JWH-018 (1-Pentyl-1-3-1-(1-Naphthoyl)Indole)
- AM-2201 (1-(5-Fluoropenty1)-3-(1-Naphthoyl)Indole)

MDMA/Ecstasy (3,4-Methylenedioxy-Methamphetamine)

The synthetic cathinones and synthetic cannabinoids listed above are Schedule I controlled substances that are not currently referenced at §2D1.1 (Unlawful Manufacturing, Importing, Exporting, or Trafficking (Including Possession with Intent to Commit These Offenses); Attempt or Conspiracy).

MDPV, methylone, and mephedrone, are synthetic cathinones. According to the National Institute on Drug Abuse, synthetic cathinones, also known as "bath salts," are man-made substances related to cathinone, a stimulant found in the khat plant. See National Institute on Drug Abuse, DrugFacts: Synthetic Cathinones ("Bath Salts") (Revised January 2016) available at https://www.drugabuse.gov/publications/drugfacts/synthetic-cathinones-bath-salts.

JWH-018 and AM-2201 are synthetic cannabinoids, sometimes referred to as "Spice" or "K2." These substances are also man-made and, in liquid form, can be sprayed on shredded plant material so they can be smoked. See National Institute of Drug Abuse, DrugFacts: Synthetic Cannabinoids (Revised November 2015) available at https://www.drugabuse.gov/publications/drugfacts/synthetic-cannabinoids.

MDMA is a synthetic drug that alters the user's mood and perception of surrounding objects and conditions. MDMA, also known as "ecstasy" or "molly," is both a stimulant and hallucinogen, and is typically taken in tablet or capsule form. See National Institute of Drug Abuse, DrugFacts: MDMA (Ecstasy/Molly) (Revised October 2016) available at

https://www.drugabuse.gov/publications/drugfacts/mdma-ecstasymolly.

Guidelines Penalty Structure.—When a drug trafficking offense involves a controlled substance not specifically referenced in the guidelines, the Commentary to §2D1.1 instructs the court to "determine the base offense level using the marihuana equivalency of the most closely related controlled substance referenced in [§2D1.1]." See USSG §2D1.1, comment. (n.6). The guidelines establish a three-step process for making this determination. See USSG §2D1.1, comment. (n.6, 8).

First, courts must determine the most closely related controlled substance by considering the following factors to the extent practicable:

(A) Whether the controlled substance not referenced in §2D1.1 has a chemical structure that is substantially similar to a controlled substance referenced in this guideline.

(B) Whether the controlled substance not referenced in §2D1.1 has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance referenced in this guideline.

(C) Whether a lesser or greater quantity of the controlled substance not referenced in §2D1.1 is needed to produce a substantially similar effect on the central nervous system as a controlled substance referenced in this guideline.

Once the most closely related controlled substance is determined, the next step is to refer to the marihuana equivalency from the Drug Equivalency Tables at Application Note 8(D) for the most closely related controlled substance to convert the quantity of controlled substance in the offense into its equivalent quantity of marihuana. The final step is to find the equivalent quantity of marihuana in the Drug Quantity Table at §2D1.1(c) and use the corresponding offense level as the base offense level of the controlled substance involved in the offense.

For example, in cases involving methylone, Commission data indicates that in fiscal year 2015, the courts always identified MDMA as its most closely related controlled substance. The marihuana equivalency of MDMA is 1 gm MDMA = 500 gm marihuana. Pursuant to the Drug Equivalency Tables, when sentencing methylone offenders, this is the equivalency to be used. Thus, if an offender is accountable for 50 grams of methylone, the base offense level at §2D1.1 would be determined by multiplying the 50 grams by 500 grams of marihuana. The resulting equivalency of 25,000 grams of marihuana provides for a base offense level 16.

In recent years, the Commission has received comment from the public suggesting that questions regarding "the most closely related controlled substance" require courts to hold extensive hearings. In addition, the Commission has heard that courts have identified different controlled substances as the "most closely related controlled substance" to the synthetic cathinones and synthetic cannabinoids included in the Commission's study and, in some cases, adjusted the marihuana equivalency to account for perceived differences between the "most closely related controlled substance" and the controlled substance involved in the offense. Both

outcomes may result in sentencing disparities among similarly situated defendants. To possibly alleviate these issues, one possible outcome of the Commission's study may be to establish marihuana equivalencies for each of the synthetic cathinones (MDPV, methylone, and mephedrone) and synthetic cannabinoids (JWH-018 and AM-2201). The Commission decided to include MDMA in its study because courts have identified MDMA as the most closely related controlled substance referenced in §2D1.1 to methylone.

Issue for Comment.—In determining the marihuana equivalencies for specific controlled substances, the Commission has considered, among other things, the chemical structure, the pharmacological effects, the legislative and scheduling history, potential for addiction and abuse, the pattern of abuse and harms associated with abuse, and the patterns of trafficking and harms associated with trafficking.

The Commission invites general comment on any or all of these factors as they relate to the Commission's study of synthetic cathinones (MDPV, methylone, and mephedrone) and synthetic cannabinoids (JWH-018 and AM-2201).

The Commission further seeks broad comment on offenses involving synthetic cathinones (MDPV, methylone, and mephedrone) and synthetic cannabinoids (JWH-018 and AM-2201), and the offenders involved in such offenses. What is the conduct involved in such offenses and the nature and seriousness of the harms posed by such offenses? How these offenses and offenders compare with other drug offenses and drug offenders? How are these substances manufactured, distributed, possessed, and used? What are the characteristics of the offenders involved in these

various activities? What harms are posed by these activities?

Which of the controlled substances currently referenced in §2D1.1 should be identified as the "most closely related controlled substance" to any of the synthetic cathinones and synthetic cannabinoids included in the Commission's study? To what extent does the synthetic cathinone or synthetic cannabinoid differ from its "most closely related controlled substance"?

AUTHORITY: 28 U.S.C. 994(a), (o), (p), (x); USSC Rules of Practice and Procedure 4.4.

Patti B. Saris,

Chair

[FR Doc. 2016-30490 Filed: 12/16/2016 8:45 am; Publication Date: 12/19/2016]

National Institute on Drug Abuse
DrugFacts
www.drugabuse.gov

Synthetic Cannabinoids

What are synthetic cannabinoids?

Synthetic cannabinoids refer to a growing number of man-made mind-altering chemicals that are either sprayed on dried, shredded plant material so they can be smoked (herbal incense) or sold as liquids to be vaporized and inhaled in e-cigarettes and other devices (liquid incense).

These chemicals are called *cannabinoids* because they are related to chemicals found in the marijuana plant. Because of this similarity, synthetic cannabinoids are sometimes misleadingly called "synthetic marijuana" (or "fake weed"), and they are often marketed as "safe," legal alternatives to that drug. In fact, they may affect the brain much more powerfully than marijuana; their actual effects can be unpredictable and, in some cases, severe or even life-threatening.

Synthetic cannabinoids are included in a group of drugs called "new psychoactive substances" (NPS). NPS are unregulated psychoactive (mind-altering) substances that have become newly available on the market and are intended to copy the effects of illegal drugs. Some of these substances may have been around for years but have reentered the market in altered chemical forms or due to renewed popularity.

False Advertising

Synthetic cannabinoid products are often labeled "not for human consumption." Labels also often claim that they contain "natural" material taken from a variety of plants. However, the only parts of these products that are natural are the dried plant materials. Chemical tests show that the active, mind-altering ingredients are cannabinoid compounds made in laboratories.

Manufacturers sell these herbal incense products in colorful foil packages and sell similar liquid incense products, like other e-cigarette fluids, in plastic bottles. They market these products under a wide variety of specific brand names; in past years, K2 and Spice were common. Hundreds of other brand names now exist, such as Joker, Black Mamba, Kush, and Kronic.

For several years, synthetic cannabinoid mixtures have been easy to buy in drug paraphernalia shops, novelty stores, gas stations, and through the Internet. Because the chemicals used in them have a high potential for abuse and no medical benefit, authorities have made it illegal to sell, buy, or possess some of these chemicals. However, manufacturers try to sidestep these laws by changing the chemical formulas in their mixtures.

Easy access and the belief that synthetic cannabinoid products are "natural" and therefore harmless have likely contributed to their use among young people. Another reason for their use is that standard drug tests cannot easily detect many of the chemicals used in these products.

How do people use synthetic cannabinoids?

Users usually smoke the dried plant material sprayed with synthetic cannabinoids. Sometimes they mix the sprayed plant material with marijuana, or they brew it as tea. Other users buy synthetic cannabinoid products as liquids to vaporize them in e-cigarettes.

How do synthetic cannabinoids affect the brain?

Synthetic cannabinoids act on the same brain cell receptors as *delta-9-tetrahydrocannabinol* (THC), the mind-altering ingredient in marijuana.

So far, there have been few scientific studies of the effects of synthetic cannabinoids on the human brain, but researchers do know that some of them bind more strongly than marijuana to the cell receptors affected by THC, and may produce much stronger effects. The resulting health effects can be unpredictable.

Because the chemical composition of many synthetic cannabinoid products is unknown and may change from batch to batch, these products are likely to contain substances that cause dramatically different effects than the user might expect.

Synthetic cannabinoid users report some effects similar to those produced by marijuana:

- elevated mood
- relaxation
- altered *perception*—awareness of surrounding objects and conditions
- symptoms of *psychosis*—delusional or disordered thinking detached from reality

Psychotic effects include:

- extreme anxiety
- confusion
- *paranoia*—extreme and unreasonable distrust of others
- *hallucinations*—sensations and images that seem real though they are not

iStock.com/trendobjects

What are some other health effects of synthetic cannabinoids?

People who have used synthetic cannabinoids and have been taken to emergency rooms have shown severe effects including:

- rapid heart rate
- vomiting
- violent behavior
- suicidal thoughts

Synthetic cannabinoids can also raise blood pressure and cause reduced blood supply to the heart, as well as kidney damage and seizures. Use of these drugs is associated with a rising number of deaths.

Are synthetic cannabinoids addictive?

Humannet/Shutterstock

Yes, synthetic cannabinoids can be addictive. Regular users trying to quit may have the following withdrawal symptoms:

- headaches
- anxiety
- depression
- irritability

Behavioral therapies and medications have not specifically been tested for treatment of addiction to these products.

Points to Remember

- Synthetic cannabinoids refer to a growing number of man-made mind-altering chemicals sprayed on dried, shredded plant material or vaporized to get high.
- Synthetic cannabinoids are sometimes misleadingly called "synthetic marijuana" (or "fake weed") because they act on the same brain cell receptors as *delta-9-tetrahydrocannabinol*, the mind-altering ingredient in marijuana.
- The effects of synthetic cannabinoids can be unpredictable and severe or even life-threatening.
- The only parts of synthetic cannabinoid products that are "natural" are the dried plant materials. Chemical tests show that their active ingredients are man-made cannabinoid compounds.
- Synthetic cannabinoid users report some effects similar to those produced by marijuana:
    - elevated mood
    - relaxation
    - altered perception
    - symptoms of psychosis
- Synthetic cannabinoids can also cause serious mental and physical health problems including:
    - rapid heart rate
    - vomiting
    - violent behavior
    - suicidal thoughts
- Synthetic cannabinoids can be addictive.
- Behavioral therapies and medications have not specifically been tested for treatment of addiction to these products.

Learn More

For more information about synthetic cannabinoids, visit:

www.dea.gov/druginfo/drug_data_sheets/K2_Spice.pdf

Updated November 2015

National Institute on Drug Abuse
DrugFacts
www.drugabuse.gov

Synthetic Cathinones ("Bath Salts")

What are synthetic cathinones?

Synthetic cathinones, more commonly known as "bath salts," are synthetic (human-made) drugs chemically related to cathinone, a stimulant found in the khat plant. Khat is a shrub grown in East Africa and southern Arabia, and people sometimes chew its leaves for their mild stimulant effects. Synthetic variants of cathinone can be much stronger than the natural product and, in some cases, very dangerous (Baumann, 2014).

In Name Only

Synthetic cathinone products marketed as "bath salts" should not be confused with products such as Epsom salts that people use during bathing. These bathing products have no mind-altering ingredients.

Synthetic cathinones are included in a group of drugs that concern public health officials called "new psychoactive substances" (NPS). NPS are unregulated psychoactive (mind-altering) substances that have become newly available on the market and are intended to copy the effects of illegal drugs. Some of these substances may have been around for years but have reentered the market in altered chemical forms or due to renewed popularity.

Photo by DEA/ www.dea.gov/pr/multimedia-library/image-gallery/bath-salts/bath-salts04.jpg

Synthetic cathinones are marketed as cheap substitutes for other stimulants such as methamphetamine and cocaine, and products sold as Molly (MDMA) often contain synthetic cathinones instead (see "Synthetic Cathinones and Molly" on page 3).

Synthetic cathinones usually take the form of a white or brown crystal-like powder and are sold in small plastic or foil packages labeled "not for human consumption." Also sometimes labeled as "plant food," "jewelry cleaner," or

"phone screen cleaner," people can buy them online and in drug paraphernalia stores under a variety of brand names, which include:

- Flakka
- Bloom
- Cloud Nine
- Lunar Wave
- Vanilla Sky
- White Lightning
- Scarface

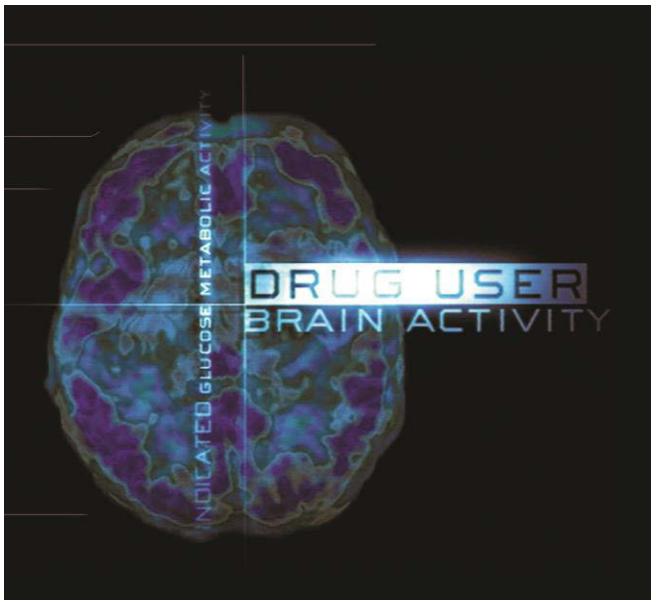
How do people use synthetic cathinones?

People typically swallow, snort, smoke, or inject synthetic cathinones.

How do synthetic cathinones affect the brain?

Much is still unknown about how synthetic cathinones affect the human brain. Researchers do know that synthetic cathinones are chemically similar to amphetamines, cocaine, and MDMA. These drugs can cause a range of effects including lowered inhibition, anxiety, and depression. Read more about amphetamines, cocaine, and MDMA:

- *DrugFacts: Stimulant ADHD Medications – Methylphenidate and Amphetamines* www.drugabuse.gov/publications/drugfacts/stimulant-adhd-medications-methylphenidate-amphetamines
- *DrugFacts: Cocaine* www.drugabuse.gov/publications/drugfacts/cocaine
- *DrugFacts: MDMA* www.drugabuse.gov/publications/drugfacts/mdma-ecstasy-or-molly



Synthetic cathinones are chemically similar to amphetamines, cocaine, and MDMA and may produce similar effects on the brain.
Photo by NIDA

People who have taken synthetic cathinones have reported energizing and often agitating effects. Synthetic cathinones can also raise heart rate and blood pressure. A recent study found that *3,4-methylenedioxypyrovalerone* (MDPV), a common synthetic cathinone, affects the brain in a manner similar to cocaine but is at least 10 times more powerful. MDPV is the most common synthetic cathinone found in the blood and urine of patients admitted to emergency departments after taking "bath salts" (Baumann et al., 2013).

Synthetic cathinones can produce effects that include:

- *paranoia*—extreme and unreasonable distrust of others
- *hallucinations*—experiencing sensations and images that seem real though they are not
- increased sociability
- increased sex drive
- panic attacks
- *excited delirium*—extreme agitation and violent behavior

Synthetic Cathinones and Molly

Molly—slang for "molecular," refers to the pure crystal powder form of *3,4-methylenedioxy-metamphetamine* (MDMA). Usually purchased in capsules, Molly has become more popular in the past few years. Users may be seeking out Molly to avoid the additives commonly found in MDMA pills sold as Ecstasy, such as caffeine, methamphetamine, and other harmful drugs. But those who take what they think is "pure" Molly may be exposing themselves to the same risks. News stories have reported Molly capsules containing harmful substances that include synthetic cathinones. For example, hundreds of Molly capsules tested in two South Florida crime labs in 2012 contained methylone, a dangerous synthetic cathinone.

What are other health effects of synthetic cathinones?

Nosebleeds, sweating, and nausea are some other health effects of synthetic cathinones. People who experience excited delirium often suffer from dehydration, breakdown of skeletal muscle tissue, and kidney failure.

Intoxication from synthetic cathinones has resulted in death. The worst outcomes are associated with snorting or needle injection.

Are synthetic cathinones addictive?

Yes, synthetic cathinones can be addictive. Animal studies show that rats will compulsively self-administer synthetic cathinones. Human users have reported that the drugs trigger intense cravings—uncontrollable urges to use the drug again. Taking synthetic cathinones often may cause strong withdrawal symptoms that include:

- depression
- anxiety
- tremors
- problems sleeping
- paranoia

How can people get treatment for addiction to synthetic cathinones?

Behavioral therapy may be used to treat addiction to synthetic cathinones. Examples include:

- cognitive-behavioral therapy
- contingency management, or motivational incentives—providing rewards to patients who remain substance free
- motivational enhancement therapy

- behavioral treatments geared to teens

No medications are currently available to treat addiction to synthetic cathinones.

Points to Remember

- Synthetic cathinones, more commonly known as "bath salts," are drugs that contain one or more synthetic (human-made) chemicals related to cathinone. Cathinone is a stimulant found in the khat plant.
- Synthetic cathinones are marketed as cheap substitutes for other stimulants such as methamphetamine and cocaine, and products sold as Molly (MDMA) often contain synthetic cathinones instead.
- People typically swallow, snort, smoke, or inject synthetic cathinones.
- Much is still unknown about how all of the chemicals in synthetic cathinones affect the human brain.
- Synthetic cathinones can cause:
  - nosebleeds
  - paranoia
  - increased sociability
  - increased sex drive
  - hallucinations
  - panic attacks
- Intoxication from synthetic cathinones has resulted in death.
- Synthetic cathinones can be addictive.
- Behavioral therapy may be used to treat addiction to synthetic cathinones.
- No medications are currently available to treat addiction to synthetic cathinones.

Learn More

For more information about synthetic cathinones, visit:
www.drugabuse.gov/drugs-abuse/commonly-abused-drugs-charts

www.emcdda.europa.eu/publications/drug-profiles/synthetic-cathinones

www.justice.gov/archive/ndic/pubs44/44571/44571p.pdf

For more information about treatment, visit:
www.drugabuse.gov/publications/drugfacts/treatment-approaches-drug-addiction

Updated January 2016

References

Baumann MH. Awash in a sea of 'bath salts': implications for biomedical research and public health. *Addiction.* 2014;109(10): 1577-1579.

Baumann MH, Partilla JS, Lehner KR, et al. Powerful cocaine-like actions of 3,4-methylenedioxypyrovalerone (MDPV), a principal constituent of psychoactive 'bath salts' products. *Neuropsychopharmacology.* 2013;38(4):552-562.

National Institute on Drug Abuse
DrugFacts
www.drugabuse.gov

MDMA (Ecstasy/Molly)

What is MDMA?

3,4-methylenedioxy-methamphetamine (MDMA) is a synthetic drug that alters mood and perception (awareness of surrounding objects and conditions). It is chemically similar to both stimulants and hallucinogens, producing feelings of increased energy, pleasure, emotional warmth, and distorted sensory and time perception.

MDMA was initially popular in the nightclub scene and at all-night dance parties ("raves"), but the drug now affects a broader range of people who more commonly call the drug Ecstasy or Molly.

How do people use MDMA?

People who use MDMA usually take it as a capsule or tablet, though some swallow it in liquid form or snort the powder. The popular nickname Molly (slang for "molecular") often refers to the supposedly "pure" crystalline powder form of MDMA, usually sold in capsules. However, people who purchase powder or capsules sold as Molly often actually get other drugs such as synthetic cathinones ("bath salts") instead (see "Added Risk of MDMA" on page 2).

Photo courtesy of commons.wikimedia.org/CC0

Some people take MDMA in combination with other drugs such as alcohol or marijuana.

How does MDMA affect the brain?

MDMA increases the activity of three brain chemicals:

- Dopamine—causes a surge in euphoria and increased energy/activity
- Norepinephrine—increases heart rate and blood pressure, which are particularly risky for people with heart and blood vessel problems

- Serotonin—affects mood, appetite, sleep, and other functions. It also triggers hormones that affect sexual arousal and trust. The release of large amounts of serotonin likely causes the emotional closeness, elevated mood, and empathy felt by those who use MDMA.

Other health effects include:

- nausea
- muscle cramping
- involuntary teeth clenching
- blurred vision
- chills
- sweating

Photo by ©Jochen Schoenfield/Shutterstock/ shutterstock.com/pic.mhtml?id=126526058&src=id

MDMA's effects last about 3 to 6 hours, although many of those who use the drug take a second dose as the effects of the first dose begin to fade. Over the course of the week following moderate use of the drug, a person may experience:

- irritability
- impulsiveness and aggression
- depression
- sleep problems
- anxiety
- memory and attention problems
- decreased appetite
- decreased interest in and pleasure from sex

It's possible that some of these effects may be due to the combined use of MDMA with other drugs, especially marijuana.

What are other health effects of MDMA?

High doses of MDMA can affect the body's ability to regulate temperature. This can lead to a spike in body temperature that can occasionally result in liver, kidney, or heart failure or even death.

In addition, because MDMA can promote trust and closeness, its use—especially combined with sildenafil (Viagra®)—may encourage unsafe sexual behavior. This increases people's risk of contracting or transmitting HIV/AIDS or hepatitis.

Read more about drug use and HIV/AIDS in *DrugFacts: HIV/AIDS and Drug Abuse: Intertwined Epidemics* at drugabuse.gov/publications/drugfacts/hivaids-drug-abuse-intertwined-epidemics.

Read more about drug use and hepatitis at drugabuse.gov/related-topics/viral-hepatitis-very-real-consequence-substance-use.

Is MDMA addictive?

Research results vary on whether MDMA is addictive. Experiments have shown that animals will self-administer MDMA—an important indicator of a drug's abuse potential—although to a lesser degree than some other drugs such as cocaine.

Some people report signs of addiction, including the following withdrawal symptoms:

- fatigue
- loss of appetite
- depression
- trouble concentrating

Added Risk of MDMA

Adding to MDMA's risks is that pills, capsules, or powders sold as Ecstasy and supposedly "pure" Molly may contain other drugs instead of or in addition to MDMA. Much of the Molly seized by the police contains additives such as cocaine, ketamine, methamphetamine, over-the-counter cough medicine, or synthetic cathinones ("bath salts"). These substances may be extremely dangerous if the person does not know what he or she is taking. They may also be dangerous when combined with MDMA. People who purposely or unknowingly combine such a mixture with other substances, such as marijuana and alcohol, may be putting themselves at even higher risk for harmful health effects.

Does MDMA Have Value in Therapy?

MDMA was first used in the 1970s as an aid in psychotherapy (mental disorder treatment using "talk therapy"). The drug didn't have the support of clinical trials (studies using humans) or approval from the U.S. Food and Drug Administration. In 1985, The U.S. Drug Enforcement Administration labeled MDMA as an illegal drug with no recognized medicinal use. Some researchers remain interested in its value in psychotherapy when given to patients under carefully controlled conditions. MDMA is currently in clinical trials as a possible treatment aid for post-traumatic stress disorder and anxiety in terminally ill patients, and for social anxiety in autistic adults.

How can people get treatment for addiction to MDMA?

There are no specific medical treatments for MDMA addiction. Some people seeking treatment for MDMA addiction have found behavioral therapy to be helpful. Scientists need more research to determine how effective this treatment option is for addiction to MDMA.

Points to Remember

- *3,4-methylenedioxy-methamphetamine* (MDMA) is a synthetic drug that alters mood and perception. It is chemically similar to stimulants and hallucinogens.
- MDMA is commonly called Ecstasy or Molly.
- People who use MDMA typically take it as a capsule or tablet. Many people take it in combination with other drugs.
- MDMA acts by increasing the activity of three brain chemicals: dopamine, norepinephrine, and serotonin.
- Effects include euphoria, increased energy, distorted perception, involuntary teeth clenching, dangerously high body temperature, and depression.
- Many people are unaware that Ecstasy and supposedly "pure" Molly also often contain not only pure MDMA but other drugs that may be particularly dangerous when mixed with MDMA.
- Research results vary on whether MDMA is addictive. Some people report signs of addiction.
- Some people seeking treatment for MDMA addiction have found behavioral therapy to be helpful. There are no specific medical treatments for MDMA addiction.

Learn More

For more information about MDMA, visit:
drugabuse.gov/drugs-abuse/mdma-ecstasymolly

drugabuse.gov/drugs-abuse/commonly-abused-drugs-charts#MDMA

teens.drugabuse.gov/drug-facts/mdma-ecstasy-or-molly

Updated October 2016

PUBLIC HEARING ON
ALTERNATIVE TO INCARCERATION
COURT PROGRAMS AND SYNTHETIC DRUGS
MARCH 15, 2017
WASHINGTON, DC

Panel III. Drugs: Introduction and Trafficking Patterns

Eric Wish, Ph.D.
Director
Center for Substance Abuse Research (CESAR)
University of Maryland
College Park, MD

Shontal Linder
Section Chief, Synthetic Drugs and Chemicals Section
Diversion Control Division
Drug Enforcement Administration

Eric Wish, Ph.D.
Director
Center for Substance Abuse Research (CESAR)
University of Maryland
College Park, MD

Dr. Eric Wish is Director of the Center for Substance Abuse Research (CESAR) at the University of Maryland at College Park, MD. CESAR informs policymakers, practitioners, and the general public about the problems associated with substance abuse. In 2014, CESAR was awarded a five-year project to work with the National Institute on Drug Abuse (NIDA) to develop the National Drug Early Warning System (NDEWS), a public health surveillance system to identify new drugs and drug trends as they emerge. As a part of NDEWS, Dr. Wish works with substance abuse experts in 19 NDEWS sites across the United States studying new drugs, such as synthetic cannabinoids (Spice/K2) and designer stimulants (Molly). Dr. Wish is also an Associate Professor in the University of Maryland's Criminology and Criminal Justice Department.

Dr. Wish received his Ph.D. from Washington University in St. Louis in 1977. He subsequently completed a NIDA post-doctoral fellowship in psychiatric epidemiology in the Department of Psychiatry at the Washington University School of Medicine.

PLACEHOLDER

FOR TESTIMONY OF

Dr. Eric Wish
Director
Center for Substance Abuse Research (CESAR)
University of Maryland
College Park, MD

Shontal P. Linder, DBA
Section Chief
Synthetic Drugs and Chemicals Section
Diversion Control Division
U.S. Drug Enforcement Administration

Dr. Linder is the Section Chief of the Synthetic Drugs and Chemicals Section, Diversion Control Division, Drug Enforcement Administration (DEA, U.S. Department of Justice). Her responsibilities include managing a group of Agents, Diversion Investigators, and Program Analysts who work together to assist field investigations involving the trafficking of synthetic drugs and chemicals. The group routinely provides trend information and operational support to field investigations, assists other state and federal agencies in gathering information, and works with foreign counterparts and with DEA registrants to aid in the pursuit of criminal and administrative cases pertaining to synthetic drugs of abuse and their related precursor chemicals.

STATEMENT OF

DR. TERRY L. BOOS, CHIEF

DRUG AND CHEMICAL EVALUATION SECTION

and

SHONTAL LINDER, CHIEF

SYNTHETIC DRUGS AND CHEMICALS SECTION

DIVERSION CONTROL DIVISION

DRUG ENFORCEMENT ADMINISTRATION

- - -

BEFORE THE

UNITED STATES SENTENCING COMMISSION

- - -

HEARING ON

SENTENCING POLICY FOR SYNTHETIC DRUGS

- - -

WASHINGTON, D.C.

March 15, 2017

I. Introduction

Judge Pryor and members of the Sentencing Commission: Thank you for holding this hearing today and for providing the opportunity to discuss the threat posed by and trafficking patterns associated with the illicit manufacturing and distribution of synthetic drugs, or what are often refer to as new psychoactive substances (NPS).

The trafficking and use of NPS continues to be a challenge for public health and law enforcement. The recreational use of NPS is associated with high levels of abuse and toxicity. These substances continue to be introduced into drug markets as replacements for traditional controlled substances and pose a great risk to the public due to both their often predictable and unpredictable health effects. While NPS challenges increase, there has been a resurgence in MDMA use and availability, presenting additional challenges for public health and law enforcement. Some drug markets have witnessed an increase in MDMA content in tablets; in the United States we have witnessed an increase, decrease, then leveling off of MDMA drug seizures. Drug seizure data demonstrate MDMA is still a popular drug of abuse and being encountered regularly by law enforcement. The scientific information continues to demonstrate MDMA is a threat to public health and safety due to its pharmacological effects and abuse.

In many instances, new psychoactive substances were initially used as research tools to investigate biological systems such as endogenous neurotransmitter systems. This is particularly true of the synthetic cannabinoids JWH-018 and AM-2201. These two substances, having higher potency than Δ9-tetrahydrocannabinol (THC) at the cannabinoid receptors, were initially part of research programs before being used illicitly for their psychoactive effects. Two of the drug classes that rapidly emerged on the illicit drug market were the synthetic cannabinoids and the synthetic cathinones. Due to deceptive marketing, users may have mistakenly perceived them as safe alternatives to traditional drugs of abuse. The arising problems from the introduction of improperly tested substances prompted regulatory control to protect the public from those preying on vulnerable populations. In many cases, use is directly linked to harmful events, including emergency medical intervention, dependence, and death. As a result, serious adverse health and safety outcomes have been reported and present on-going challenges for communities. Scientists, health-care professionals, and treatment providers have quickly mobilized to better understand and treat the outcomes.

The five substances the Department has recommended for addition to the sentencing guidelines belong to two drug classes: synthetic cathinones and synthetic cannabinoids, based on their respective structure and/or effect. Mephedrone, methylone, and MDPV are synthetic cathinones, while JWH-018 and AM-2201 are synthetic cannabinoids. All five substances are schedule I controlled substances as a result of legislation or DEA regulation.[1] Schedule I substances are substances with a high potential for abuse and no approved medical use. Further, they have no industrial use and were introduced on the designer drug market and abused for their psychoactive properties. As a result of trafficking and abuse, four of the five substances were emergency (temporarily) controlled by the Drug Enforcement Administration (DEA) in 2011

[1] See 76 Fed. Reg. 65371 (Oct. 21, 2011); and Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144,126 Stat. 993 (2012).

upon the finding they posed an imminent hazard to public safety.[2] As they continued to appear on the illicit market, researchers continued to collect information to investigate the neurobiological and psychological correlates and risk factors associated with their misuse. As would be expected, there are no published studies in the scientific literature suggesting any beneficial effects or therapeutic value for the individual. The DEA, in collaboration with the National Institute on Drug Abuse, initiated pharmacological studies on NPS, including these five substances, to collect additional information and further characterize and compare them with known drugs of abuse. Based on these studies and the information published in the scientific literature, direct comparisons can be made to substances currently listed under the federal sentencing guidelines. Further, MDMA continues to be encountered in investigations, and NPS mimics for MDMA are a recent development in the illicit market.

Trafficking Findings and Patterns

Synthetic cannabinoids, such as JWH-018 and AM-2201, and cathinones, such as MDMA and methylone, are almost entirely manufactured in China. They are then typically imported into the United States through mail services. Once in the United States, the bulk shipments are most often packaged into individual saleable units – or mixed with organic leaves and then packaged. Prior to being placed in Schedule I, they were distributed for sale at gas stations, convenience stores and head shops or sold directly to individuals via the Internet. They were sold in packages adorned with bright colors and cartoons to attract younger users, and they were often marketed using flavors such as blueberry, strawberry, mango, and bubblegum. Since being scheduled, the market for these drugs has gone underground and now resembles the market for other illegal drugs.

Unfortunately, when DEA initiates temporary control of a synthetic designer drug like these using statutory or administrative procedures, those who traffic them will often alter the chemical composition of the drugs slightly, and in doing so create a different chemical structure not specifically identified in the controlling statutes or regulations. Despite the alterations, these new chemical compounds remain just as potent and just as harmful.

Large profits can be made selling synthetic cannabinoids and cathinones, driving the wholesale and retail distribution of these products. Information DEA has obtained through its investigations show that a $1,500 purchase of a bulk synthetic drug from China can generate as much as $250,000 of revenue at the retail level. It is clear that the income generated from distributing these products is, and will continue to be, a driving factor for manufacturers, distributors, and retailers to seek and find substitute products that are not yet controlled or banned by federal or state law and thus stay one step ahead of enforcement authorities.

According to the National Forensic Laboratory Information System (NFLIS), seizures of synthetic cannabinoids by federal, state, and local forensic laboratories increased from 23 reports in 2009 to 32,784 reports in 2013. Seizures of synthetic cathinones increased from 29 reports in 2009 to 15,673 reports in 2013.

[2] See 76 Fed. Reg. 65371 (Oct. 21, 2011).

Synthetic Cathinones

Synthetic cathinones are a class of β-ketoamphetamine substances that emerged as NPS and are known for their hallucinogenic and psychostimulant properties, as well as for their abuse and toxicity. Synthetic cathinones are structurally and pharmacologically similar to amphetamine, methylenedioxymethamphetamine (MDMA), and cathinone. Synthetic cathinones produce their effects via the release or reuptake of various neurotransmitters including dopamine, norepinephrine, and/or serotonin.[3] Studies suggest that cathinones have high blood-brain barrier permeability.[4] The onset of drug effects is rapid with the side effects lasting from hours to days. Since their introduction into the illicit drug market, synthetic cathinones have been implicated by coroners' offices in the death of many individuals.[5]

Methylone, mephedrone, and MDPV are synthetic cathinones that have many similarities with the Schedule I substances cathinone, methcathinone, and MDMA, and the Schedule II stimulants amphetamine, methamphetamine, and cocaine. The clinical presentation of intoxication from these three substances is like that seen with MDMA and other substances (*e.g.*, cathinone, methcathinone, MDMA, amphetamine, methamphetamine, and cocaine) that have a stimulant effect on the central nervous system. Adverse effects associated with the consumption of methylone, mephedrone and MDPV include palpitations, hyperthermia, seizures, hyponatremia, bruxism, sweating, hypertension, tachycardia, headache, thirst, mydriasis, tremor, fever, confusion, psychosis, paranoia, hallucinations, combativeness, agitation, and death.[6]

The DEA has encountered these synthetic cathinones being trafficked for their psychoactive properties. These substances are falsely marketed as "research chemicals," "plant food or fertilizer," "jewelry cleaner," "stain remover," "insect repellant," or "bath salts." Prior to being regulated, they were sold at smoke shops, head shops, convenience stores, adult book stores, gas stations, and on the Internet, with packaging that contains the warning "not for human consumption." In addition, methylone, mephedrone, and MDPV at one time were promoted as

---

[3] RA Gregg & SM Raws. *Behavioral Pharmacology of Designer Cathinones: A Review of the Preclinical Literature*, 97.1 LIFE SCI. 27, 27-30 (2014).

[4] LD Simmler et al., *Pharmacological Characteriztion of Designer Cathinones In Vitro*, 168.2 BRIT. J. PHARMACOLOGY 458, 458-470 (2013).

[5] LJ Marinetti & HM Antonicides. *Analysis of Synthetic Cathinones Commonly Found in Bath Salts in Human Performance and Postmortem Toxicology: Method Development, Drug Distribution, and Interpretation of Results*, 137 J. ANALYTICAL TOXICOLOGY 135, 135-146 (2013); JF Wyman et al., *Postmortem Tissue Distribution of MDPV Following Lethal Intoxication by "Bath Salts"*, 37.3 J. ANALYTICAL TOXICOLOGY 182, 182-185 (2013); SJ deRoux & WA Dunn, *"Bath Salts" the New York City Medical Examiner Experience: A 3-Year Retrospective Review* J. FORENSIC SCI., ahead of print; TH Wright et al., *Deaths Involving Methylenedioxypyrovalerone (MDPV) in Upper East Tennessee*, 58.6 J. FORENSIC SCI. 1558, 1558-1562 (2013); PN Carbone et al., *Sudden Cardiac Death Associated with Methylone Use*, 34.1 AM. J. FORENSIC MED. AND PATHOLOGY 26, 26-28 (2013).

[6] JM Pearson et al., *Three Fatal Intoxications Due to Methylone*, 36 J. ANALYTICAL TOXICOLOGY 444, 444-451 (2012); B. Warrick et al., *Lethal Serotonin Syndrome After Methylone and Butylone Ingestion*, 8 J. MED. TOXICOLOGY 65, 65-68 (2012); B. Cawrse et al., *Distribution of Methylone in Four Postmortem Cases*, 36 J. ANALYTICAL TOXICOLOGY 434, 434-439 (2012); J. Wyman et al., *Postmortem Tissue Distribution of MDPV Following Lethal Intoxication by "Bath Salts*," 37 J. ANALYTICAL TOXICOLOGY 182, 182-185 (2013); B. Murray *et al.*, *Death Following Recreational Use Of Designer Drug "Bath Salts" Containing 3,4-Methylenedioxypyrovalerone (MDPV)*, 8 J. MED. TOXICOLOGY 69, 69-75 (2012); K. Kesha et al., *Methylenedioxypyrovalerone ("Bath Salts"), Related Death: Case Report And Review Of The Literature*, 58 J. FORENSIC SCI. 1654, 1654-1659 (2013).

being "legal" alternatives to cocaine, methamphetamine, and MDMA, because at that time detection of these substances was not included in the routine drug screen for illicit substances.

On October 21, 2011, the Administrator of the DEA published a Final Order in the Federal Register temporarily placing methylone, mephedrone and MDPV into Schedule I of the CSA upon finding that these substances pose an imminent threat to public safety.[7] On July 9, 2012, President Obama signed the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144) (FDASIA), which amended several provisions of the CSA. In particular, the FDASIA amended Schedule I of section 202(c) of the CSA to include the synthetic cathinones mephedrone and MDPV. Methylone was permanently controlled via the administrative scheduling process on April 12, 2013.[8]

Methylone

Research in anti-depressant and anti-Parkinson agents resulted in the development and patenting of methylone in 1996.[9] However, there is no evidence that methylone has a legitimate non-research use and, according to the Department of Health and Human Services (HHS), there are no approved drug products or new drug applications that contain methylone. Evidence indicates that methylone is abused by individuals for its psychoactive effects. Desired effects reported by abusers of synthetic cathinones substances include euphoria, increased sociability, energy, empathy, increased alertness, and improved concentration and focus.

Scientific Evidence of the Substance's Pharmacological Effect

Studies indicate that methylone is more similar in its pharmacological effects to MDMA than to methamphetamine or amphetamine. In microdialysis studies, methylone produces elevations in the dialysates dopamine and serotonin (5-HT) with a preferential increase in 5-HT, which are qualitatively analogous to the effects of MDMA but less potent.[10] In contrast, methamphetamine causes preferential increase in dialysate dopamine rather than serotonin. These selective effects on the neurotransmitters (dopamine and serotonin) are relevant properties of the substances. They show that methylone is a weak psychomotor stimulant compared to methamphetamine. Whereas methamphetamine elicits a sustained increase in horizontal locomotor activity, methylone produces a transient increase in locomotor activity. However, in a study by Lopez-Annau (2012), methylone, compared to MDMA, had similar effects on locomotor activity.[11]

Studies indicate that methylone, like MDMA, produces pharmacological effects that are similar to those of substances that cause a stimulant effect on the central nervous system. The drug discrimination paradigm is used as an animal model of human subjective effects. This procedure provides a direct measure of stimulus specificity of a test drug in comparison with a

[7] 76 Fed. Reg. 65371 (Oct. 21, 2011).
[8] 78 Fed. Reg. 21818 (Apr. 12, 2013).
[9] P Jacob and A Shulgin, U.S. Patent No. WO 1996039122 (filed Jun. 6, 1996).
[10] MH Baumann et al., *The Designer Methcathinone Analogs, Mephedrone and Methylone, are Substrates for Monoamine Transporters*, 37 NEUROPSYCHOPHARMACOLOGY 1192, 1192-1203 (2012).
[11] R Lopez-Arnau et al., *Comparative Neuropharmacology Of Three Psychostimulant Cathinone Derivatives: Butylone, Mephedrone and Methylone*. 167.2 BRIT. J. PHARMACOLOGY 407, 407-420 (2012).

known standard drug, or a neutral stimulus (*e.g.* injection of saline water). In the drug discrimination paradigm, if a new drug or substance has discriminative stimulus effects in animals similar to a known drug of abuse, it is highly likely that this new drug will produce pharmacological effects (including subjective effects) in humans that would be qualitatively and quantitatively similar to the known drug of abuse and would be similarly abused by humans.[12] Data from a published drug discrimination study indicates that methylone (ED_{50} = 1.60 mg/kg) fully substitutes for the discriminative stimulus effects produced by MDMA (ED_{50}=0.76 mg /kg) in rats.[13] Similarly, data from another published drug discrimination study also indicate that methylone (ED_{50} = 2.66 mg/kg) fully substitutes for the discriminative stimulus effects produced by methamphetamine.[14] MDMA (ED_{50} = 1.83 mg/kg), which was previously tested by these authors, also fully substitutes for the discriminative stimulus effects produced by methamphetamine.[15] Based on these studies, methylone is approximately half as potent as MDMA in these drug discrimination studies.

The Substance's History and Current Pattern of Abuse

DEA forensic laboratories have analyzed drug exhibits received from state, local, or federal law enforcement agencies that were found to contain methylone. Methylone, like MDMA, is commonly encountered in powder, capsule, and tablet form. Information from published scientific studies indicate that the most common routes of administration for methylone are by swallowing capsules or tablets or by snorting the powder. The reported average amount of use reported for methylone ranged from 100 mg to 250 mg.[16] In contrast, the average amount of MDMA used ranged from 75 mg to 125 mg.[17] Evidence from poison centers, published case reports, and law enforcement encounters suggest that the main users of methylone are young adults. There is evidence that methylone may be co-ingested with other substances including other synthetic cathinones, pharmaceutical agents, or other recreational substances. In fact, some products that were sold as MDMA (marketed as "Molly") were found to contain methylone.

[12] JB Kamien et al., *Drug Discrimination by Humans Compared to Nonhumans: Current Status and Future Directions*, 111.3 PSYCHOPHARMACOLOGY 259, 259-270 (1993); RL Balster & GE Bigelow, *Guidelines and Methodological Reviews Concerning Drug Abuse Liability Assessment*, 70.3 DRUG AND ALCOHOL DEPENDENCE Suppl, S13, S13-S40 (2003); LV Panlilio & SR Goldberg, *Self-Administration of Drugs in Animal and Humans as a Model and an Investigative Tool*, 102.12 ADDICTION 1863, 1863-1870 (2007).

[13] TA Dal Cason et al., *Cathinone: an Investigative of Several N-Alkyl and Methylenedioxy-substituted Analogs*, 58.4 PHARMACOLOGY BIOCHEMISTRY AND BEHAVIOR 1109, 1109-1116 (1997).

[14] MB Gatch et al., *Locomotor Stimulant and Discriminative Stimulus Effects of 'Bath Salt' Cathinone*,24.5-24.6BEHAVIORAL PHARMACOLOGY 437, 437-447 (2013).

[15] National Institute on Drug Abuse email communication (2012).

[16] JP Kelly et al., *Cathinone Derivatives: a Review of Their Chemistry, Pharmacology, Toxicology*, 7-8 DRUG TESTING AND ANALYSIS 439, 439-453 (2011).

[17] J Cami et al, *Human Pharmacology of 3,4-Methylenedioxymethamphetamine ("Ecstasy"): Psychomotor, Performance and Subjective Effects*, 20.4 J. CLINICAL PSYCHOPHARMACOLOGY, 455, 455-466 (2000); AC Parrott, *Human Psychobiology of MDMA or 'Ecstasy': an Overview of 25 Years of Empirical research*, 28.4 HUMAN PSYCHOPHARMACOLOGY, 289, 289-307 (2013).

The Scope, Duration and Significance of Abuse

According to forensic laboratory data as reported by the National Forensic Information Laboratory System (NFLIS),[18, 19] law enforcement began encountering methylone in February 2009. Through January 2017, NFLIS has reported 21,839 law enforcement encounters involving methylone.[20] Additionally, the U.S. Customs and Border Protection (CBP) has seized large quantities of methylone during this same period.

Risk to Public Health

Methylone has been reported to cause a number of stimulant-like adverse effects. The clinical presentation of intoxication from methylone is similar to that seen with MDMA and other substances that have a stimulant effect on the central nervous system (*e.g.*, cathinone, methcathinone, MDMA, amphetamine, methamphetamine, and cocaine). Adverse effects associated with the consumption of methylone include palpitations, hyperthermia, seizures, hyponatremia, bruxism, sweating, hypertension, tachycardia, headache, thirst, mydriasis, tremor, fever, confusion, psychosis, paranoia, hallucinations, combativeness, agitation, and death. Some published case reports describing adverse effects of methylone are summarized below.

- A study by Pearson reported on a 19-year-old female who took a pill known as "Molly" collapsed and recovered then complained of not feeling well.[21] Thereafter, she developed seizures. Emergency personnel were called and the female was transported to the hospital. At the hospital she suffered cardiac complications and later died. Toxicology tests identified methylone in specimens from the decedent. No other recreational substances were detected. The medical examiner concluded that the cause of death was methylone intoxication.

- The Pearson study also described the death of a 23-year-old male.[22] The decedent was witnessed to take what was thought to be LSD at a club. The decedent was acting erratically and irrationally and so the decedent was removed from the club and placed in the back of a van by securing the decedent to a chair using saran wrap. Sometime later, the decedent was found having seizures. Emergency personnel were called and the decedent was transported to the hospital. The decedent had hyperthermia and cardiac

[18] The NFLIS is a program of the DEA, Diversion Control Division. NFLIS systematically collects drug identification results and associated information from drug cases submitted to and analyzed by Federal, State and local forensic laboratories. NFLIS represents an important resource in monitoring illicit drug abuse and trafficking, including the diversion of legally manufactured pharmaceuticals into illegal markets. NFLIS is a comprehensive information system that includes data from forensic laboratories that handle approximately 98% of an estimated nearly 1.0 million distinct annual State and local drug analysis cases. NFLIS includes drug chemistry results from completed analyses only.

[19] While NFLIS data is not direct evidence of abuse, it can lead to an inference that a drug has been diverted and abused. See 76 Fed. Reg. 77330, 77332 (Dec. 12, 2011).

[20] Query date February 27, 2017, Federal, State, and local laboratories.

[21] JM Pearson et al., *Three Fatal Intoxications Due to Methylone*, 36.6 J. ANALYTICAL TOXICOLOGY 444, 444-451 (2012).

[22] *Id.*

complications. The decedent died 45 minutes after his arrival at the hospital. The medical examiner listed the cause of death as intoxication by methylone.

- Another incident reported by Pearson involved the death of a 23-year-old male initially suspected of using methylone.[23] The decedent was walking in and out of traffic and acting belligerently. The decedent was detained by law enforcement and transported to the hospital. The decedent had a high temperature and subsequently went into respiratory failure. After several attempts by medical personnel to stabilize the decedent, he died. Toxicology testing identified methylone in specimens from this individual. The medical examiner listed the cause of death as intoxication by methylone.

- Warrick *et al.* described the death of a 24-year-old female who ingested two capsules of what was thought to be "Ecstasy" at a concert.[24] After being found unconscious by emergency personnel, the decedent was taken to the emergency department. The comatose patient suffered from hyperthermia, tachycardia, mydriasis, tachypnea and some tremors and later died. Toxicology tests identified methylone and butylone in specimens from this individual. Laboratory analysis also identified methylone and butylone in the powder obtained from a capsule that was found on the decedent. The cause of death mentioned by the medical examiner was serotonin syndrome secondary to methylone and butylone intoxication.

- Cawrse *et al.* described the death of a 19-year-old male.[25] The decedent died while performing a physical fitness assessment. Toxicology tests identified methylone in specimens from this individual. The cause of death was cardiac arrest associated with methylone.

- The death of a 39-year-old male was reported by Wyman *et al.*[26] Family members indicated that the male, who had a history of schizophrenia, depression, and drug abuse, had been snorting "bath salts." The subject was found dead in his bed. Empty jars of "bath salts" ("TranQuility" and "Infinity") and synthetic cannabinoids ("Demon" and "Flame") were found in the trash. A toxicological screen detected MDPV in multiple tissues, urine and blood samples from the decedent. Other substances detected were nicotine, cotinine, pseudoephedrine, m-chlorophenylpiperazine and methylone. The cause of death was acute MDPV intoxication.

- Kovacs *et al.* described the case of a 16-year-old male who lost consciousness at a party.[27] The decedent died of sudden cardiac death at the hospital after attempts to save his life were unsuccessful. The decedent suffered from cardiac malformation and

---

[23] *Id.*
[24] BJ Warrick et al., *Lethal Serotonin Syndrome after Methylone and Butylone Ingestion*, 8.1 J. MED. TOXICOLOGY 65, 65-68 (2012).
[25] BM Cawrse et al., *Distribution of Methylone in Four Postmortem Cases*, 36.6 J. ANALYTICAL TOXICOLOGY 434, 434-439 (2012).
[26] JF Wyman et al., *Postmortem Tissue Distribution of MDPV Following Lethal Intoxication by "Bath Salts"*.,37 J. ANALYTICAL TOXICOLOGY 182, 182-185 (2013).
[27] K Kovacs et al., *A New Designer Drug: Methylone Related Death*. 157.7 ORV HETIL 271, 271-276 (2012).

bronchial asthma. The toxicology testing identified methylone in the specimens from this individual. The authors concluded that the predisposing factors along with methylone may have resulted in the sudden cardiac death of this individual.

- A 22-year-old female developed rhabdomyolysis after ingesting "legal ecstasy" which was analyzed to be a mixture of methylone and ethcathinone.[28] She also suffered from recurrent seizures, severe hyponatremia (abnormally low concentration of sodium in the blood), nystagmus (involuntary rapid eye movement), hyperreflexia, and bruxism. All her symptoms resolved after treatment that required hospitalization.

- Katagi *et al.* reported two cases of acute toxicity from the confirmed ingestion of methylone.[29] A 19-year-old male was taken to the emergency department suffering from dementia after ingesting an unknown amount of methylone powder. In the second case, a 29-year-old male was taken to the emergency department suffering from acute toxicity after taking an unknown amount of a mixture of methylone and a hallucinogen.

- A 19-year-old female with a history of illicit drug use was found 100 yards from the beach. High blood and liver concentrations of methylone were found with THC. The cause of death was certified as drowning due to acute methylone intoxication and the manner of death was certified as accidental.[30]

- A 19-year-old male collapsed while jogging and died.[31] He had no significant health issues. A toxicology report confirmed the presence of methylone but found no other substances including synthetic cathinones (4-FMC, mephedrone, ethylone, butylone, MDPV, and naphyrone).

- A 21-year-old male who ingested cannabis and methylone died.[32] After ingesting the substances he had difficulty breathing. Emergency medical services were called and found the individual in cardiopulmonary arrest. An autopsy report concluded that death was due to respiratory distress that may have been provoked by the absorption of toxic substances. An analysis of biological specimens from the decedent identified methylone and cannabinoids. Other routine drugs of abuse were not detected.

Mephedrone

Mephedrone, also known as "m-cat," "Meow," and "mad cow," is a psychoactive synthetic cathinone that is structurally and pharmacologically similar to the Schedule I and II substances cathinone, methcathinone, MDMA, and methamphetamine. There is no evidence that

[28] C Boulanger-Gobeil *et al.*, *Seizures and Hyponatremia Related to Ethcathinone and Methylone Poisoning*, 8 J. MED. TOXICOLOGY 59, 59-61 (2011).
[29] L Katagi et al., *Metabolism and Forensic Toxicology Analysis of the Extensively Abused Designer Drug Methylone*, 40 TIAFT BULLETIN 30, 30-35(2010).
[30] IM McIntyre et al., *Acute Methylone Intoxication in an Accidental drowning – A Case Report*, 231 FORENSIC SCI. INT'L e1, e1-e3 (2013),
[31] P Carbone et al., *Sudden Cardiac Death Associated with Methylone Use, 34.1* AM J. FORENSIC MED. AND PATHOLOGY,26, 26-28 (2013).
[32] L Barrios et al., *Death Following Ingestion of Methylone*, 30.2 INL'T J. LEGAL MED. 381, 381-385. (2016).

mephedrone has a legitimate non-research use, and according to HHS, there are no approved drug products or new drug applications that contain mephedrone. Evidence indicates that mephedrone is being abused by individuals for its psychoactive effects. Desired effects reported by abusers of synthetic cathinone substances include euphoria, increased sociability, energy, empathy, increased alertness, and improved concentration and focus.

Scientific Evidence of the Substance's Pharmacologic Effect

To date, there is one human study evaluating the efficacy and potency of mephedrone relative to MDMA. Data that was presented at the 77th Annual Scientific Meeting of the College on Problems of Drug Dependence described the abuse liability of mephedrone in humans compared to MDMA.[33] In this small clinical study (12 healthy males who used psychostimulants recreationally), 200 mg of mephedrone was found to be similar to MDMA (100 mg) in somatic (*i.e.,* blood pressure, heart rate and temperature) and subjective effects (visual analog scales –VAS, ARCI-49 short form and VESSPA questionnaire). Based on this study, mephedrone has a stimulant effect that is similar to MDMA but less potent. However, these conclusions are made with the limitations since the number or participants were small and only one dose of mephedrone was evaluated.

Studies indicate that mephedrone is more similar in its pharmacological effects to MDMA than to methamphetamine or amphetamine.[34] In microdialysis studies, mephedrone produces elevations in the dialysates dopamine and serotonin (with preferential effects on serotonin), which are qualitatively analogous to the effects of MDMA but less potent.[35] In contrast, methamphetamine causes preferential increase in the dialysate dopamine rather than serotonin. Studies also show that mephedrone is a weak psychomotor stimulant compared to methamphetamine. Whereas methamphetamine elicits a sustained increase in horizontal locomotor activity, mephedrone produces a transient increase in locomotor activity. Data from other studies support the comparison of mephedrone to MDMA. The neurochemical and functional properties of mephedrone resemble those of MDMA as demonstrated in another microdialysis study.[36] In an additional study that claims MDMA-like drugs can be discerned

[33] M Farre et al., *A Comparison of the Clinical Abuse Liability of MDMA and Mephedrone*, 37.8 CLINICAL THERAPEUTICS e130 (2015).
[34] J Kehr et al., *Mephedrone, Compared with MDMA (Ecstasy) and Amphetamine, Rapidly, Increases Both Dopamine and 5-HT Levels in Nucleus Accumbens of Awake Rats*, 164.8 BRIT. J. PHARMACOLOGY 1949, 1949-1958 (2011); MH Baumann et al., *The Designer Methcathinone Analogs, Mephedrone and Methylone, are Substrates for Monoamine Transporters*, 37 NEUROPSYCHOPHARMACOLOGY 1192, 1192-1203 (2012); P-K Huang et al., *Contrasting Effects of d-Methamphetamine,3,4-Methylenedioxymethamphetamine, 3,4-Methylenedioxypyrovalerone, and 4-Methylmethcathinone on Wheel Activity in Rats*, 126.1-126.2 DRUG AND ALCOHOL DEPENDENCE 168, 168-175 (2012).
[35] MH Baumann et al., *The Designer Methcathinone Analogs, Mephedrone and Methylone, are Substrates for Monoamine Transporters*, 37 NEUROPSYCHOPHARMACOLOGY1192, 1192-1203 (2012).
[36] J Kehr et al., *Mephedrone, Compared with MDMA (Ecstasy) and Amphetamine, Rapidly, Increases Both Dopamine and 5-HT Levels in Nucleus Accumbens of Awake Rats*, 164.8 BRIT. J. PHARMACOLOGY 1949, 1949-1958 (2011).

from methamphetamine-like drugs by measuring a specific locomotor activity (voluntary wheel activity), mephedrone is more similar to MDMA than to MDPV or methamphetamine.[37]

In support of the clinical study mentioned earlier, data from drug discrimination studies in rats indicate that mephedrone, like MDMA, produces pharmacological effects that are similar to those of substances that cause a stimulant effect on the central nervous system. The drug discrimination paradigm is used as an animal model of human subjective effects. This procedure provides a direct measure of stimulus specificity of a test drug in comparison with a known standard drug, or a neutral stimulus (*e.g.* injection of saline water). In the drug discrimination paradigm, if a new drug or substance has discriminative stimulus effects in animals similar to a known drug of abuse, it is highly likely that this new drug will produce pharmacological effects (including subjective effects) in humans that would be qualitatively and quantitatively similar to the known drug of abuse and would be similarly abused by humans.[38] Data from a published drug discrimination study indicate that MDMA fully substitutes for the discriminative stimulus effects produced by mephedrone (ED_{50}=0.90 mg/kg) in rats.[39] The potency values were not stated in the article but the ranked order of potency as determined from the figure is: methamphetamine ≥ mephedrone > MDMA > cocaine. Thus, mephedrone is substantially similar to MDMA in pharmacological effect but more potent than MDMA in this assay.

The Substance's History and Current Pattern of Abuse

DEA forensic laboratories have analyzed drug exhibits received from state, local, or federal law enforcement agencies that were found to contain mephedrone. Mephedrone, like MDMA, is commonly encountered in the form of powders, capsules, and tablets. Information from published scientific studies indicate that the most common routes of administration for methylone are ingestion by swallowing capsules or tablets or nasal insufflation by snorting the powder. The reported average amount of use of mephedrone ranged from 0.5 to 4 grams depending on the route of administration and the number of doses taken. According to self-reported drug users, the amounts for snorting mephedrone ranged from 5 to 75 milligrams whereas for oral administration it ranged from 150 to 250 milligrams.[40] It has also been reported that mephedrone is used in binges. Abusers have reported that typical sessions using mephedrone have last approximately 10.4 hours with some individuals administering several times throughout a session. A possible reason for binging may be to prolong the duration of effects. The average amount of MDMA used ranged from 75 mg to 125 mg (oral

[37] P-K Huang et al., *Contrasting Effects of d-Methamphetamine,3,4-Methylenedioxymethamphetamine, 3,4-Methylenedioxypyrovalerone, and 4-Methylmethcathinone on Wheel Activity in Rats*, 126.1-126.2 DRUG AND ALCOHOL DEPENDENCE 168, 168-175 (2012).
[38] JB Kamien et al., *Drug Discrimination by Humans Compared to Nonhumans: Current Status and Future Directions*, 111.3 PSYCHOPHARMACOLOGY 259, 259-270 (1993); RL Balster & GE Bigelow, *Guidelines and Methodological Reviews Concerning Drug Abuse Liability Assessment*, 70.3 DRUG AND ALCOHOL DEPENDENCESuppl, S13, S13-S40 (2003); LV Panlilio & SR Goldberg, *Self-Administration of Drugs in Animal and Humans as a Model and an Investigative Tool*, 102.12 ADDICTION, 1863, 1863-1870 (2007).
[39] KJ Varner et al., *Comparison of the Behavioral and Cardiovascular Effects of Mephedrone with Other Drugs of Abuse in Rats*, 225.3 PSYCHOPHARMACOLOGY 675, 675-685 (2013).
[40] JP Kelly et al., *Cathinone Derivatives: a Review of Their Chemistry, Pharmacology, Toxicology*, 7-8 DRUG TESTING AND ANALYSIS 439, 439-453 (2011).

administration).[41] Evidence from poison centers, published case reports, and law enforcement encounters suggest that the main users of mephedrone are young adults. There is evidence that mephedrone may be co-ingested with other substances including other synthetic cathinones, pharmaceutical agents, or other recreational substances.

Users from drug surveys reported that mephedrone, like methylone, MDPV, and other synthetic cathinones, has an effect profile similar to known drugs of abuse like cocaine and MDMA. The desired psychoactive effects reported by users include euphoria, general stimulation, empathy, enhanced music appreciation, hallucinations, increased insight, elevated mood, decreased hostility, improved mental function, and mild sexual stimulation.[42] Participants in a survey of readers of a popular UK dance music magazine reported that mephedrone gave a better high than cocaine. Another survey that was advertised on websites frequented by drug users found that users considered the effects of mephedrone to be similar to those of MDMA. This is consistent with studies in animals that demonstrated that methylone resembles MDMA in its behavioral profile. As explained above, some products that were sold as MDMA (marketed as "Molly") actually contained methylone; other products were found to contain mephedrone.

The Scope, Duration and Significance of Abuse

According to forensic laboratory data as reported by the National Forensic Information Laboratory System (NFLIS), mephedrone started to be encountered by law enforcement in April 2009. Through January 2017, NFLIS has reported 716 law enforcement encounters involving mephedrone (query date February 27, 2017, Federal, State, and local laboratories). Additionally, seizures of mephedrone have occurred by the U.S. Customs and Border Protection (CBP).

Risk to Public Health

Mephedrone has been reported to cause a number of stimulant-like adverse effects. The clinical presentation of intoxication from mephedrone is similar to MDMA and other substances that have a stimulant effect on the central nervous system (*e.g.*, cathinone, methcathinone, MDMA, amphetamine, methamphetamine, and cocaine). Adverse effects associated with the consumption of mephedrone include palpitations, hyperthermia, seizures, hyponatremia, bruxism, sweating, hypertension, tachycardia, headache, thirst, mydriasis, tremor, fever, confusion, psychosis, paranoia, hallucinations, combativeness, agitation, and death. Published case reports describing mephedrone related adverse effects are summarized below.

- A 22-year-old male was found unresponsive at his home. He was transported to the hospital where he died. An autopsy revealed heroin and high concentrations of mephedrone. Multiple drug toxicity associated with mephedrone and heroin use was reported as the cause of death.[43]

[41] AC Parrott, *Human Psychobiology of MDMA or 'Ecstasy': an Overview of 25 Years of Empirical Research*, 28.4 HUMAN PSYCHOPHARMACOLOGY 289, 289-307 (2013).
[42] 76 FR 65371.
[43] AJ Dickson et al., *Multiple-drug Toxicity Caused by Coadministration of 4-Methylmethcathinone (Mephedrone) and Heroin*, 34.3 J. ANALYTICAL CHEMISTRY 162, 162-166 (2010).

- A 49-year-old female died after snorting approximately 0.5g of mephedrone that she purchased from the Internet. She also consumed alcohol and smoked marijuana. A few hours after taking mephedrone, she complained of a sore chest, vomited, and then collapsed. She was transported to the hospital by emergency services but died despite efforts to resuscitate her. A medical examiner attributed this death to the adverse effects of mephedrone.[44]

- A 19-year-old male died after taking an unknown amount of mephedrone along with alcohol, and MDMA at a party. Others at the party described the 19-year-old as being sweaty and acting strangely and subsequently he collapsed. Emergency services were called and he was taken to the hospital but efforts to resuscitate him were unsuccessful. A medical examiner found mephedrone to be the principal cause of death.[32]

- A 55-year-old female was found dead in bed. Her death was attributed to the combined effects of mephedrone and methadone.[32]

- A 17-year-old male died from injuries sustained in a vehicular collision. While driving on the wrong side of the road he collided head-on with an oncoming car. Mephedrone was detected in his blood and is suspected to have affected the ability of this individual to drive.[32]

- A 36-year-old man died from substantial blood loss that may have led to aggravated heart and blood pressure problems after he was arrested by police for extreme agitation.[45] Mephedrone was identified in the tablets found in the house of the deceased. Toxicological analyses of the post-mortem samples from the decedent detected mephedrone, cocaine, MDMA, oxazepam, midazolam.

- An approximately 30-year-old man was found in a critical state in a staircase. Efforts to save him were unsuccessful. Authors concluded that death was due to fatal mephedrone intoxication.[46]

- Acute mephedrone-related toxicity was analytically confirmed in seven male patients. The most common symptom/sign reported was agitation. Other symptoms/signs included palpitations, chest pain, seizures, headaches (acute sympathomimetic toxidrome).[47]

- Nicholson *et al*. described a case involving a 19-year-old man who presented to the emergency room with central crushing chest pain.[48] Clinical tests showed myocardial

---

[44] PD Maskell et al., *Mephedrone (4-Methylmethcathinone)-related Deaths*, 35.3 J. ANALYTICAL CHEMISTRY 189, 189-191 (2011).
[45] KJ Lusthof et al., *A Case of Extreme Agitation and Death after the Use of Mephedrone in The Netherlands*, 206.1-206.3 FORENSIC SCI. INT'L e93, e93-e95 (2011).
[46] P Adamowicz et al., *Fatal Mephedrone Intoxication – A Case Report*, 37.1 J. ANALYTICAL TOXICOLOGY 37, 37-42 (2013).
[47] DM Wood et al., *Recreational Use of Mephedrone (4-Methylmethcathinone, 4-MMC) with Associated Sypathomimetic Toxicity*,.6.3 J. MED. TOXICOLOGY 327, 327-330 (2010).
[48] PJ Nicholson et al., *Headshop Heartache: Acute Mephedrone 'Meow' Myocarditis*, 96.24 HEART 2051, 2051-2052 (2010).

inflammation. He admitted to ingesting plant food that contained mephedrone. Toxicology screening of biological samples confirmed the presence of mephedrone. No other neurostimulant drugs were detected. He was successfully treated and discharged five days after his admission.

- Debruyne *et al.* reported that seven cases in France related to the use of mephedrone were reported to the Center of Evaluation and Information on Pharmacodependence (Addictovigilance).[49] In one case, a young man was involved in a vehicular accident after snorting mephedrone. His blood tested positive for mephedrone. In another case, an individual used mephedrone in place of cocaine.

- Wood *et al.* reported a case of acute toxicity in the United Kingdom after the abuse of mephedrone.[50] A 22-year-old male presented to the emergency room with sympathomimetic toxicity after ingesting 200 milligrams of mephedrone. He developed palpitation, blurred vision, mydriasis, agitation, tachycardia, and an elevated body temperature. His symptoms resolved after treatment. Mephedrone was the only substance detected in his serum.

- Torrance and Cooper reported the death of four individuals whose blood samples tested positive for mephedrone.[51] These fatalities were not attributed to the sole use of mephedrone but they can be considered to be evidence of the misuse of mephedrone and the subsequent harm they may cause to the user or general public.

Methylenedioxypyrovalerone

Methylenedioxypyrovalerone (MDPV) is closely related in structure to phenethylamines such as the Schedule I and II substances methamphetamine, cathinone, methcathinone, and methylenedioxymethamphetamine (MDMA). MDPV is also structurally related to pyrovalerone, which is a psychoactive drug that was used to treat chronic lethargy and fatigue. There is no evidence that MDPV has a legitimate non-research use, and according to HHS, there are no approved drug products or new drug applications that contain MDPV. MDPV and other cathinone derivatives (including those which bear ring-group substituents) have been reported to induce subjective effects similar to those induced by stimulant drugs of abuse such as cocaine, amphetamine, MDMA, and methcathinone. Indeed, evidence indicates that MDPV is being abused by individuals for its psychoactive effects. Desired effects reported by abusers of synthetic cathinone substances include euphoria, increased sociability, energy, empathy, increased alertness, and improved concentration and focus.

Scientific Evidence of the Drug's Pharmacological Effects

[49] D Debruyne et al., *Mephedrone: a Designer Drug of recent Use in France*, 65.6 THERAPIE 519, 519-524(2010).
[50] DM Wood et al., *Recreational Use of Mephedrone (4-Methylmethcatinone, 4-MMC) with Associated Sympathomimetic Toxicity*, 6.3 J. MED. TOXICOLOGY 327, 327-330 (2010).
[51] H Torrance & G Cooper, *The Detection of Mephedrone (4-Methylmethcathinone) in 4 Fatalities in Scotland*, 202.1-202.3 FORENSIC SCI. INT'L E62, e62-e63 (2010).

In a study that claims MDMA-like drugs can be discerned from methamphetamine-like drugs by measuring a specific locomotor activity (voluntary wheel activity), MDPV is more similar to methamphetamine than to MDMA.[52] In addition, MDPV is a powerful locomotor stimulant like methamphetamine.[53]

Drug discrimination studies indicate that MDPV produces pharmacological effects that are similar to those of methamphetamine and cocaine. As described above, the drug discrimination paradigm is used as an animal model of human subjective effects. This procedure provides a direct measure of stimulus specificity of a test drug in comparison with a known standard drug, or a neutral stimulus (*e.g*. injection of saline water). In the drug discrimination paradigm, if a new drug or substance has discriminative stimulus effects in animals similar to a known drug of abuse, it is highly likely that this new drug will produce pharmacological effects (including subjective effects) in humans that are qualitatively and quantitatively similar to the known drug of abuse and would be similarly abused by humans.[54] Data from a published drug discrimination study indicate that MDPV (ED_{50} = 0.67 mg/kg) fully substitutes for the discriminative stimulus effects produced by methamphetamine (ED_{50} = 0.37 mg/kg) in rats.[55] Data from another published drug discrimination study indicate that MDPV (ED_{50} = 0.03 mg/kg) fully substitutes for the discriminative stimulus effects produced by methamphetamine (ED_{50} = 0.08 mg/kg) in mice.[56] Based on these drug discrimination studies, MDPV is at least as potent if not more potent than methamphetamine. The self-administration study is another behavioral study done in rodents that has been used to predict the abuse liability (*i.e.*, the likelihood that the drug will be abused) of novel substances. Aarde and colleagues reported that MDPV, similar to methamphetamine, was self-administered in rats and rats consistently self-administered a greater amount of MDPV. As a result, the authors concluded that MDPV poses a substantial threat for compulsive use that is potentially greater than that for methamphetamine.[57]

---

[52] P-K Huang et al., *Contrasting Effects of d-Methamphetamine,3,4-Methylenedioxymethamphetamine, 3,4-Methylenedioxypyrovalerone, and 4-Methylmethcathinone on Wheel Activity in Rats*, 126.1 DRUG AND ALCOHOL DEPENDENCE 168, 168-175 (2012).

[53] MH Baumann et al., *Powerful Cocaine-like Actions of 3,4-Methylenedioxypyrovalerone (MDPV), a Principal Constituent of Psychoactive 'Bath Salt' Products*, 38.4 NEUROPSYCHOPHARMACOLOGY 552, 552-562 (2013); WE Fantegrossi et al., *In Vivo Effects of Abused 'Bath Salt' Constituent 3,4-Methylenedioxypyrovalerone (MDPV) in Mice: Drug Discrimination, Thermoregulation, and Locomotor Activity*, 38.4 NEUROPSYCHOPHARMACOLOGY 563, 563-573 (2013); M Gatch et al., *Locomotor Stimulant and Discriminative Stimulus Effects of 'Bath Salt' Cathinones*, 24 BEHAVIORAL PHARMACOLOGY 437, 437-447 (2013); JA Marusich et al., *Pharmacology of Novel Synthetic Stimulants Structurally Related to "Bath Salts" Constituents 3,4-Methylenedioxypyrovalerone (MDPV)*, 87 NEUROPHARMACOLOGY 206, 206-213 (2014).

[54] RI Balster & GE Bigelow, *Guidelines and Methodological Reviews Concerning Drug Abuse Liability Assessment*, 70 DRUG AND ALCOHOL DEPENDENCE s13-40 (2003); LV Panllio & SR Goldberg, *Self-Administration of Drugs in Animals and Humans as a Model and an Investigative Tool* 102.12 ADDICTION 1863, 1863-1870 (2007).

[55] M Gatch et al., *Locomotor Stimulant and Discriminative Stimulus Effects of 'Bath Salt' Cathinones*, 24BEHAVIORAL PHARMACOLOGY 437, 437-447 (2013).

[56] WE Fantegrossi *et al.*, *In Vivo Effects of Abused 'Bath Salt' Constituent 3,4-Methylenedioxypyrovalerone (MDPV) in Mice: Drug Discrimination, Thermoregulation, and Locomotor Activity*, 38.4 NEUROPSYCHOPHARMACOLOGY 563, 563-573 (2013).

[57] SM Aarde et al., *The Novel Recreational Drug 3,4-Methylenedioxypyrovalerone (MDPV) is a Potent Psychomotor Stimulant: Self-administration and Locomotor Activity in Rats*, 71 NEUROPSYCHOPHARMACOLOGY 130, 130-140 (2013); M Gatch et al., *Locomotor Stimulant and Discriminative Stimulus Effects of 'Bath Salt' Cathinones*, 24 BEHAVIORAL PHARMACOLOGY 437, 437-447 (2013); JA Marusich et al., *Pharmacology of Novel Synthetic Stimulants Structurally Related to "Bath Salts" Constituents 3,4-Methylenedioxypyrovalerone (MDPV)*, 87 NEUROPHARMACOLOGY 206, 206-213 (2014).

The Substance's History and Current Pattern of Abuse

DEA forensic laboratories have analyzed drug exhibits received from state, local, or federal law enforcement agencies that were found to contain MDPV. MDPV, like methamphetamine, is commonly encountered in the form of powders, capsules, and tablets. Information from published scientific studies indicate that the most common routes of administration for MDPV is ingestion by swallowing capsules or tablets or nasal insufflation by snorting the powder. The reported average amount of use of MDPV ranged widely (from approximately 25 milligrams – 5 grams) depending on the substance, duration of intake, and route of administration.[58] The dose range for snorting MDPV ranges from as little as 25 milligrams to as much as 5 grams. Even low doses can cause psychoactive effects. Ingestion of high doses of MDPV has been associated with severe adverse effects such as psychosis, paranoia, and death. Similarly, methamphetamine has been reported to cause psychoactive effects at low doses (range from 5 to 30 mg) and psychosis at higher doses.[59] Evidence from poison centers, published case reports, and law enforcement encounters suggest that the main users of MDPV, similar to synthetic cathinones, are young adults. There is evidence that MDPV may be co-ingested with other substances including other synthetic cathinones, pharmaceutical agents, or other recreational substances.

The Scope, Duration and Significance of Abuse

According to forensic laboratory data as reported by the National Forensic Information Laboratory System (NFLIS), MDPV started to be encountered by law enforcement in December 2009. Through January 2017, NFLIS has reported 9,511 law enforcement encounters involving MDPV (query date February 27, 2017, Federal, State, and local laboratories). Additionally, large seizures of MDPV have occurred by CBP.

Risk to Public Health

MDPV has been reported to cause a number of stimulant-like adverse effects. The clinical presentation of intoxication from MDPV is like that seen with methamphetamine and other substances (*e.g.,* cathinone, methcathinone, MDMA, amphetamine, methamphetamine, and cocaine) that have a stimulant effect on the central nervous system. Adverse effects associated with the consumption of MDPV include palpitations, hyperthermia, seizures, hyponatremia, bruxism, sweating, hypertension, tachycardia, headache, thirst, mydriasis, tremor, fever, confusion, psychosis, paranoia, hallucinations, combativeness, agitation, and death. Published case reports describing MDPV related adverse effects are summarized below.

- The death of a 39-year-old male was reported by Wyman *et al.*[60] Family members indicated that the male, who had a history of schizophrenia, depression, and drug abuse,

[58] ADVISORY COUNCIL ON THE MISUSE OF DRUGS, *Consideration of the Cathinones.* (Iversen), London, (Mar. 31, 2010).
[59] CC Cruickshank & KR Dyer, *A Review of the Clinical Pharmacology of Methamphetamine*, 104.7 ADDICTION1085, 1085-1099 (2009).
[60] JF Wyman et al., *Postmortem Tissue Distribution of MDPV Following Lethal Intoxication by "Bath Salts"*, 37 J. ANALYTICAL TOXICOLOGY 182, 182-185 (2013).

had been snorting "bath salts." The subject was found dead in his bed. Empty jars of "bath salts" ("TranQuility" and "Infinity") and synthetic cannabinoids ("Demon" and "Flame") were found in the trash. The cause of death was acute MDPV intoxication.[43]

- A 40-year-old male injected and snorted MDPV and became agitated, aggressive, and suffered from cardiac arrest. He later developed hyperthermia, rhabdomyolysis, coagulopathy, acidosis, anoxic brain injury and died. Other symptoms included mydriasis, labored breathing, and increased heart rate.[61]

- A 39-year-old delusional man with a medical history of depression, back pain, and alcoholism was found outside his residence talking to himself and wandering about in clothes inappropriate for the weather. Law enforcement took the victim to the emergency room. Medical staff noted whitish powder around the mouth of the victim. The victim admitted to using "bath salts." The victim became tachycardic, hyperthermic, followed by bradycardia. After further attempts to save him the victim died. MDPV was identified in samples from the decedent. Autopsy report cited MDPV toxicity to be the primary factor contributing to the death.[62]

- A 46-year-old male was found dead after several days of using the bath salt "Drone." The decedent had complained of weakness, difficulty walking, increased falling, nausea and vomiting prior to his death. He had a history of drug use and diabetes. Toxicology results confirmed MDPV in blood and urine. The cause of death was determined to be diabetic ketoacidosis in a setting of MDPV abuse.[63]

- A 40-year-old male was found dead at his home. The decedent was alleged to have been snorting and smoking bath salts. The decedent had HIV and had taken a variety of medications. Toxicology results confirmed MDPV in blood and urine. Death was determined to be attributed to relevant natural causes in a setting of MDPV abuse.[46]

- Rohrig described the case of a 21-year-old who was struck and killed by a van after he ran into oncoming traffic.[64] A witness reported that the decedent was let out of the car on the side of a local interstate after he acted wildly and belligerently after ingesting "bath salts" and smoking "K2" (a synthetic cannabinoid containing product). MDPV was detected in serum samples from the decedent.

---

[61] BL Murray et al., *Death Following Recreational Use of Designer Drug "Bath Salts" Containing 3,4-Methylenedioxypyrovalerone (MDPV)*, 8 J. MED. TOXICOLOGY 69, 69-75(2012).
[62] K Kesha et al., *Methylenedioxypyrovalerone ("Bath Salts") Related Death: Case Report and Review of the Literature*, 58.6 J. FORENSIC TOXICOLOGY 1654, 1654-1659 (2013).
[63] TH Wright et al., *Deaths Involving Methylenedioxypyrovalerone (MDPV) in Upper East Tennessee*, 58.6 J. FORENSIC TOXICOLOGY, 1558, 1558-1562 (2013).
[64] T Rohrig, California Association of Toxicologist(CAT) Proceedings, *Designer Drugs- The Future of Drug Abuse? Pharmacology of Cathinone Analogs AKA "Bath Salts"*. May 5-6, Napa, CA (2011).

- A 30-year-old man who reportedly spent the day snorting bath salts jumped from a second story window of a hotel. He was found dead in a creek near the hotel. MDPV was detected in blood samples from this individual.[65]

- A 25-year-old man was transported to the emergency department after he was found with marked agitation and altered mental status. He presented with elevated blood pressure, pulse rate and temperature. He also suffered from mydriasis, combativeness, and other symptoms. He was treated at the hospital by extubation, and hemodialysis. Urine tested positive for MDPV. He recovered and was released from the hospital on day 18.[66]

- Sadeg *et al.* described a case of a 47-year-old man who was brought to the emergency department by firemen for behavioral changes with delirious thoughts.[67] His wife described the man as restless and soliloquizing for the last three days. At the hospital the patient was suspicious, anxious, and agitated. He suffered an acute episode of delirium with persecution, megalomaniac themes and focused on the feeling of being watched and monitored as well as having the power to remotely control electrical circuits. He was treated with antipsychotics and benzodiazepines. Testing of products purchased by the patient on the Internet and ingested identified MDPV. The patient reported experiencing euphoria, increase energy with restlessness, empathy, and openness. Analysis of serum of patient also identified MDPV. The patient recovered the following day and treatment ceased. However, three weeks after the patient was discharged he took again to craving the MDPV-containing product which led to a new occurrence of psychosis with visual hallucinations.

- Penders and Gestring reported three cases of paranoid psychotic delirium (presenting as paranoid hallucinatory psychosis) following the alleged abuse of "bath salts" containing MDPV.[68] Interestingly, in these three cases of delirium, some memory loss was reported during the time of abuse of the "bath salts."

- Kriikku *et al.* described cases involving drivers suspected of being under the influence of drugs (DUID) in Finland.[69] Blood samples from individuals suspected of DUIDs from August 2009 to August 2010 were screened for the presence of MDPV. Of 3000 samples tested, 259 were found to be positive for MDPV. The concentration of MDPV ranged from 0.020 – 8.4 mg/L (limit of detection is 0.003 mg/L). Although other drugs may have been detected, the authors concluded that MDPV is a significant problem in DUID cases in Finland.

---

[65] JW Spencer et al., *Acute Psychiatric, Cardiopulmonary, and Neurologic Effects of Laboratory-Confirmed Use of Methylenedioxypyrovalerone (MDPV) "Bath Salts"*, 49 CLINICAL TOXICOLOGY (Phila)515, 515–562 (2011).
[66] HA Borek & CP Holstege, *Hyperthermia and Multiorgan Failure After Abuse of "Bath Salts" Containing 3,4-Methylenedioxypyrovalerone*, 60.1 ANNUALS OF EMERGENCY MEDICINE103, 103-105 (2012).
[67] N Sadeg et al., *Case Report of Cathinone-Like Designer Drug Intoxication Psychosis and Addiction with Serum Identification*, 13.1 ADDICTIVE DISORDERS & THEIR TREATMENT 38, 38-43 (2014).
[68] TM Penders & R Gestring, *Excited Delirium Following Use of MDPV: 'Bath Salts'*. 36.2 GEN. HOSPITAL PSYCHIATRY 647, 647-650 (2011).
[69] P Kriikku et al., *New Designer Drug of Abuse: 3,4-Methylenedioxypyrovalerone (MDPV). Findings from Apprehended Drivers in Finland*. 210.1-210.3 FORENSIC SCI. INT'L 195, 195-200 (2011).

- A 47-year-old male with a history of psychoactive substance abuse experienced severe adverse effects after ingesting "bath salts" that contained MDPV.[70] Routine drugs of abuse were not detected in biological specimens from the patient. Adverse effects included terrifying hallucinations, coma, seizure, multi-organ failure and ischemic colitis. His symptoms resolved after treatment.

In summary the scientific, medical, case reports, and law enforcement information details serious adverse health effects directly attributable to the abuse of methylone, mephedrone, or MDPV. These substances have been directly compared to substances listed under the sentencing guidelines as to effect and potency.

Synthetic Cannabinoids

Although the abuse of JWH-018, AM-2201 and other synthetic cannabinoids are a more recent challenge for law enforcement and public health, the design and investigation of many of these substances date back more than 20 years. Synthetic cannabinoids are cannabinoid agonists that target the cannabinoid receptor 1. These substances are functionally similar to THC, the main psychoactive ingredient in marijuana. In 2008, synthetic cannabinoids were detected in herbal smoking blends and many generations have been encountered since the initial finding in an attempt to stay ahead of regulatory controls. According to some reports the intoxication or high produced by synthetic cannabinoids is more intense than that produced by cannabis. The increased affinity of these substances for the cannabinoid receptor relative to THC and the greater activation of the receptor are attributable to the greater potency of these substances relative to marijuana.[71] Thus, an identical amount of JWH-018 or AM-2201 to THC would be expected to show greater intoxication.[72]

JWH-018 and AM-2201 are synthetic cannabinoids and share pharmacological similarities with THC. Serious adverse health effects, as discussed below, are associated with the ingestion of these synthetic cannabinoids. The term "Spice" is commonly used to describe the diverse types of herbal blends that encompass synthetic cannabinoids being laced on plant material for recreational use. Since the emergence of these smokeable herbal product blends, there has been a relatively high incidence of adverse health effects.

These substances are used for their psychoactive properties, and are promoted as "legal" alternatives to marijuana. Synthetic cannabinoids in bulk powder form are smuggled from overseas via common carrier into the United States, and final products for distribution are made in the United States. The powdered forms of JWH-018 or AM-2201 are typically dissolved in solvents (*e.g.*, acetone) before being applied to a plant material or dissolved in a propellant

---

[70] G Gavriilidis et al., *"Bath Salts" Intoxication with Multiorgan Failure and Left-sided Ischemic Colitis: A Case Report.* 19.4 HIPPOKRATIA 363, 363-365. (2015).

[71] BK Atwood et al., *JWH018, a Common Constituent of 'Spice' Herbal Blends, is a Potent and Efficacious Cannabinoid CB1 Receptor Agonist*, 160 BRITISH PHARMACOLOGICAL SOC'Y 585, 585-593 (2010); G Griffin et al., *Evaluation of Cannabinoid Receptor Agonists and Antagonists Using the Guanosine-5'-O-(3-[^{35}S]thio)-triphosphate Binding Assay in Rat Cerebellar Membranes*, 285.2 J. PHARMACOLOGY AND EXPERIMENTAL THERAPEUTICS, 553, 553-560 (1998).

[72] JL Wiley et al., *Hijacking of Basic Research: The Case of Synthetic Cannabinoids*. RTI Press publication No. OP-0007-1111. Research Triangle Park, NC: RTI Press. Retrieved from http://www.rti.org/rtipress.

intended for use in e-cigarette devices. Law enforcement personnel have encountered various application methods including buckets or cement mixers in which plant material and one or more synthetic cannabinoids, such as JWH-018 and/or AM2201, are mixed together, as well as large areas where the plant material is spread out so that a dissolved synthetic cannabinoid can be applied directly.

Adverse health effects following ingestion of JWH-018 have been reported to include short-term memory defects, hypertension, delusions, chest pain, intractable abdominal pain, nausea, vomiting, tachycardia, anxiety, paranoia, auditory and visual hallucinations, seizure, coma and death.[73] Adverse effects following ingestion of AM-2201 have been reported to include convulsions, intractable abdominal pain, nausea, vomiting, confusion, disorientation, psychiatric complications including self-induced lethal trauma and death.[74]

On March 1, 2011, a final order to temporarily place JWH-018 into Schedule I of the CSA was published in the Federal Register (76 FR 11075) upon finding that this substance poses an imminent threat to public safety. On July 9, 2012, JWH-018, AM2201, and 13 other synthetic cannabinoids were permanently placed into Schedule I of the CSA following congressional action (section 1152 of Food and Drug Administration Safety and Innovation Act (FDASIA)). The FDASIA also amended the CSA by adding the term "cannabimimetic agents" which was defined to include substances within defined structural classes that are demonstrated by binding studies and functional assays to be cannabinoid receptor type 1 (CB1 receptor) agonists.

The data available and reviewed for JWH–018 and AM-2201 indicate that these synthetic cannabinoids have a high potential for abuse, no currently accepted medical use in treatment in the United States and lack an accepted safety for use under medical supervision.

JWH-018

JWH-018 is a synthetic cannabinoid of the indole-derived cannabinoids and was one of the initial synthetic cannabinoids identified in the smokable herbal products. The synthesis and evaluation of JWH-018 had been published in the scientific literature many years prior to discovery of the substance on plant material. Early clinical reports documenting JWH-018 abuse note patients presenting with symptoms atypical of marijuana use, noting extreme agitation, syncope, tachycardia, and visual and auditory hallucinations.[75]

[73] SMR Gurney et al., *Pharmacology, Toxicology, and Adverse Effects of Synthetic Cannabinoid Drugs*, 26.1 FORENSIC SCI. REV., 54, 54-78 (2014).
[74] S Gurney et al., *Pharmacology, Toxicology, and Adverse Effects of Synthetic Cannabinoid Drugs*, 26.1 FORENSIC SCI. REV. 53, 54-78 (2014); A. Patton et al., *K2 Toxicity: Fatal Case of Psychiatric Complications Following AM2201 Exposure*, 58.6 J. FORENSIC SCI. 1676, 1676-1680 (2013).
[75] D Vearrier & KC Osterhoudt, *A Teenager With Agitation: Higher Than She Should Have Climbed*, 26 PEDIATRIC EMERGENCY CARE 462, 462–465 (2010); H Muller et al., *The Synthetic Cannabinoid Spice as a Trigger for an Acute Exacerbation of Cannabis Induced Recurrent Psychotic Episodes*, 118 SCHIZOPHRENIA RES. 309, 309–310 (2010); S Every-Palmer, *Warning: Legal Synthetic Cannabinoid-Receptor Agonists Such As JWH-018 May Precipitate Psychosis in Vulnerable Individuals*, 105 ADDICTION 1859, 1859–1860 (2010); AB Schneir et al., *"Spice" Girls: Synthetic Cannabinoid Intoxication*, 40.3 J. EMERGENCY MED. 296, 296-299 (2010).

Scientific Evidence of the Substance's Pharmacological Effect

The effect of the acute administration of JWH-018 (0.01-6 mg/kg i.p.) on sensorimotor function in male CD-1 mice was compared to those effects caused by the administration of THC (0.01-6 mg/kg i.p.).[76] JWH-018 inhibited sensorimotor responses at the lower doses (0.01-0.1 mg/kg), reduced spontaneous locomotion at intermediate to high doses (1-6 mg/kg) and induced convulsions, myoclonia and hyperreflexia at high dose (6 mg/kg). THC reduced sensorimotor responses in mice but it did not inhibit spontaneous locomotion and it did not induce neurological alterations. JWH-018 was more potent than THC in this study and the greater activity could be due to the higher affinity at the CB1 receptor.

Cannabinoid agonists elicit a characteristic cluster of effects in laboratory animals. This cluster of classical endpoints of analgesia, hypothermia, catalepsy, and locomotor suppression is known as the cannabinoid tetrad and is a classic test. JWH-018 elicits characteristic tetrad effects in mice after intraperitoneal injection.[77] Wiley and colleagues found JWH-018 to be 2.5 times more potent than THC in the tetrad battery.[78] In another tetrad study, JWH-018 was found to be more potent than THC by inhalation and intraperitoneal injection.[79] These results demonstrate that JWH-018 elicits a THC-like profile in a test battery in mice and would be likely to produce cannabimimetic discriminative stimulus effects in rodents, confirmed below, and would be predicted to have marijuana-like effects in humans. JWH-018 displayed greater potency than THC in the three studies detailed above. Drug discriminative studies selective for cannabinoid agonism is a powerful tool comparing effects of cannabinoids and is highly selective for CB1 receptor. The results are highly predictive of subjective effects for cannabis.[80] This is important for it would be inappropriate to dose humans with substances such as JWH-018 in the absence of safety evaluations. Data from published drug discrimination studies indicate that JWH-018 is similar to THC in its discriminative stimulus effects and it substitutes fully for the discriminative stimulus effects of THC in animals trained to discriminate THC from its vehicle.[81] This study reported potencies (ED_{50}) of 0.18 mg/kg and 0.56 mg/kg for JWH-018 and THC, respectively. Thus JWH-018 is approximately three times more potent than THC in this assay. Jarbe *et al.* found JWH-018 to be approximately 8 times more potent than THC in rats.[82] In monkeys, the ED_{50} values were reported as 0.013 mg/kg for JWH-018 and 0.044 for THC.[83]

---

[76] A Ossato et al., *JWH-018 Impairs Sensorimotor Functions in Mice*, 300 NEUROSCIENCE 174, 174-188 (2015).
[77] LK Brents et al., *Monohydroxylated Metabolites of the K2 Synthetic Cannabinoid JWH-073 Retain Intermediate to High Cannabinoid 1 Receptor (CB1R) Affinity and Exhibit Neutral Antagonist to Partial Agonist Activity*, 83.7 BIOCHEMISTRY AND PHARMACOLOGY 952, 952–961 (2012).
[78] JL Wiley et al., *1-Pentyl-3-Phenylacetylindoles and JWH-018 Share In Vivo Cannabinoid Profiles in Mice*, 123.1-123.3 DRUG AND ALCOHOL DEPENDENCE 148, 148–153 (2012).
[79] R Marshell et al., *In Vivo Effects of Synthetic Cannabinoids JWH-018 and JWH-073 and Phytocannabinoid Δ^9-THC in Mice: Inhalation Versus Intraperitoneal Injection*, 124 PHARMACOLOGY BIOCHEMISTRY AND BEHAVIOR 40, 40-47 (2014).
[80] RL Balaster & WR Prescott, *Δ^9-Tetrahydrocannabinol Discrimination in Rats as a Model for Cannabis Intoxication*, 16 NEUROSCIENCE AND BIOBEHAVIORAL REV. 55, 55-62 (1992).
[81] MB Gatch & MJ Forester, *Δ^9-Tetrahydrocannabinol-Like Discriminative Stimulus Effects of Compounds Commonly Found in K2/Spice, 8* BEHAVIORAL PHARMACOLOGY 750, 750-757 (2014).
[82] Jarbe et al., *Cannabinergic Aminoalkylindoles, Including AM678=JWH018 Found in 'Spice', Examined Using Drug (Δ9-THC) Discrimination for Rats*, 22.5-22.6 BEHAVIORAL PHARMACOLOGY 498, 498–507 (2011).
[83] BC Ginsburg et al., *JWH-018 and JWH-073: Δ^9-Tetrahydrocannabinol-Like Discriminative Stimulus Effects in Monkeys*, 340.1 J. PHARMACOLOGY AND EXPERIMENTAL THERAPEUTICS 37, 37-45 (2012).

Adverse Effects/Deaths Involving JWH-018

Adverse health effects following ingestion of JWH-018 (as confirmed by toxicology results) have included: short-term memory defects, hypertension, delusions, chest pain, intractable abdominal pain, nausea, vomiting, tachycardia, anxiety, paranoia, auditory and visual hallucinations, seizure, coma and death.[84]

JWH-018 was confirmed in 8 of 29 synthetic cannabinoid presentations in response to recreational use.[85] The acute adverse reactions displayed included restlessness/agitation, changes in perception/hallucinations, vertigo, somnolence, anesthesia/paraesthesis, shivering/shaking, tachycardia, other electrocardiographic changes, hypertension, thoratic pain, nausea/vomiting, mydriasis, and conjunctival hyperaemia. Seizures developed in 1 of the 8 JWH-018 patients.

- According to the data gathered by DEA, in September 2011, a 19-year-old male complained of cramping and vision changes, and was transported to a local emergency facility for further assessment. The victim was admitted but ultimately died four days later. Upon autopsy, postmortem analysis demonstrated extensive multi-organ failure. Postmortem toxicology detected JWH-018N, a metabolite of JWH-018. The cause of death was determined to be excited delirium which was associated with drug toxicity. The manner of death was ruled accidental.

- In a case report published by Wikstrom *et al.*, a 26-year-old male ingested multiple synthetic substances, ultimately resulting in his death.[86] Postmortem toxicology results obtained during autopsy revealed a high concentration of methoxetamine (MXE), along with three different synthetic cannabinoids (AM694, AM2201 and JWH-018). Authors stated that the high MXE concentration pointed to an acute fatal intoxication with MXE; however, the presence of the three synthetic cannabinoids may have contributed to the death.

NFLIS reports for JWH-018

According to forensic laboratory data as reported by the National Forensic Information Laboratory System[87,88] (NFLIS), JWH-018 was first encountered by law enforcement in August

[84] SMR Gurney et al., *Pharmacology, Toxicology, and Adverse Effects of Synthetic Cannabinoid Drugs*, 26.1 FORENSIC SCI. REV. 54, 54-78 (2014).
[85] M Hermanns-Clausen et al., *Acute Toxicity Due to the Confirmed Consumption of Synthetic Cannabinoids: Clinical and Laboratory Findings*, 108.3 ADDICTION 1-11 (2012).
[86] M Wikstrom et al., *An Accidental Fatal Intoxication with Methoxetamine*, 37.1 J. ANALYTICAL TOXICOLOGY PSYCHOPHARMACOLOGY 43, 43-46 (2013).
[87] The NFLIS is a program of the DEA, Diversion Control Division. NFLIS systematically collects drug identification results and associated information from drug cases submitted to and analyzed by Federal, State and local forensic laboratories. NFLIS represents an important resource in monitoring illicit drug abuse and trafficking, including the diversion of legally manufactured pharmaceuticals into illegal markets. NFLIS is a comprehensive information system that includes data from forensic laboratories that handle approximately 98% of an estimated nearly 1.0 million distinct annual State and local drug analysis cases. NFLIS includes drug chemistry results from completed analyses only.
[88] While NFLIS data is not direct evidence of abuse, it can lead to an inference that a drug has been diverted and abused. See 76 Fed. Reg. 77330, 77332, (Dec. 12, 2011).

2009. Through January 2017, NFLIS has reported 7,144 law enforcement encounters involving JWH-018 (query date February 27, 2017, Federal, State, and local laboratories).

Summary JWH-018

JWH-018 is comparable pharmacologically to the Schedule I substance THC. JWH-018 binds to actives the CB1 receptor, the same receptor as THC. In standard behavioral studies, JWH-018 is at least three times more potent than THC. It was not found to be less potent than THC in any study. Ginsburg and colleagues stated that JWH-018 has abuse liability similar to THC and possibly greater and that anecdotal reports of intoxication suggest alternative sites of action.[89] Further, the short duration and increased efficacy of JWH-018 could lead to more frequent and habitual use.[47]

AM-2201

AM-2201 is a synthetic cannabinoid of the indole-derived cannabinoids and was encountered around the time JWH-018 was temporarily controlled by the DEA. AM-2201 is similar in structure to JWH-018, differing by the addition of a single fluorine atom. Information regarding AM-2201 was initially published in the patent literature many years prior to the encounter of the substance by law enforcement. Early clinical reports documenting the abuse of AM-2201 note patients present to emergency departments with a host of symptoms many of which are atypical of marijuana use, noting extreme agitation, syncope, tachycardia, and visual and auditory hallucinations.[90]

Scientific Evidence of the Substance's Pharmacological Effect

Data from a published drug discrimination studies indicate that AM-2201 is similar to THC in its discriminative stimulus effects and it substitutes fully for the discriminative stimulus effects of THC in animals trained to discriminate THC from its vehicle.[91] This study reported potencies (ED_{50}) of 0.11 mg/kg and 0.56 mg/kg for AM-2201 and THC, respectively. Thus AM2201 is approximately five times more potent than THC in this assay.

Adverse Effects/Deaths Involving AM-2201

[89] BC Ginsburg et al., *JWH-018 and JWH-073: Δ^9-Tetrahydrocannabinol-Like Discriminative Stimulus Effects in Monkeys*, 340.1 J. PHARMACOLOGY AND EXPERIMENTAL THERAPEUTICS 37, 37-45 (2012).
[90] D Vearrier & KC Osterhoudt, , 26 PEDIATRIC EMERGENCY CARE462, 462–465 (2010); H Muller *et al*., *The Synthetic Cannabinoid Spice as a Trigger for an Acute Exacerbation of Cannabis Induced Recurrent Psychotic Episodes*, 118 SCHIZOPHRENIA RES.309, 309–310 (2010); S Every-Palmer, *Warning: Legal Synthetic Cannabinoid-Receptor Agonists Such As JWH-018 May Precipitate Psychosis in Vulnerable Individuals*, 105 ADDICTION 1859, 1859–1860 (2010); AB Schneir et al., *"Spice" Girls: Synthetic Cannabinoid Intoxication*, 40.3 J. EMERGENCY MED. 296, 296-299 (2010).
[91] MB Gatch & MJ Forester, *Δ^9-Tetrahydrocannabinol-Like Discriminative Stimulus Effects of Compounds Commonly Found in K2/Spice*, 8 BEHAVIORAL PHARMACOLOGY 750, 750-757 (2014).

Adverse effects following ingestion of AM-2201 (as confirmed by toxicology results) have included: convulsions, intractable abdominal pain, nausea, vomiting, confusion, disorientation, psychiatric complications including self-induced lethal trauma and death.[92]

- In August 2011, a 23-year-old male suffered self-inflicted lethal trauma in the form of sharp-force neck wounds following ingesting a synthetic cannabinoid. A high concentration of AM-2201 was found in both postmortem blood and evidence collected.[93]

- According to the data gathered by DEA, in February 2012, a 26-year-old male was found dead in his residence. He had a history of abusing natural and synthetic cannabinoids. The autopsy was essentially negative, however the comprehensive postmortem toxicology analysis revealed presence of three synthetic cannabinoids in the blood (AM-2201, JWH-122 and JWH-210), results further confirmed by an outside laboratory. The cause of death is ascribed to "sudden cardiac death associated with the use of synthetic cannabinoids. The manner of death is classified as accidental.

- According to the data gathered by DEA, in March 2012, a 16-year-old male was found dead in a hot tub at his parent's residence. The medical examiner concluded that the young man was intoxicated by the synthetic cannabinoid AM-2201 at the time of his death. Results of toxicology testing for both the decedent's blood and evidence collected were positive for AM-2201. Detailed blood toxicological tests revealed no additional therapeutic or illicit drugs that could have caused or contributed to his death. A full autopsy showed no evidence of natural diseases or significant traumatic injuries. The manner of death was classified as accidental.

- In a case report published by Wikstrom *et al.*, a 26-year-old male ingested multiple synthetic substances, ultimately resulting in his death.[94] Postmortem toxicology results obtained during autopsy revealed a high concentration of methoxetamine (MXE), along with three synthetic cannabinoids (AM-694, AM-2201 and JWH-018). Authors stated that the high MXE concentration pointed to an acute fatal intoxication with MXE; however, the presence of the three synthetic cannabinoids may have contributed to the death.

- A 19-year-old male in his normal state of health had a witnessed generalized 1- to 2-min convulsion while smoking a product "Happy Tiger Incense."[95] He vomited and had second generalized convulsions during transport. On admission to the emergency department, he had blood pressure 177/82 mm Hg, heart rate 84 beats/min. JWH-018, JWH-081, JWH-250, and AM-2201 were identified in the product.

---

[92] SMR Gurney et al., *Pharmacology, Toxicology, and Adverse Effects of Synthetic Cannabinoid Drugs*, 26.1 FORENSIC SCI. REV. 53, 53-78 (2014); AL Patton et al., *K2 Toxicity: Fatal Case of Psychiatric Complications Following AM2201 Exposure*, 58.6 J. FORENSIC SCIENCES 1676, 1676-1680 (2013).

[93] AL Patton et al., *K2 Toxicity: Fatal Case of Psychiatric Complications Following AM2201 Exposure*, 58.6 J. FORENSIC SCI., 1776, 1676-1680 (2013).

[94] M Wikstrom et al., *An Accidental Fatal Intoxication with Methoxetamine*, 37.1 J. ANALYTICAL TOXICOLOGY PSYCHOPHARMACOLOGY 43, 43-46 (2013).

[95] AB Schnier & T Baumbacher, *Convulsions Associated with the Use of a Synthetic Cannabinoid Product*, 8 J. MED.L TOXICOLOGY 62, 62-64 (2012).

- A 20-year-old male smoked the product "Black Mamba" and rapidly after smoking, he had a generalised self-terminating tonic-clonic convulsion.[96] After 2 hours of observation in the Emergency Department (ED), the patient self-discharged against medical advice. Analysis of urine detected metabolites of AM-2201; no other drugs were detected on extensive analytic screening.

NFLIS reports for AM-2201

According to forensic laboratory data as reported by the National Forensic Information Laboratory System (NFLIS), AM-2201 was first encountered by law enforcement in February 2010. Through May 2015, NFLIS has reported 24,165 law enforcement encounters involving AM-2201 (query date February 27, 2017, Federal, State, and local laboratories). In 2013, AM-2201 was the most commonly reported synthetic cannabinoid in drug seizures and was the eighth most encountered substance by law enforcement. It ranked above common substances of abuse such as amphetamine at #11 and PCP at #19 of all drugs reported by state and local forensic labs.

Summary AM-2201

AM-2201 is comparable pharmacologically to the Schedule I substance THC. AM-2201 binds to actives the CB1 receptor, the same receptor as THC. In standard behavioral studies, AM-2201 is at least 5-times more potent than THC. It was not found to be less potent than THC in any study.

In summary, pharmacological studies and clinical reports detail the drug effects of JWH-018 and AM-2201. Animal studies are directly compared to THC and demonstrate an increased potency of JWH-018 and AM-2201 relative to THC. Additionally, serious adverse effects including coma, seizures and death following use of products containing JWH-018 and/or AM-2201 have been documented and law enforcement has detailed information regarding the trafficking and manufacture of the substances and their respective products.

Methylenedioxymethamphetamine

Methylenedioxymethamphetamine (MDMA) is a Schedule I controlled substance, meaning it has a high potential for abuse and no approved medical use. It is well established that MDMA has powerful pharmacological effects and is being abused. The substance has the capacity to cause lasting physical harm and continues to be a threat to public health and safety.[97] As a result of the intense euphoria common to MDMA, there is depletion of neurotransmitters resulting in depression and common to other drugs of abuse, MDMA triggers substance induced anxiety, panic, psychosis, and depression.

The Sentencing Commission's sentencing guidelines for MDMA, originally based on research that demonstrated neurotoxicity in users, has been strengthened since 2001 by ongoing

[96] D McQuade et al., *First European Case of Convulsions Related to Analytically Confirmed Use of the Synthetic Cannabinoid Receptor Agonist AM-2201*, 69.3 EUROPEAN J. CLINICAL PHARMACOLOGY 373, 373-376 (2013).
[97] AC Parrott, *MDMA is Certainly Damaging after 25 Years of Empirical Research: a Reply and Refutation of Doblin et al*, 29.2 HUMAN PSYCHOPHARMACOLOGY 109, 109-119 (2014).

research and publications utilizing updated and more precise measurements which repeatedly conclude that MDMA, even while taken in low doses, is neurotoxic. The neurochemistry and adverse health effects of MDMA have not changed. The substance continues to be both reinforcing and a catalyst for neurological disorders. There is a misbelief among users that the drug is safe even amidst the reports of severe acute toxicity and deaths. Particularly concerning is the rise in MDMA use by teenagers. The number of 10th and 12th grade students that have used MDMA over the past year is approaching the highest levels seen in the past decade, while over the same time period, there has been a dramatic drop in students in grades 8, 10 and 12 who feel there is a "great risk" in using MDMA once or twice, demonstrating that the perception that MDMA is a safe drug is intensifying.[98]

As described by the National Institute on Drug Abuse (NIDA), MDMA is a synthetic, psychoactive drug that is chemically similar to the stimulant methamphetamine and the hallucinogen mescaline. MDMA is a powerful recreational drug of abuse resulting in toxic outcomes to serotonin neurons within the cortex and the hippocampus, amongst other areas.[99] The desired effects of MDMA have included increased energy, euphoria and positive social and emotional feelings, accompanying these effects are a host of harms to include potential hypertension (increased blood pressure), hyperthermia (increased body temperature) and hyponatremia (electrolyte disturbance resulting in low levels of sodium) exacerbated by antidiuresis (reduced urine volume). There have been a number of peer-reviewed published studies clearly demonstrating the neurotoxicity of MDMA, especially in the form of a decrease in serotonin transporter (SERT) density and binding following MDMA use.[100] In addition to imaging studies confirming that MDMA exposure can lead to neurotoxicity, multiple recent studies have demonstrated the negative effects of MDMA use on memory. Results of clinical testing of MDMA users have demonstrated the following: (1) abnormal function of the hippocampus during memory function tests;[101] (2) significantly worse performance of male MDMA users on the tasks that correlate to cognitive flexibility and on the combined executive function task;[102] (3) using fMRI, MDMA was shown to be associated with reduced associative memory performance;[103] (4) a recently published meta-analysis of multiple studies regarding MDMA users reduced the outcomes to a single common denominator to see the average effect and concluded that there was a significant decrement in the MDMA user as compared to control subjects regarding verbal memory;[104] and (5) cortex deficiencies during a word recognition task

---

[98] National Press Release, LD Johnston et al., *Marijuana Use Continues to Rise Among U.S. Teens, While Alcohol Use Hits Historic Lows*, University of Michigan News Service, Ann Arbor, MI (December 14, 2011), *available at* http://www.monitoringthefuture.org/press.html (last visited Mar. 2, 2017).

[99] SJ Kish et al., *Decreased Cerebral Cortical Serotonin Transporter Binding in Ecstasy Users: a Positron Emission Tomography/[(11)C]DASB and Structural Brain Imaging Study*, 133 BRAIN, 1779, 1779-1797 (2010).

[100] UD McCann et al., *Positron Emission Tomographic Evidence of Toxic Effect of MDMA ("Ecstasy") on Brain Serotonin Neurons in Human Beings*, 352.9138 LANCET 1433, 1433-1437 (1998); RL Cowan, *Neuroimaging Research in Human MDMA Users: a Review,189.4* PSYCHOPHARMACOLOGY (BERL) 539, 539-556 (2007).

[101] LK Jacobsen et al., *Preliminary Evidence of Hippocampal Dysfunction in Adolescent MDMA ("Ecstasy") Users: Possible Relationship to Neurotoxic Effects*, PSYCHOPHARMACOLOGY (BERL)173, 3-4, 383-90 (2004).

[102] NA von Geusau et al., 175.3 *Impaired Executive Function in Male MDMA ("ecstasy") Users*, PSYCHOPHARMACOLOGY (BERL) 331, 331-41 (2004).

[103] G Jager et al., *Assessment of Cognitive Brain Function in Ecstasy Users and Contributions of Other Drugs of Abuse: Results From an FMRI Study*, 33.2 NEUROPSYCHOPHARMACOLOGY 247, 247-258 (2008).

[104] G Rogers et al., *The Harmful Health Effects of Recreational Ecstasy: a Systematic Review of Observational Evidence*, 13.6 HEALTH TECH. ASSESSMENT xii, iii-iv, ix-xii, 1-315(2009).

in MDMA users.[105] Lastly, in an even more compelling argument that MDMA exposure can lead to long-lasting neurotoxicity, Morgan *et al.* looked at verbal memory between current and former MDMA users, as well as polydrug users and control volunteers with no prior drug use history, and demonstrated a deficiency in verbal memory in those users who were abstinent from MDMA use on average for two years prior to testing.[106]

Clinical case reports document that regular MDMA use can be associated with chronic psychiatric symptoms after cessation of drug use. In addition to neurocognitive and neurobehavioral deficits linked to MDMA's toxicity, serious cardiovascular and respiratory complications and liver damage have been reported in connection with MDMA use. A case series published in the Journal of Intensive Care Medicine described twelve patients that presented to the emergency department with MDMA toxicity resulting in 4 patients with permanent neurological, musculoskeletal and/or renal deficits and 2 deaths, all directly resultant from MDMA ingestion.[107] Other overdose events have been reported and some with tragic outcomes.[108]

Similar to other drugs of abuse, studies demonstrate MDMA dependence is associated with intensity and lifetime use.[109] MDMA-associated overdoses commonly occur with polysubstance use, possibly used to enhance the effects of the drug. In the absence of national data for MDMA overdose deaths, the Florida Department of Law Enforcement maintains a database for drug-related deaths in Florida. From 2003 to 2010, there were a total of 388 MDMA-related deaths and MDMA was implicated as the cause of death in 86 of these deaths. This remains especially concerning as MDMA pills have increased in the amount of MDMA they contain in recent years.[110]

MDMA remains a dangerous drug of concern and the short- and long-term adverse health effects are well documented. DEA continues to encounter MDMA in our investigations. Also, morbidity and mortality information continues to be collected connected to MDMA abuse. MDMA is not a benign drug, as some suggest.

---

[105] AP Burgess et al., *Event Related Potential (ERP) Evidence for Selective Impairment of Verbal Recollection in Abstinent Recreational Methylenedioxymethamphetamine ("Ecstasy")/Polydrug Users*, 216.4 PSYCHOPHARMACOLOGY (BERL) 545, 545-556 (2011).

[106] MJ Morgan et al., *Ecstasy (MDMA): Are the Psychological Problems Associated With Its Use Reversed By Prolonged Abstinence?*, 159.3 PSYCHOPHARMACOLOGY (BERL) 294, 294-303 (2002).

[107] P Armenian et al., *Multiple MDMA (Ecstasy) Overdoses at a Rave Event: A Case Series*, 28.4 J, INTENSIVE CARE MED. 252, 252-258 (2012).

[108] Morbidity and Mortality Weekly Report, *Ecstasy Overdoses at a New Year's Eve Rave – Los Angeles, CA, 2010*. CENTER FOR DISEASE CONTROL 59, 22, 677-681 (June 11, 2010); Morbidity and Mortality Weekly Report, *Illness and Deaths Among Persons Attending an Electronic Dance Music Festival – New York City, 2013*. CENTER FOR DISEASE CONTROL 63, 50, 1195-1198 (December 19, 2014); CM Milroy, *"Ecstasy" Associated Deaths: What is the Fatal Concentration? Analysis of a Case Series*, 7.3 FORENSIC SCI. MED. AND PATHOLOGY 248, 248-252 (2011); F Schifano, *A Bitter Pill. Overview of Ecstasy (MDMA, MDA) Related Fatalities*, 173 PSYCHOPHARMACOLOGY (BERL)242, 242-248 (2004).

[109] N Bruno & PP Battaglini, *Integrating Perception and Action Through Cognitive Neuropsychology (Broadly Conceived)*, 25 COGNITIVE NEUROPSYCHOLOGY 5, 5-7, (2008); JW Hopper et al., *Incidence and Patterns of Polydrug Use and Craving for Ecstasy in Regular Ecstasy Users: an Ecological Momentary Assessment Study*, 83.3 DRUG AND ALCOHOL DEPENDENCE 221, 221-235 (2006).

[110] *Recent Changes in Europe's MDMA/Ecstasy Market*, EUROPEAN MONITORING CENTRE FOR DRUGS AND DRUG ADDICTION, (EMCCDA Rapid communication, Publication Office of the E.U., Luxembourg), April 2016.

- - -

Thank you for the opportunity to share the views of the Department of Justice. We look forward to working with the Commission on this important issue.

PUBLIC HEARING ON
ALTERNATIVE TO INCARCERATION
COURT PROGRAMS AND SYNTHETIC DRUGS
MARCH 15, 2017
WASHINGTON, DC

Panel IV. Drugs: Community Impact and Supervised Release

Captain Osvaldo Tianga
Sheriff's Captain
Broward County Sheriff's Office

Dr. John Cunha, DO
Vice-Chief of Emergency Medicine
Holy Cross Hospital, Fort Lauderdale, FL
Medical Director
Emergency Medical Services for the City of Oakland Park, FL

Dr. Lisa Rawlings
Court Services and Offender Supervision Agency
Washington, D.C.

Captain Osvaldo “Ozzy” Tianga
Sheriff’s Office
Broward County, Florida

Capt. Tianga is a 20-year veteran of the Broward County Sherriff’s Office. He currently serves as the Court Services Commander responsible for the day-to-day security and operations of all circuit and county courts in Broward County. Additionally, Capt. Tianga serves as the agency’s synthetic drug expert – regularly conducting training, participating in community outreach events, and providing interviews to local, national, and international media outlets regarding synthetic drug trends. Capt. Tianga was also a member of a Drug Enforcement Administration (DEA) taskforce that traveled to China to meet with high ranking members Ministry of Public Security of the People’s Republic of China and the U.S. Ambassador to China to discuss the synthetic drug crisis affecting south Florida. He also served as a board member at the U.S. Comptroller General’s forum for Preventing Illicit Drug Use.

Capt. Tianga received a Master’s degree in Public Administration from Barry University, and he has completed over 1,000 hours of specialized law enforcement and emergency management training. Capt. Tianga has received numerous awards, including Law Enforcement Officer of the Year, DEA Certificate of Appreciation, United States Attorney’s Office Outstanding Officer of the Year, as well as Deputy of the Month 13 times.

Testimony of Captain Ozzy Tianga, Broward County Sheriff's Office

Hello, I am Captain Ozzy Tianga and I work for the Broward County Sheriff's Department in Florida. I have worked there for 20 years, predominately in narcotics investigations. I would like to thank the Commissioners for the opportunity to testify on this important subject.

Synthetic drugs have plagued the streets for many years; however, in recent years the potency of these drugs has had new devastating effects on our community. My experience and introduction to synthetic drugs began with Methylone, known by the street name "Molly." Distributed and consumed under the false assumption that it was pure MDMA, a popular but expensive synthetic type of drug that yielded a euphoric high. Because Molly has amphetamine style properties which generated a stronger speed-like euphoric high, users falsely believed it was a more "pure" drug.

In the latter part of 2014, a new synthetic drug a-PVP, known on the streets as FLAKKA, ravaged South Florida communities. Broward County was the epicenter of this new epidemic. The drug took a strong hold on our communities.

When that drug first arrived there was tremendous confusion. The drug distributors were not completely familiar with what they were selling. Drug users did not know what the appropriate dosage was. Law enforcement did not know exactly what the drug was. In fact, street drug test kits used to identify illicit substances in the field were fooled as well. Flakka generated false-positives on field test kits for cocaine, heroin and amphetamines creating the assumption that the drug was a combination of all the drugs.

Flakka in its most common form looks a lot like crystal methamphetamine and cocaine, and it mirrors symptoms similar to those of crystal meth. It was manufactured in labs in China and smuggled into the Unites States or sold over the internet; the drug also resembles rock candy but sometimes comes in powder form. It can be injected, smoked in an e-cigarette or joint, or poured into capsules and ingested. The drug basically looks like what they want it to look like and is consumed based on user preference. It was very inexpensive; about $1,500 for a kilogram compared to a kilogram of cocaine that can be $30,000 and flakka was at least 10x more potent. Additionally, when the drug use began, Flakka was not illegal. It required emergency scheduling with minimal penalties to prohibit the substance. On the street, dosages would cost $3-5. The Broward Sheriff's Office described the drug as "five-dollar insanity."

Its effects turned people into violent zombies with superhuman strength. Its users flooded local hospitals, jails and morgues. During the time flakka was prevalent, there were multiple overdose calls every day. In fact, oftentimes we had repeat calls that were referred to as two-a-days meaning, one individual would overdose, be hospitalized, get released, and overdose again during the same shift.

Among the side effects of flakka are kidney failure, anxiety, extreme paranoia, psychosis and severe hallucinations. When the dosage is high, flakka causes "excited delirium," also called as "superman effect" because of the superhuman strength that the addict exhibits. The excited delirium stage is accompanied by very high body temperature of 105 degrees fahrenheit and higher, forcing the user to shed clothes and go naked.

Individuals experiencing excited delirium are uncontrollable; they go from 0 to 100 very, very quickly. The effects produce strength that makes them feel superhuman. Users in this state did not experience pain. This is of great concern to police officers responding to emergency calls because basic police techniques used to subdue suspects sometimes involve inflicting some pain to force compliance. In the excited delirium condition, it would take multiple paramedics and police officers to subdue just one person. A person in an excited delirium will be very calm in one moment and then in the next moment become very violent. In one case in particular, it took six cops to subdue a 105-pound female.

Some flakka users report that they are fleeing monsters. In one such incident, a user who tried to kick in the glass door at the police station; in a more serious incident, a user impaled himself atop the security fence at a police station. In other kinds of incidents, a man ran naked through traffic during rush hour; a woman who was high on the drug jumped naked through a closed window. Some incidents posed not only danger to the users but also posed imminent danger to the lives of others. In one case, a user who had stripped naked, climbed up on a roof and waived his gun in the air while threatening suicide. In another incident, a mother who was high abandoned her one-year-old baby in a supermarket.

Once we got the user to the hospital, there was no way to tell what drug was used – there was no drug test for flakka. Flakka only could be tested at the medical examiner's office by toxicology staff. Medical professionals were forced to diagnose the user by the behavior and symptoms. Compounding the problem is the fact that there was no detoxification process known for flakka. Medical professionals could not just flush the system or prescribe a remedy. Because the hospitals were treating multiple cases every night, the hospitals were over capacity. The staff was confused, drained, and overwhelmed. The treatment protocol used by paramedics and hospital staff was to stabilize the patient by pumping them with powerful antipsychotic medications, such as Haldol - which would knock the patient out. In most cases, once he or she awoke they would be released from the hospital. Rehabilitation treatment had yet to be established.

Flakka overdoses were not typical law enforcement emergencies, rather they were medical emergencies that also needed a law enforcement response. Unfortunately these "victims" posed tremendous threat to the safety of themselves and others and subduing them was not easy. This often resulted in extremely violent encounters. First responders were basically learning on the fly, how to better recognize flakka's symptoms and how to safely respond. The truth on the matter was severe force was used on individuals experiencing a medical emergency – these people were not criminals and not going to jail. To try to prevent this problem, law enforcement representatives went on a mission to educate the population, visiting schools, parks, religious institutions, association meetings and various cities in the county to speak with public about the dangers of flakka.

The fight against synthetic drugs will not end with flakka. There are synthetic drugs which mimic the effects of LSD, such as NBOMe and the powerful synthetic opioid Fentanyl. Although the side effects of Fentanyl do not commonly include psychotic episodes, severe overdoses and deaths have increased by over 200%. The potency of these drugs is so great that

accidental overdose and cross-contamination pose great danger to first responders. Most recently two drug detection canines overdosed on synthetic drugs while sniffing/searching for drugs.

Flakka and fentanyl have shown us the devastation synthetic drugs can produce, but the sad part is there will be more. These synthetic drugs which mimic the effects of other illicit drugs are inexpensive and easy to get. There are also thousands of variations that could be made to the molecular structure of each substance to skirt our laws and change the potency and effects of the drug. For the drug distributor the penalties are so little and the profits so great that frankly for a criminal– "the juice is worth the squeeze." It is incumbent upon us to develop stiff penalties for those who involve themselves with synthetic drugs.

Thank you.

Dr. John Cunha, D.O.
Vice-Chief of the Emergency Department
Holy Cross Hospital
Fort Lauderdale, Florida

Dr. Cunha is Vice-Chief of the Emergency Department of Holy Cross Hospital in Fort Lauderdale, FL, and has worked there for ten years. He is also the Medical Director of the Emergency Medical Services for the City of Oakland Park, FL. Dr. Cunha has been involved in fire/rescue and EMS for the past five years as the Emergency Medical Services Director for the Holy Cross Emergency Department.

Dr. Cunha has developed and presented lectures and slide shows on synthetic drugs, synthetic cannabinoids, cathinones, and opioids, to healthcare professionals, fire rescue professionals, law enforcement, and community outreach programs. In 2015, Dr. Cunha was called to testify in the Broward County Grand Jury Investigation on Synthetic Drugs.

Dr. Cunha received a Bachelors of Science in Biology from Rutgers, The State University of New Jersey, in 1993 and a Doctors of Osteopathic Medicine from the Kansas City University of Medicine and Biosciences in Kansas City, MO, in 1998. He completed residency training in Emergency Medicine at Newark Beth Israel Medical Center in Newark, NJ, in 2002.

3/6/17

Members of the United States Sentencing Commission:

Thank you for inviting me to testify to this panel about the demands synthetic drug overdoses place on the first responder system, specifically, EMS and emergency departments.

In the late 2000's (2006-2008) Broward County, FL found itself at the epicenter of a major problem with prescription narcotics and "pill mills." Many users and dealers came to Florida and specifically to Broward County to find easily accessible and readily available prescription narcotic pain medications. Thankfully, due to changed State and Federal sentencing guidelines, the availability of these prescription narcotics dropped severely, causing a shift in the pattern of illegal drug use/abuse and sale. Unfortunately, though predictably, other drugs filled the void. Between 2010 and 2014, the number of crime lab cases involving synthetic drugs more than doubled from 4,000 to over 10,000 per year. Use of synthetic cannabinoids (fake marijuana), the cathinones (including MDPV/Molly, bath salts, and Flakka), and MDMA (Ecstasy) skyrocketed. Once again Broward County found itself in the crosshairs.

In response to a particularly dangerous cathinone, Flakka, the United Way of Broward County organized a community task force consisting of members of law enforcement, emergency medical services, hospitals, drug rehabilitation centers, and local community service organizations. This task force, which Captain Tianga and I were a part of, used its platform to educate people about the dangers of the synthetic cathinones and other synthetic drugs of abuse. By taking the initiative and educating all the pertinent stakeholders of the county we were able to decrease the impact of some of the more dangerous drugs and help get them off the street.

It is a fine line between users getting high from synthetic drugs, and overdosing. There is batch-to-batch variability in the strengths of these drugs and overdose is common. The reason these synthetic drugs are so dangerous in overdose situations is the effect they have on the human body. Synthetics are highly psychoactive. They change the users brain chemicals, causing them to think, act, and behave differently. These drugs can also cause physical damage including heart attacks, strokes, dehydration, rhabdomyolysis (a condition that results in severe muscle wasting), kidney failure, and death.

These synthetics the commission is hearing about today are for the most part very potent stimulants. They speed up and scramble normal body processes. They cause dangerous side effects that can bring users into the emergency medical system including: severe hallucinations, aggressive behavior, hyperthermia (high body temperature), tachycardia (rapid heart rate), psychosis, extreme paranoia, anxiety, incoherent speech, seizures, and agitation.

The additive effect of these symptoms can culminate in a medical emergency called excited delirium, which is a condition in which synthetic drug users cannot control their thoughts, actions, or bodily functions. It has been referred to as "The Superman Effect," because it causes users to feel they are invincible, they have superhuman strength, and they are immune to the various restraining measures law enforcement would use to control their behavior.

To combat these unpredictable and dangerous side effects of synthetic drugs, Broward County EMS departments had to be trained specifically on protocols involving use of medical sedatives such as benzodiazepines and ketamine to safely sedate synthetic drug overdose patients.

Due to the dangerous and complicated nature of overdoses in these patients a large amount of emergency medical and law enforcement resources are needed to help save these patient's lives. In our county, typical EMS crews spend between 15 to 30 minutes on common medical cases they bring to the emergency department. When the EMS crews attend to a synthetic drug overdose case, they often spend upwards of 40 to 90 minutes stabilizing and transporting these patients. This means crews attending to synthetic drug overdose patients are not available to respond to other medical emergency calls in their towns. This causes other surrounding city EMS crews to lend mutual aid and cover for those already busy crews. Basically, one synthetic drug overdose patient can have a far-reaching effect across several city EMS department resources.

Patients who are in excited delirium are dangerous to themselves and to others around them, including first responders. Excited delirium patients may need to be physically restrained by large numbers of law enforcement even before paramedics can begin life-saving treatment.

If the patient is successfully restrained and sedated, they are then brought to an emergency department. Continued medical stabilization and treatment in the ER is often necessary as some of the effects of these drugs can last in the system for several hours. These patients are often critically ill, with abnormal vital signs and life-threatening medical problems. They require a large amount of hospital resources, such as manpower, sedative drugs, monitoring, and sometimes hospital admission, all the while taking away those resources from others in medical need and often causing disruption to the entire emergency room.

The medical issues for these synthetic overdose patients continue even after their acute hospitalizations. Some are so addicted to the drugs they sign out of the hospital "against medical advice" so they can get high again as soon as possible, putting their lives in further danger and almost ensuring another visit to the ER. The patients who are discharged safely have a very hard time finding resources to get medical, psychological, and drug rehabilitation follow-up, making it more likely they will abuse these drugs again because of lack of support. Some of the patients who are seriously ill from drug overdoses end up with long-term medical issues. There

are many documented cases of synthetic drug overdose cases that result in long-term disability and illness such as stroke, end-stage renal disease (kidney failure) and dialysis, and psychosis and extreme paranoia. Many of these patients find group drug rehabilitation impossible due to the permanent brain damage and paranoia these drugs can cause. Relapse is very common.

From a societal point of view, synthetic drugs have hit the most vulnerable and poor populations the hardest. Since synthetic drugs are generally relatively inexpensive ($5/dose is typical) they are marketed to and are widely available to indigent people. Many of these people have no insurance and no resources and cannot pay for their medical care if they overdose, or they are on a government program, and the costs are subsidized by taxpayers.

Once again, thank you for your time and I am happy to answer any questions.

John Cunha, D.O.

Works Cited

Hall, James. Drug Abuse Trends in Broward County, Florida Annual Report: June 2015. June 2015. 6 March 2017 <http://cdn.trustedpartner.com/docs/library/UWBCCommissionSubstanceAbuse2011/Content/Documents/Data%20Central/June%202015%20Broward%20Annual%20Trends%20Report.pdf>.

John P. Cunha, DO. "Synthetic Drugs on the Streets of Florida." February 2016.

Satz, Michael J. Interim Report of the Broward County Grand Jury - Synthetic Drug Investigation. 30 December 2015. 6 March 2017 <http://www.sao17.state.fl.us/assets/synthetic-drug-investigation.pdf>.

Lisa Rawlings, Ph.D.
Chief of Staff
Court Services and Offender Supervision Agency
Washington, D.C.

Dr. Lisa Rawlings is Chief of Staff at the Court Services and Offender Supervision Agency for the District of Columbia (CSOSA). CSOSA is a Federal Executive Branch agency that provides supervision and support services to adult offenders on (1) probation, as ordered by the D.C. Superior Court; (2) parole, as granted by the United States Parole Commission; and, (3) supervised release, as determined by law and administered by the United States Parole Commission.

Dr. Rawlings received a Bachelors Degree in Africana Studies and Public Health from Rutgers University, a Masters in Social Work with a concentration in Human Services Management from Howard University, and a Doctor of Philosophy degree in Social Work from Howard University. During her doctoral studies, she received several awards including the 50th Ph.D. Anniversary Fellowship, the Hawthorne Dissertation Award and the 2006 Outstanding Graduate Teaching Assistant Award.

PLACEHOLDER

FOR TESTIMONY OF

Dr. Lisa Rawlings
Court Services and
Offender Supervision Agency
Washington, D.C.

PUBLIC HEARING ON
ALTERNATIVE TO INCARCERATION
COURT PROGRAMS AND SYNTHETIC DRUGS
MARCH 15, 2017
WASHINGTON, DC

Panel V. Drugs: Chemical Structure and Pharmacological Effects

Terrence L. Boos, Ph.D.
Section Chief, Drug and Chemical Evaluation Section
Diversion Control Division
Drug Enforcement Administration

Professor Gregory Dudley, Ph.D.
Eberly Family Distinguished Professor and Department Chair
Department of Chemistry
West Virginia University

Rick Doblin, Ph.D.
Founder and Executive Director
Multidisciplinary Association for Psychedelic Studies (MAPS)

Terrence L. Boos, Ph.D.
Section Chief
Drug & Chemical Evaluation Section, Office of Diversion Control,
Operations Division
U.S. Drug Enforcement Administration

Dr. Boos is the Section Chief of the Drug & Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration (DEA, U.S. Department of Justice). Dr. Boos' responsibilities include managing a multi-disciplinary group of scientists. The group routinely initiates studies to increase and apply scientific knowledge as it pertains to drugs of abuse and chemicals for regulatory control and provides scientific support to federal, state, and local public health and law enforcement officials related to drugs of abuse. The group provides scientific information to support international control of essential and precursor chemicals and drugs of abuse under the treaty provisions of the United Nations. Additionally, the section provides scientific support to federal prosecutors.

Prior to joining DEA, Dr. Boos was a Research Fellow at the National Institute on Drug Abuse in the Drug Design and Synthesis Section.

STATEMENT OF

DR. TERRY L. BOOS, CHIEF

DRUG AND CHEMICAL EVALUATION SECTION

and

SHONTAL LINDER, CHIEF

SYNTHETIC DRUGS AND CHEMICALS SECTION

DIVERSION CONTROL DIVISION

DRUG ENFORCEMENT ADMINISTRATION

- - -

BEFORE THE

UNITED STATES SENTENCING COMMISSION

- - -

HEARING ON

SENTENCING POLICY FOR SYNTHETIC DRUGS

- - -

WASHINGTON, D.C.

March 15, 2017

I. Introduction

Judge Pryor and members of the Sentencing Commission: Thank you for holding this hearing today and for providing the opportunity to discuss the threat posed by and trafficking patterns associated with the illicit manufacturing and distribution of synthetic drugs, or what are often refer to as new psychoactive substances (NPS).

The trafficking and use of NPS continues to be a challenge for public health and law enforcement. The recreational use of NPS is associated with high levels of abuse and toxicity. These substances continue to be introduced into drug markets as replacements for traditional controlled substances and pose a great risk to the public due to both their often predictable and unpredictable health effects. While NPS challenges increase, there has been a resurgence in MDMA use and availability, presenting additional challenges for public health and law enforcement. Some drug markets have witnessed an increase in MDMA content in tablets; in the United States we have witnessed an increase, decrease, then leveling off of MDMA drug seizures. Drug seizure data demonstrate MDMA is still a popular drug of abuse and being encountered regularly by law enforcement. The scientific information continues to demonstrate MDMA is a threat to public health and safety due to its pharmacological effects and abuse.

In many instances, new psychoactive substances were initially used as research tools to investigate biological systems such as endogenous neurotransmitter systems. This is particularly true of the synthetic cannabinoids JWH-018 and AM-2201. These two substances, having higher potency than Δ9-tetrahydrocannabinol (THC) at the cannabinoid receptors, were initially part of research programs before being used illicitly for their psychoactive effects. Two of the drug classes that rapidly emerged on the illicit drug market were the synthetic cannabinoids and the synthetic cathinones. Due to deceptive marketing, users may have mistakenly perceived them as safe alternatives to traditional drugs of abuse. The arising problems from the introduction of improperly tested substances prompted regulatory control to protect the public from those preying on vulnerable populations. In many cases, use is directly linked to harmful events, including emergency medical intervention, dependence, and death. As a result, serious adverse health and safety outcomes have been reported and present on-going challenges for communities. Scientists, health-care professionals, and treatment providers have quickly mobilized to better understand and treat the outcomes.

The five substances the Department has recommended for addition to the sentencing guidelines belong to two drug classes: synthetic cathinones and synthetic cannabinoids, based on their respective structure and/or effect. Mephedrone, methylone, and MDPV are synthetic cathinones, while JWH-018 and AM-2201 are synthetic cannabinoids. All five substances are schedule I controlled substances as a result of legislation or DEA regulation.[1] Schedule I substances are substances with a high potential for abuse and no approved medical use. Further, they have no industrial use and were introduced on the designer drug market and abused for their psychoactive properties. As a result of trafficking and abuse, four of the five substances were emergency (temporarily) controlled by the Drug Enforcement Administration (DEA) in 2011

[1] See 76 Fed. Reg. 65371 (Oct. 21, 2011); and Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144,126 Stat. 993 (2012).

upon the finding they posed an imminent hazard to public safety.[2] As they continued to appear on the illicit market, researchers continued to collect information to investigate the neurobiological and psychological correlates and risk factors associated with their misuse. As would be expected, there are no published studies in the scientific literature suggesting any beneficial effects or therapeutic value for the individual. The DEA, in collaboration with the National Institute on Drug Abuse, initiated pharmacological studies on NPS, including these five substances, to collect additional information and further characterize and compare them with known drugs of abuse. Based on these studies and the information published in the scientific literature, direct comparisons can be made to substances currently listed under the federal sentencing guidelines. Further, MDMA continues to be encountered in investigations, and NPS mimics for MDMA are a recent development in the illicit market.

Trafficking Findings and Patterns

Synthetic cannabinoids, such as JWH-018 and AM-2201, and cathinones, such as MDMA and methylone, are almost entirely manufactured in China. They are then typically imported into the United States through mail services. Once in the United States, the bulk shipments are most often packaged into individual saleable units – or mixed with organic leaves and then packaged. Prior to being placed in Schedule I, they were distributed for sale at gas stations, convenience stores and head shops or sold directly to individuals via the Internet. They were sold in packages adorned with bright colors and cartoons to attract younger users, and they were often marketed using flavors such as blueberry, strawberry, mango, and bubblegum. Since being scheduled, the market for these drugs has gone underground and now resembles the market for other illegal drugs.

Unfortunately, when DEA initiates temporary control of a synthetic designer drug like these using statutory or administrative procedures, those who traffic them will often alter the chemical composition of the drugs slightly, and in doing so create a different chemical structure not specifically identified in the controlling statutes or regulations. Despite the alterations, these new chemical compounds remain just as potent and just as harmful.

Large profits can be made selling synthetic cannabinoids and cathinones, driving the wholesale and retail distribution of these products. Information DEA has obtained through its investigations show that a $1,500 purchase of a bulk synthetic drug from China can generate as much as $250,000 of revenue at the retail level. It is clear that the income generated from distributing these products is, and will continue to be, a driving factor for manufacturers, distributors, and retailers to seek and find substitute products that are not yet controlled or banned by federal or state law and thus stay one step ahead of enforcement authorities.

According to the National Forensic Laboratory Information System (NFLIS), seizures of synthetic cannabinoids by federal, state, and local forensic laboratories increased from 23 reports in 2009 to 32,784 reports in 2013. Seizures of synthetic cathinones increased from 29 reports in 2009 to 15,673 reports in 2013.

[2] See 76 Fed. Reg. 65371 (Oct. 21, 2011).

Synthetic Cathinones

Synthetic cathinones are a class of β-ketoamphetamine substances that emerged as NPS and are known for their hallucinogenic and psychostimulant properties, as well as for their abuse and toxicity. Synthetic cathinones are structurally and pharmacologically similar to amphetamine, methylenedioxymethamphetamine (MDMA), and cathinone. Synthetic cathinones produce their effects via the release or reuptake of various neurotransmitters including dopamine, norepinephrine, and/or serotonin.[3] Studies suggest that cathinones have high blood-brain barrier permeability.[4] The onset of drug effects is rapid with the side effects lasting from hours to days. Since their introduction into the illicit drug market, synthetic cathinones have been implicated by coroners' offices in the death of many individuals.[5]

Methylone, mephedrone, and MDPV are synthetic cathinones that have many similarities with the Schedule I substances cathinone, methcathinone, and MDMA, and the Schedule II stimulants amphetamine, methamphetamine, and cocaine. The clinical presentation of intoxication from these three substances is like that seen with MDMA and other substances (*e.g.*, cathinone, methcathinone, MDMA, amphetamine, methamphetamine, and cocaine) that have a stimulant effect on the central nervous system. Adverse effects associated with the consumption of methylone, mephedrone and MDPV include palpitations, hyperthermia, seizures, hyponatremia, bruxism, sweating, hypertension, tachycardia, headache, thirst, mydriasis, tremor, fever, confusion, psychosis, paranoia, hallucinations, combativeness, agitation, and death.[6]

The DEA has encountered these synthetic cathinones being trafficked for their psychoactive properties. These substances are falsely marketed as "research chemicals," "plant food or fertilizer," "jewelry cleaner," "stain remover," "insect repellant," or "bath salts." Prior to being regulated, they were sold at smoke shops, head shops, convenience stores, adult book stores, gas stations, and on the Internet, with packaging that contains the warning "not for human consumption." In addition, methylone, mephedrone, and MDPV at one time were promoted as

---

[3] RA Gregg & SM Raws. *Behavioral Pharmacology of Designer Cathinones: A Review of the Preclinical Literature*, 97.1 LIFE SCI. 27, 27-30 (2014).

[4] LD Simmler et al., *Pharmacological Characteriztion of Designer Cathinones In Vitro*, 168.2 BRIT. J. PHARMACOLOGY 458, 458-470 (2013).

[5] LJ Marinetti & HM Antonicides. *Analysis of Synthetic Cathinones Commonly Found in Bath Salts in Human Performance and Postmortem Toxicology: Method Development, Drug Distribution, and Interpretation of Results*, 137 J. ANALYTICAL TOXICOLOGY 135, 135-146 (2013); JF Wyman et al., *Postmortem Tissue Distribution of MDPV Following Lethal Intoxication by "Bath Salts"*, 37.3 J. ANALYTICAL TOXICOLOGY 182, 182-185 (2013); SJ deRoux & WA Dunn, *"Bath Salts" the New York City Medical Examiner Experience: A 3-Year Retrospective Review* J. FORENSIC SCI., ahead of print; TH Wright et al., *Deaths Involving Methylenedioxypyrovalerone (MDPV) in Upper East Tennessee*, 58.6 J. FORENSIC SCI. 1558, 1558-1562 (2013); PN Carbone et al., *Sudden Cardiac Death Associated with Methylone Use*, 34.1 AM. J. FORENSIC MED. AND PATHOLOGY 26, 26-28 (2013).

[6] JM Pearson et al., *Three Fatal Intoxications Due to Methylone*, 36 J. ANALYTICAL TOXICOLOGY 444, 444-451 (2012); B. Warrick et al., *Lethal Serotonin Syndrome After Methylone and Butylone Ingestion*, 8 J. MED. TOXICOLOGY 65, 65-68 (2012); B. Cawrse et al., *Distribution of Methylone in Four Postmortem Cases*, 36 J. ANALYTICAL TOXICOLOGY 434, 434-439 (2012); J. Wyman et al., *Postmortem Tissue Distribution of MDPV Following Lethal Intoxication by "Bath Salts*," 37 J. ANALYTICAL TOXICOLOGY 182, 182-185 (2013); B. Murray *et al.*, *Death Following Recreational Use Of Designer Drug "Bath Salts" Containing 3,4-Methylenedioxypyrovalerone (MDPV)*, 8 J. MED. TOXICOLOGY 69, 69-75 (2012); K. Kesha et al., *Methylenedioxypyrovalerone ("Bath Salts"), Related Death: Case Report And Review Of The Literature*, 58 J. FORENSIC SCI. 1654, 1654-1659 (2013).

being "legal" alternatives to cocaine, methamphetamine, and MDMA, because at that time detection of these substances was not included in the routine drug screen for illicit substances.

On October 21, 2011, the Administrator of the DEA published a Final Order in the Federal Register temporarily placing methylone, mephedrone and MDPV into Schedule I of the CSA upon finding that these substances pose an imminent threat to public safety.[7] On July 9, 2012, President Obama signed the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144) (FDASIA), which amended several provisions of the CSA. In particular, the FDASIA amended Schedule I of section 202(c) of the CSA to include the synthetic cathinones mephedrone and MDPV. Methylone was permanently controlled via the administrative scheduling process on April 12, 2013.[8]

Methylone

Research in anti-depressant and anti-Parkinson agents resulted in the development and patenting of methylone in 1996.[9] However, there is no evidence that methylone has a legitimate non-research use and, according to the Department of Health and Human Services (HHS), there are no approved drug products or new drug applications that contain methylone. Evidence indicates that methylone is abused by individuals for its psychoactive effects. Desired effects reported by abusers of synthetic cathinones substances include euphoria, increased sociability, energy, empathy, increased alertness, and improved concentration and focus.

Scientific Evidence of the Substance's Pharmacological Effect

Studies indicate that methylone is more similar in its pharmacological effects to MDMA than to methamphetamine or amphetamine. In microdialysis studies, methylone produces elevations in the dialysates dopamine and serotonin (5-HT) with a preferential increase in 5-HT, which are qualitatively analogous to the effects of MDMA but less potent.[10] In contrast, methamphetamine causes preferential increase in dialysate dopamine rather than serotonin. These selective effects on the neurotransmitters (dopamine and serotonin) are relevant properties of the substances. They show that methylone is a weak psychomotor stimulant compared to methamphetamine. Whereas methamphetamine elicits a sustained increase in horizontal locomotor activity, methylone produces a transient increase in locomotor activity. However, in a study by Lopez-Annau (2012), methylone, compared to MDMA, had similar effects on locomotor activity.[11]

Studies indicate that methylone, like MDMA, produces pharmacological effects that are similar to those of substances that cause a stimulant effect on the central nervous system. The drug discrimination paradigm is used as an animal model of human subjective effects. This procedure provides a direct measure of stimulus specificity of a test drug in comparison with a

[7] 76 Fed. Reg. 65371 (Oct. 21, 2011).
[8] 78 Fed. Reg. 21818 (Apr. 12, 2013).
[9] P Jacob and A Shulgin, U.S. Patent No. WO 1996039122 (filed Jun. 6, 1996).
[10] MH Baumann et al., *The Designer Methcathinone Analogs, Mephedrone and Methylone, are Substrates for Monoamine Transporters*, 37 NEUROPSYCHOPHARMACOLOGY 1192, 1192-1203 (2012).
[11] R Lopez-Arnau et al., *Comparative Neuropharmacology Of Three Psychostimulant Cathinone Derivatives: Butylone, Mephedrone and Methylone*. 167.2 BRIT. J. PHARMACOLOGY 407, 407-420 (2012).

known standard drug, or a neutral stimulus (*e.g.* injection of saline water). In the drug discrimination paradigm, if a new drug or substance has discriminative stimulus effects in animals similar to a known drug of abuse, it is highly likely that this new drug will produce pharmacological effects (including subjective effects) in humans that would be qualitatively and quantitatively similar to the known drug of abuse and would be similarly abused by humans.[12] Data from a published drug discrimination study indicates that methylone (ED_{50} = 1.60 mg/kg) fully substitutes for the discriminative stimulus effects produced by MDMA (ED_{50}=0.76 mg /kg) in rats.[13] Similarly, data from another published drug discrimination study also indicate that methylone (ED_{50} = 2.66 mg/kg) fully substitutes for the discriminative stimulus effects produced by methamphetamine.[14] MDMA (ED_{50} = 1.83 mg/kg), which was previously tested by these authors, also fully substitutes for the discriminative stimulus effects produced by methamphetamine.[15] Based on these studies, methylone is approximately half as potent as MDMA in these drug discrimination studies.

The Substance's History and Current Pattern of Abuse

DEA forensic laboratories have analyzed drug exhibits received from state, local, or federal law enforcement agencies that were found to contain methylone. Methylone, like MDMA, is commonly encountered in powder, capsule, and tablet form. Information from published scientific studies indicate that the most common routes of administration for methylone are by swallowing capsules or tablets or by snorting the powder. The reported average amount of use reported for methylone ranged from 100 mg to 250 mg.[16] In contrast, the average amount of MDMA used ranged from 75 mg to 125 mg.[17] Evidence from poison centers, published case reports, and law enforcement encounters suggest that the main users of methylone are young adults. There is evidence that methylone may be co-ingested with other substances including other synthetic cathinones, pharmaceutical agents, or other recreational substances. In fact, some products that were sold as MDMA (marketed as "Molly") were found to contain methylone.

[12] JB Kamien et al., *Drug Discrimination by Humans Compared to Nonhumans: Current Status and Future Directions*, 111.3 PSYCHOPHARMACOLOGY 259, 259-270 (1993); RL Balster & GE Bigelow, *Guidelines and Methodological Reviews Concerning Drug Abuse Liability Assessment*, 70.3 DRUG AND ALCOHOL DEPENDENCE Suppl, S13, S13-S40 (2003); LV Panlilio & SR Goldberg, *Self-Administration of Drugs in Animal and Humans as a Model and an Investigative Tool*, 102.12 ADDICTION 1863, 1863-1870 (2007).

[13] TA Dal Cason et al., *Cathinone: an Investigative of Several N-Alkyl and Methylenedioxy-substituted Analogs*, 58.4 PHARMACOLOGY BIOCHEMISTRY AND BEHAVIOR 1109, 1109-1116 (1997).

[14] MB Gatch et al., *Locomotor Stimulant and Discriminative Stimulus Effects of 'Bath Salt' Cathinone*,24.5-24.6BEHAVIORAL PHARMACOLOGY 437, 437-447 (2013).

[15] National Institute on Drug Abuse email communication (2012).

[16] JP Kelly et al., *Cathinone Derivatives: a Review of Their Chemistry, Pharmacology, Toxicology*, 7-8 DRUG TESTING AND ANALYSIS 439, 439-453 (2011).

[17] J Cami et al, *Human Pharmacology of 3,4-Methylenedioxymethamphetamine ("Ecstasy"): Psychomotor, Performance and Subjective Effects*, 20.4 J. CLINICAL PSYCHOPHARMACOLOGY, 455, 455-466 (2000); AC Parrott, *Human Psychobiology of MDMA or 'Ecstasy': an Overview of 25 Years of Empirical research*, 28.4 HUMAN PSYCHOPHARMACOLOGY, 289, 289-307 (2013).

The Scope, Duration and Significance of Abuse

According to forensic laboratory data as reported by the National Forensic Information Laboratory System (NFLIS),[18, 19] law enforcement began encountering methylone in February 2009. Through January 2017, NFLIS has reported 21,839 law enforcement encounters involving methylone.[20] Additionally, the U.S. Customs and Border Protection (CBP) has seized large quantities of methylone during this same period.

Risk to Public Health

Methylone has been reported to cause a number of stimulant-like adverse effects. The clinical presentation of intoxication from methylone is similar to that seen with MDMA and other substances that have a stimulant effect on the central nervous system (*e.g.*, cathinone, methcathinone, MDMA, amphetamine, methamphetamine, and cocaine). Adverse effects associated with the consumption of methylone include palpitations, hyperthermia, seizures, hyponatremia, bruxism, sweating, hypertension, tachycardia, headache, thirst, mydriasis, tremor, fever, confusion, psychosis, paranoia, hallucinations, combativeness, agitation, and death. Some published case reports describing adverse effects of methylone are summarized below.

- A study by Pearson reported on a 19-year-old female who took a pill known as "Molly" collapsed and recovered then complained of not feeling well.[21] Thereafter, she developed seizures. Emergency personnel were called and the female was transported to the hospital. At the hospital she suffered cardiac complications and later died. Toxicology tests identified methylone in specimens from the decedent. No other recreational substances were detected. The medical examiner concluded that the cause of death was methylone intoxication.

- The Pearson study also described the death of a 23-year-old male.[22] The decedent was witnessed to take what was thought to be LSD at a club. The decedent was acting erratically and irrationally and so the decedent was removed from the club and placed in the back of a van by securing the decedent to a chair using saran wrap. Sometime later, the decedent was found having seizures. Emergency personnel were called and the decedent was transported to the hospital. The decedent had hyperthermia and cardiac

[18] The NFLIS is a program of the DEA, Diversion Control Division. NFLIS systematically collects drug identification results and associated information from drug cases submitted to and analyzed by Federal, State and local forensic laboratories. NFLIS represents an important resource in monitoring illicit drug abuse and trafficking, including the diversion of legally manufactured pharmaceuticals into illegal markets. NFLIS is a comprehensive information system that includes data from forensic laboratories that handle approximately 98% of an estimated nearly 1.0 million distinct annual State and local drug analysis cases. NFLIS includes drug chemistry results from completed analyses only.

[19] While NFLIS data is not direct evidence of abuse, it can lead to an inference that a drug has been diverted and abused. See 76 Fed. Reg. 77330, 77332 (Dec. 12, 2011).

[20] Query date February 27, 2017, Federal, State, and local laboratories.

[21] JM Pearson et al., *Three Fatal Intoxications Due to Methylone*, 36.6 J. ANALYTICAL TOXICOLOGY 444, 444-451 (2012).

[22] *Id.*

complications. The decedent died 45 minutes after his arrival at the hospital. The medical examiner listed the cause of death as intoxication by methylone.

- Another incident reported by Pearson involved the death of a 23-year-old male initially suspected of using methylone.[23] The decedent was walking in and out of traffic and acting belligerently. The decedent was detained by law enforcement and transported to the hospital. The decedent had a high temperature and subsequently went into respiratory failure. After several attempts by medical personnel to stabilize the decedent, he died. Toxicology testing identified methylone in specimens from this individual. The medical examiner listed the cause of death as intoxication by methylone.

- Warrick *et al.* described the death of a 24-year-old female who ingested two capsules of what was thought to be "Ecstasy" at a concert.[24] After being found unconscious by emergency personnel, the decedent was taken to the emergency department. The comatose patient suffered from hyperthermia, tachycardia, mydriasis, tachypnea and some tremors and later died. Toxicology tests identified methylone and butylone in specimens from this individual. Laboratory analysis also identified methylone and butylone in the powder obtained from a capsule that was found on the decedent. The cause of death mentioned by the medical examiner was serotonin syndrome secondary to methylone and butylone intoxication.

- Cawrse *et al.* described the death of a 19-year-old male.[25] The decedent died while performing a physical fitness assessment. Toxicology tests identified methylone in specimens from this individual. The cause of death was cardiac arrest associated with methylone.

- The death of a 39-year-old male was reported by Wyman *et al.*[26] Family members indicated that the male, who had a history of schizophrenia, depression, and drug abuse, had been snorting "bath salts." The subject was found dead in his bed. Empty jars of "bath salts" ("TranQuility" and "Infinity") and synthetic cannabinoids ("Demon" and "Flame") were found in the trash. A toxicological screen detected MDPV in multiple tissues, urine and blood samples from the decedent. Other substances detected were nicotine, cotinine, pseudoephedrine, m-chlorophenylpiperazine and methylone. The cause of death was acute MDPV intoxication.

- Kovacs *et al.* described the case of a 16-year-old male who lost consciousness at a party.[27] The decedent died of sudden cardiac death at the hospital after attempts to save his life were unsuccessful. The decedent suffered from cardiac malformation and

---

[23] *Id.*
[24] BJ Warrick et al., *Lethal Serotonin Syndrome after Methylone and Butylone Ingestion*, 8.1 J. MED. TOXICOLOGY 65, 65-68 (2012).
[25] BM Cawrse et al., *Distribution of Methylone in Four Postmortem Cases*, 36.6 J. ANALYTICAL TOXICOLOGY 434, 434-439 (2012).
[26] JF Wyman et al., *Postmortem Tissue Distribution of MDPV Following Lethal Intoxication by "Bath Salts"*.,37 J. ANALYTICAL TOXICOLOGY 182, 182-185 (2013).
[27] K Kovacs et al., *A New Designer Drug: Methylone Related Death*. 157.7 ORV HETIL 271, 271-276 (2012).

bronchial asthma. The toxicology testing identified methylone in the specimens from this individual. The authors concluded that the predisposing factors along with methylone may have resulted in the sudden cardiac death of this individual.

- A 22-year-old female developed rhabdomyolysis after ingesting "legal ecstasy" which was analyzed to be a mixture of methylone and ethcathinone.[28] She also suffered from recurrent seizures, severe hyponatremia (abnormally low concentration of sodium in the blood), nystagmus (involuntary rapid eye movement), hyperreflexia, and bruxism. All her symptoms resolved after treatment that required hospitalization.

- Katagi *et al.* reported two cases of acute toxicity from the confirmed ingestion of methylone.[29] A 19-year-old male was taken to the emergency department suffering from dementia after ingesting an unknown amount of methylone powder. In the second case, a 29-year-old male was taken to the emergency department suffering from acute toxicity after taking an unknown amount of a mixture of methylone and a hallucinogen.

- A 19-year-old female with a history of illicit drug use was found 100 yards from the beach. High blood and liver concentrations of methylone were found with THC. The cause of death was certified as drowning due to acute methylone intoxication and the manner of death was certified as accidental.[30]

- A 19-year-old male collapsed while jogging and died.[31] He had no significant health issues. A toxicology report confirmed the presence of methylone but found no other substances including synthetic cathinones (4-FMC, mephedrone, ethylone, butylone, MDPV, and naphyrone).

- A 21-year-old male who ingested cannabis and methylone died.[32] After ingesting the substances he had difficulty breathing. Emergency medical services were called and found the individual in cardiopulmonary arrest. An autopsy report concluded that death was due to respiratory distress that may have been provoked by the absorption of toxic substances. An analysis of biological specimens from the decedent identified methylone and cannabinoids. Other routine drugs of abuse were not detected.

Mephedrone

Mephedrone, also known as "m-cat," "Meow," and "mad cow," is a psychoactive synthetic cathinone that is structurally and pharmacologically similar to the Schedule I and II substances cathinone, methcathinone, MDMA, and methamphetamine. There is no evidence that

[28] C Boulanger-Gobeil *et al.*, *Seizures and Hyponatremia Related to Ethcathinone and Methylone Poisoning*, 8 J. MED. TOXICOLOGY 59, 59-61 (2011).
[29] L Katagi et al., *Metabolism and Forensic Toxicology Analysis of the Extensively Abused Designer Drug Methylone*, 40 TIAFT BULLETIN 30, 30-35(2010).
[30] IM McIntyre et al., *Acute Methylone Intoxication in an Accidental drowning – A Case Report*, 231 FORENSIC SCI. INT'L e1, e1-e3 (2013),
[31] P Carbone et al., *Sudden Cardiac Death Associated with Methylone Use, 34.1* AM J. FORENSIC MED. AND PATHOLOGY,26, 26-28 (2013).
[32] L Barrios et al., *Death Following Ingestion of Methylone*, 30.2 INL'T J. LEGAL MED. 381, 381-385. (2016).

mephedrone has a legitimate non-research use, and according to HHS, there are no approved drug products or new drug applications that contain mephedrone. Evidence indicates that mephedrone is being abused by individuals for its psychoactive effects. Desired effects reported by abusers of synthetic cathinone substances include euphoria, increased sociability, energy, empathy, increased alertness, and improved concentration and focus.

Scientific Evidence of the Substance's Pharmacologic Effect

To date, there is one human study evaluating the efficacy and potency of mephedrone relative to MDMA. Data that was presented at the 77th Annual Scientific Meeting of the College on Problems of Drug Dependence described the abuse liability of mephedrone in humans compared to MDMA.[33] In this small clinical study (12 healthy males who used psychostimulants recreationally), 200 mg of mephedrone was found to be similar to MDMA (100 mg) in somatic (*i.e.,* blood pressure, heart rate and temperature) and subjective effects (visual analog scales –VAS, ARCI-49 short form and VESSPA questionnaire). Based on this study, mephedrone has a stimulant effect that is similar to MDMA but less potent. However, these conclusions are made with the limitations since the number or participants were small and only one dose of mephedrone was evaluated.

Studies indicate that mephedrone is more similar in its pharmacological effects to MDMA than to methamphetamine or amphetamine.[34] In microdialysis studies, mephedrone produces elevations in the dialysates dopamine and serotonin (with preferential effects on serotonin), which are qualitatively analogous to the effects of MDMA but less potent.[35] In contrast, methamphetamine causes preferential increase in the dialysate dopamine rather than serotonin. Studies also show that mephedrone is a weak psychomotor stimulant compared to methamphetamine. Whereas methamphetamine elicits a sustained increase in horizontal locomotor activity, mephedrone produces a transient increase in locomotor activity. Data from other studies support the comparison of mephedrone to MDMA. The neurochemical and functional properties of mephedrone resemble those of MDMA as demonstrated in another microdialysis study.[36] In an additional study that claims MDMA-like drugs can be discerned

[33] M Farre et al., *A Comparison of the Clinical Abuse Liability of MDMA and Mephedrone*, 37.8 CLINICAL THERAPEUTICS e130 (2015).
[34] J Kehr et al., *Mephedrone, Compared with MDMA (Ecstasy) and Amphetamine, Rapidly, Increases Both Dopamine and 5-HT Levels in Nucleus Accumbens of Awake Rats*, 164.8 BRIT. J. PHARMACOLOGY 1949, 1949-1958 (2011); MH Baumann et al., *The Designer Methcathinone Analogs, Mephedrone and Methylone, are Substrates for Monoamine Transporters*, 37 NEUROPSYCHOPHARMACOLOGY 1192, 1192-1203 (2012); P-K Huang et al., *Contrasting Effects of d-Methamphetamine,3,4-Methylenedioxymethamphetamine, 3,4-Methylenedioxypyrovalerone, and 4-Methylmethcathinone on Wheel Activity in Rats*, 126.1-126.2 DRUG AND ALCOHOL DEPENDENCE 168, 168-175 (2012).
[35] MH Baumann et al., *The Designer Methcathinone Analogs, Mephedrone and Methylone, are Substrates for Monoamine Transporters*, 37 NEUROPSYCHOPHARMACOLOGY1192, 1192-1203 (2012).
[36] J Kehr et al., *Mephedrone, Compared with MDMA (Ecstasy) and Amphetamine, Rapidly, Increases Both Dopamine and 5-HT Levels in Nucleus Accumbens of Awake Rats*, 164.8 BRIT. J. PHARMACOLOGY 1949, 1949-1958 (2011).

from methamphetamine-like drugs by measuring a specific locomotor activity (voluntary wheel activity), mephedrone is more similar to MDMA than to MDPV or methamphetamine.[37]

In support of the clinical study mentioned earlier, data from drug discrimination studies in rats indicate that mephedrone, like MDMA, produces pharmacological effects that are similar to those of substances that cause a stimulant effect on the central nervous system. The drug discrimination paradigm is used as an animal model of human subjective effects. This procedure provides a direct measure of stimulus specificity of a test drug in comparison with a known standard drug, or a neutral stimulus (*e.g.* injection of saline water). In the drug discrimination paradigm, if a new drug or substance has discriminative stimulus effects in animals similar to a known drug of abuse, it is highly likely that this new drug will produce pharmacological effects (including subjective effects) in humans that would be qualitatively and quantitatively similar to the known drug of abuse and would be similarly abused by humans.[38] Data from a published drug discrimination study indicate that MDMA fully substitutes for the discriminative stimulus effects produced by mephedrone (ED_{50}=0.90 mg/kg) in rats.[39] The potency values were not stated in the article but the ranked order of potency as determined from the figure is: methamphetamine ≥ mephedrone > MDMA > cocaine. Thus, mephedrone is substantially similar to MDMA in pharmacological effect but more potent than MDMA in this assay.

The Substance's History and Current Pattern of Abuse

DEA forensic laboratories have analyzed drug exhibits received from state, local, or federal law enforcement agencies that were found to contain mephedrone. Mephedrone, like MDMA, is commonly encountered in the form of powders, capsules, and tablets. Information from published scientific studies indicate that the most common routes of administration for methylone are ingestion by swallowing capsules or tablets or nasal insufflation by snorting the powder. The reported average amount of use of mephedrone ranged from 0.5 to 4 grams depending on the route of administration and the number of doses taken. According to self-reported drug users, the amounts for snorting mephedrone ranged from 5 to 75 milligrams whereas for oral administration it ranged from 150 to 250 milligrams.[40] It has also been reported that mephedrone is used in binges. Abusers have reported that typical sessions using mephedrone have last approximately 10.4 hours with some individuals administering several times throughout a session. A possible reason for binging may be to prolong the duration of effects. The average amount of MDMA used ranged from 75 mg to 125 mg (oral

[37] P-K Huang et al., *Contrasting Effects of d-Methamphetamine,3,4-Methylenedioxymethamphetamine, 3,4-Methylenedioxypyrovalerone, and 4-Methylmethcathinone on Wheel Activity in Rats*, 126.1-126.2 DRUG AND ALCOHOL DEPENDENCE 168, 168-175 (2012).
[38] JB Kamien et al., *Drug Discrimination by Humans Compared to Nonhumans: Current Status and Future Directions*, 111.3 PSYCHOPHARMACOLOGY 259, 259-270 (1993); RL Balster & GE Bigelow, *Guidelines and Methodological Reviews Concerning Drug Abuse Liability Assessment*, 70.3 DRUG AND ALCOHOL DEPENDENCESuppl, S13, S13-S40 (2003); LV Panlilio & SR Goldberg, *Self-Administration of Drugs in Animal and Humans as a Model and an Investigative Tool*, 102.12 ADDICTION, 1863, 1863-1870 (2007).
[39] KJ Varner et al., *Comparison of the Behavioral and Cardiovascular Effects of Mephedrone with Other Drugs of Abuse in Rats*, 225.3 PSYCHOPHARMACOLOGY 675, 675-685 (2013).
[40] JP Kelly et al., *Cathinone Derivatives: a Review of Their Chemistry, Pharmacology, Toxicology*, 7-8 DRUG TESTING AND ANALYSIS 439, 439-453 (2011).

administration).[41] Evidence from poison centers, published case reports, and law enforcement encounters suggest that the main users of mephedrone are young adults. There is evidence that mephedrone may be co-ingested with other substances including other synthetic cathinones, pharmaceutical agents, or other recreational substances.

Users from drug surveys reported that mephedrone, like methylone, MDPV, and other synthetic cathinones, has an effect profile similar to known drugs of abuse like cocaine and MDMA. The desired psychoactive effects reported by users include euphoria, general stimulation, empathy, enhanced music appreciation, hallucinations, increased insight, elevated mood, decreased hostility, improved mental function, and mild sexual stimulation.[42] Participants in a survey of readers of a popular UK dance music magazine reported that mephedrone gave a better high than cocaine. Another survey that was advertised on websites frequented by drug users found that users considered the effects of mephedrone to be similar to those of MDMA. This is consistent with studies in animals that demonstrated that methylone resembles MDMA in its behavioral profile. As explained above, some products that were sold as MDMA (marketed as "Molly") actually contained methylone; other products were found to contain mephedrone.

The Scope, Duration and Significance of Abuse

According to forensic laboratory data as reported by the National Forensic Information Laboratory System (NFLIS), mephedrone started to be encountered by law enforcement in April 2009. Through January 2017, NFLIS has reported 716 law enforcement encounters involving mephedrone (query date February 27, 2017, Federal, State, and local laboratories). Additionally, seizures of mephedrone have occurred by the U.S. Customs and Border Protection (CBP).

Risk to Public Health

Mephedrone has been reported to cause a number of stimulant-like adverse effects. The clinical presentation of intoxication from mephedrone is similar to MDMA and other substances that have a stimulant effect on the central nervous system (*e.g.*, cathinone, methcathinone, MDMA, amphetamine, methamphetamine, and cocaine). Adverse effects associated with the consumption of mephedrone include palpitations, hyperthermia, seizures, hyponatremia, bruxism, sweating, hypertension, tachycardia, headache, thirst, mydriasis, tremor, fever, confusion, psychosis, paranoia, hallucinations, combativeness, agitation, and death. Published case reports describing mephedrone related adverse effects are summarized below.

- A 22-year-old male was found unresponsive at his home. He was transported to the hospital where he died. An autopsy revealed heroin and high concentrations of mephedrone. Multiple drug toxicity associated with mephedrone and heroin use was reported as the cause of death.[43]

[41] AC Parrott, *Human Psychobiology of MDMA or 'Ecstasy': an Overview of 25 Years of Empirical Research*, 28.4 HUMAN PSYCHOPHARMACOLOGY 289, 289-307 (2013).
[42] 76 FR 65371.
[43] AJ Dickson et al., *Multiple-drug Toxicity Caused by Coadministration of 4-Methylmethcathinone (Mephedrone) and Heroin*, 34.3 J. ANALYTICAL CHEMISTRY 162, 162-166 (2010).

- A 49-year-old female died after snorting approximately 0.5g of mephedrone that she purchased from the Internet. She also consumed alcohol and smoked marijuana. A few hours after taking mephedrone, she complained of a sore chest, vomited, and then collapsed. She was transported to the hospital by emergency services but died despite efforts to resuscitate her. A medical examiner attributed this death to the adverse effects of mephedrone.[44]

- A 19-year-old male died after taking an unknown amount of mephedrone along with alcohol, and MDMA at a party. Others at the party described the 19-year-old as being sweaty and acting strangely and subsequently he collapsed. Emergency services were called and he was taken to the hospital but efforts to resuscitate him were unsuccessful. A medical examiner found mephedrone to be the principal cause of death.[32]

- A 55-year-old female was found dead in bed. Her death was attributed to the combined effects of mephedrone and methadone.[32]

- A 17-year-old male died from injuries sustained in a vehicular collision. While driving on the wrong side of the road he collided head-on with an oncoming car. Mephedrone was detected in his blood and is suspected to have affected the ability of this individual to drive.[32]

- A 36-year-old man died from substantial blood loss that may have led to aggravated heart and blood pressure problems after he was arrested by police for extreme agitation.[45] Mephedrone was identified in the tablets found in the house of the deceased. Toxicological analyses of the post-mortem samples from the decedent detected mephedrone, cocaine, MDMA, oxazepam, midazolam.

- An approximately 30-year-old man was found in a critical state in a staircase. Efforts to save him were unsuccessful. Authors concluded that death was due to fatal mephedrone intoxication.[46]

- Acute mephedrone-related toxicity was analytically confirmed in seven male patients. The most common symptom/sign reported was agitation. Other symptoms/signs included palpitations, chest pain, seizures, headaches (acute sympathomimetic toxidrome).[47]

- Nicholson *et al*. described a case involving a 19-year-old man who presented to the emergency room with central crushing chest pain.[48] Clinical tests showed myocardial

---

[44] PD Maskell et al., *Mephedrone (4-Methylmethcathinone)-related Deaths*, 35.3 J. ANALYTICAL CHEMISTRY 189, 189-191 (2011).
[45] KJ Lusthof et al., *A Case of Extreme Agitation and Death after the Use of Mephedrone in The Netherlands*, 206.1-206.3 FORENSIC SCI. INT'L e93, e93-e95 (2011).
[46] P Adamowicz et al., *Fatal Mephedrone Intoxication – A Case Report*, 37.1 J. ANALYTICAL TOXICOLOGY 37, 37-42 (2013).
[47] DM Wood et al., *Recreational Use of Mephedrone (4-Methylmethcathinone, 4-MMC) with Associated Sypathomimetic Toxicity*,.6.3 J. MED. TOXICOLOGY 327, 327-330 (2010).
[48] PJ Nicholson et al., *Headshop Heartache: Acute Mephedrone 'Meow' Myocarditis*, 96.24 HEART 2051, 2051-2052 (2010).

inflammation. He admitted to ingesting plant food that contained mephedrone. Toxicology screening of biological samples confirmed the presence of mephedrone. No other neurostimulant drugs were detected. He was successfully treated and discharged five days after his admission.

- Debruyne *et al.* reported that seven cases in France related to the use of mephedrone were reported to the Center of Evaluation and Information on Pharmacodependence (Addictovigilance).[49] In one case, a young man was involved in a vehicular accident after snorting mephedrone. His blood tested positive for mephedrone. In another case, an individual used mephedrone in place of cocaine.

- Wood *et al.* reported a case of acute toxicity in the United Kingdom after the abuse of mephedrone.[50] A 22-year-old male presented to the emergency room with sympathomimetic toxicity after ingesting 200 milligrams of mephedrone. He developed palpitation, blurred vision, mydriasis, agitation, tachycardia, and an elevated body temperature. His symptoms resolved after treatment. Mephedrone was the only substance detected in his serum.

- Torrance and Cooper reported the death of four individuals whose blood samples tested positive for mephedrone.[51] These fatalities were not attributed to the sole use of mephedrone but they can be considered to be evidence of the misuse of mephedrone and the subsequent harm they may cause to the user or general public.

Methylenedioxypyrovalerone

Methylenedioxypyrovalerone (MDPV) is closely related in structure to phenethylamines such as the Schedule I and II substances methamphetamine, cathinone, methcathinone, and methylenedioxymethamphetamine (MDMA). MDPV is also structurally related to pyrovalerone, which is a psychoactive drug that was used to treat chronic lethargy and fatigue. There is no evidence that MDPV has a legitimate non-research use, and according to HHS, there are no approved drug products or new drug applications that contain MDPV. MDPV and other cathinone derivatives (including those which bear ring-group substituents) have been reported to induce subjective effects similar to those induced by stimulant drugs of abuse such as cocaine, amphetamine, MDMA, and methcathinone. Indeed, evidence indicates that MDPV is being abused by individuals for its psychoactive effects. Desired effects reported by abusers of synthetic cathinone substances include euphoria, increased sociability, energy, empathy, increased alertness, and improved concentration and focus.

Scientific Evidence of the Drug's Pharmacological Effects

[49] D Debruyne et al., *Mephedrone: a Designer Drug of recent Use in France*, 65.6 THERAPIE 519, 519-524(2010).
[50] DM Wood et al., *Recreational Use of Mephedrone (4-Methylmethcatinone, 4-MMC) with Associated Sympathomimetic Toxicity*, 6.3 J. MED. TOXICOLOGY 327, 327-330 (2010).
[51] H Torrance & G Cooper, *The Detection of Mephedrone (4-Methylmethcathinone) in 4 Fatalities in Scotland*, 202.1-202.3 FORENSIC SCI. INT'L E62, e62-e63 (2010).

In a study that claims MDMA-like drugs can be discerned from methamphetamine-like drugs by measuring a specific locomotor activity (voluntary wheel activity), MDPV is more similar to methamphetamine than to MDMA.[52] In addition, MDPV is a powerful locomotor stimulant like methamphetamine.[53]

Drug discrimination studies indicate that MDPV produces pharmacological effects that are similar to those of methamphetamine and cocaine. As described above, the drug discrimination paradigm is used as an animal model of human subjective effects. This procedure provides a direct measure of stimulus specificity of a test drug in comparison with a known standard drug, or a neutral stimulus (*e.g*. injection of saline water). In the drug discrimination paradigm, if a new drug or substance has discriminative stimulus effects in animals similar to a known drug of abuse, it is highly likely that this new drug will produce pharmacological effects (including subjective effects) in humans that are qualitatively and quantitatively similar to the known drug of abuse and would be similarly abused by humans.[54] Data from a published drug discrimination study indicate that MDPV (ED_{50} = 0.67 mg/kg) fully substitutes for the discriminative stimulus effects produced by methamphetamine (ED_{50} = 0.37 mg/kg) in rats.[55] Data from another published drug discrimination study indicate that MDPV (ED_{50} = 0.03 mg/kg) fully substitutes for the discriminative stimulus effects produced by methamphetamine (ED_{50} = 0.08 mg/kg) in mice.[56] Based on these drug discrimination studies, MDPV is at least as potent if not more potent than methamphetamine. The self-administration study is another behavioral study done in rodents that has been used to predict the abuse liability (*i.e.*, the likelihood that the drug will be abused) of novel substances. Aarde and colleagues reported that MDPV, similar to methamphetamine, was self-administered in rats and rats consistently self-administered a greater amount of MDPV. As a result, the authors concluded that MDPV poses a substantial threat for compulsive use that is potentially greater than that for methamphetamine.[57]

---

[52] P-K Huang et al., *Contrasting Effects of d-Methamphetamine,3,4-Methylenedioxymethamphetamine, 3,4-Methylenedioxypyrovalerone, and 4-Methylmethcathinone on Wheel Activity in Rats*, 126.1 DRUG AND ALCOHOL DEPENDENCE 168, 168-175 (2012).

[53] MH Baumann et al., *Powerful Cocaine-like Actions of 3,4-Methylenedioxypyrovalerone (MDPV), a Principal Constituent of Psychoactive 'Bath Salt' Products*, 38.4 NEUROPSYCHOPHARMACOLOGY 552, 552-562 (2013); WE Fantegrossi et al., *In Vivo Effects of Abused 'Bath Salt' Constituent 3,4-Methylenedioxypyrovalerone (MDPV) in Mice: Drug Discrimination, Thermoregulation, and Locomotor Activity*, 38.4 NEUROPSYCHOPHARMACOLOGY 563, 563-573 (2013); M Gatch et al., *Locomotor Stimulant and Discriminative Stimulus Effects of 'Bath Salt' Cathinones*, 24 BEHAVIORAL PHARMACOLOGY 437, 437-447 (2013); JA Marusich et al., *Pharmacology of Novel Synthetic Stimulants Structurally Related to "Bath Salts" Constituents 3,4-Methylenedioxypyrovalerone (MDPV)*, 87 NEUROPHARMACOLOGY 206, 206-213 (2014).

[54] RI Balster & GE Bigelow, *Guidelines and Methodological Reviews Concerning Drug Abuse Liability Assessment*, 70 DRUG AND ALCOHOL DEPENDENCE s13-40 (2003); LV Panllio & SR Goldberg, *Self-Administration of Drugs in Animals and Humans as a Model and an Investigative Tool* 102.12 ADDICTION 1863, 1863-1870 (2007).

[55] M Gatch et al., *Locomotor Stimulant and Discriminative Stimulus Effects of 'Bath Salt' Cathinones*, 24BEHAVIORAL PHARMACOLOGY 437, 437-447 (2013).

[56] WE Fantegrossi *et al.*, *In Vivo Effects of Abused 'Bath Salt' Constituent 3,4-Methylenedioxypyrovalerone (MDPV) in Mice: Drug Discrimination, Thermoregulation, and Locomotor Activity*, 38.4 NEUROPSYCHOPHARMACOLOGY 563, 563-573 (2013).

[57] SM Aarde et al., *The Novel Recreational Drug 3,4-Methylenedioxypyrovalerone (MDPV) is a Potent Psychomotor Stimulant: Self-administration and Locomotor Activity in Rats*, 71 NEUROPSYCHOPHARMACOLOGY 130, 130-140 (2013); M Gatch et al., *Locomotor Stimulant and Discriminative Stimulus Effects of 'Bath Salt' Cathinones*, 24 BEHAVIORAL PHARMACOLOGY 437, 437-447 (2013); JA Marusich et al., *Pharmacology of Novel Synthetic Stimulants Structurally Related to "Bath Salts" Constituents 3,4-Methylenedioxypyrovalerone (MDPV)*, 87 NEUROPHARMACOLOGY 206, 206-213 (2014).

The Substance's History and Current Pattern of Abuse

DEA forensic laboratories have analyzed drug exhibits received from state, local, or federal law enforcement agencies that were found to contain MDPV. MDPV, like methamphetamine, is commonly encountered in the form of powders, capsules, and tablets. Information from published scientific studies indicate that the most common routes of administration for MDPV is ingestion by swallowing capsules or tablets or nasal insufflation by snorting the powder. The reported average amount of use of MDPV ranged widely (from approximately 25 milligrams – 5 grams) depending on the substance, duration of intake, and route of administration.[58] The dose range for snorting MDPV ranges from as little as 25 milligrams to as much as 5 grams. Even low doses can cause psychoactive effects. Ingestion of high doses of MDPV has been associated with severe adverse effects such as psychosis, paranoia, and death. Similarly, methamphetamine has been reported to cause psychoactive effects at low doses (range from 5 to 30 mg) and psychosis at higher doses.[59] Evidence from poison centers, published case reports, and law enforcement encounters suggest that the main users of MDPV, similar to synthetic cathinones, are young adults. There is evidence that MDPV may be co-ingested with other substances including other synthetic cathinones, pharmaceutical agents, or other recreational substances.

The Scope, Duration and Significance of Abuse

According to forensic laboratory data as reported by the National Forensic Information Laboratory System (NFLIS), MDPV started to be encountered by law enforcement in December 2009. Through January 2017, NFLIS has reported 9,511 law enforcement encounters involving MDPV (query date February 27, 2017, Federal, State, and local laboratories). Additionally, large seizures of MDPV have occurred by CBP.

Risk to Public Health

MDPV has been reported to cause a number of stimulant-like adverse effects. The clinical presentation of intoxication from MDPV is like that seen with methamphetamine and other substances (*e.g.,* cathinone, methcathinone, MDMA, amphetamine, methamphetamine, and cocaine) that have a stimulant effect on the central nervous system. Adverse effects associated with the consumption of MDPV include palpitations, hyperthermia, seizures, hyponatremia, bruxism, sweating, hypertension, tachycardia, headache, thirst, mydriasis, tremor, fever, confusion, psychosis, paranoia, hallucinations, combativeness, agitation, and death. Published case reports describing MDPV related adverse effects are summarized below.

- The death of a 39-year-old male was reported by Wyman *et al.*[60] Family members indicated that the male, who had a history of schizophrenia, depression, and drug abuse,

[58] ADVISORY COUNCIL ON THE MISUSE OF DRUGS, *Consideration of the Cathinones.* (Iversen), London, (Mar. 31, 2010).
[59] CC Cruickshank & KR Dyer, *A Review of the Clinical Pharmacology of Methamphetamine*, 104.7 ADDICTION1085, 1085-1099 (2009).
[60] JF Wyman et al., *Postmortem Tissue Distribution of MDPV Following Lethal Intoxication by "Bath Salts"*, 37 J. ANALYTICAL TOXICOLOGY 182, 182-185 (2013).

had been snorting "bath salts." The subject was found dead in his bed. Empty jars of "bath salts" ("TranQuility" and "Infinity") and synthetic cannabinoids ("Demon" and "Flame") were found in the trash. The cause of death was acute MDPV intoxication.[43]

- A 40-year-old male injected and snorted MDPV and became agitated, aggressive, and suffered from cardiac arrest. He later developed hyperthermia, rhabdomyolysis, coagulopathy, acidosis, anoxic brain injury and died. Other symptoms included mydriasis, labored breathing, and increased heart rate.[61]

- A 39-year-old delusional man with a medical history of depression, back pain, and alcoholism was found outside his residence talking to himself and wandering about in clothes inappropriate for the weather. Law enforcement took the victim to the emergency room. Medical staff noted whitish powder around the mouth of the victim. The victim admitted to using "bath salts." The victim became tachycardic, hyperthermic, followed by bradycardia. After further attempts to save him the victim died. MDPV was identified in samples from the decedent. Autopsy report cited MDPV toxicity to be the primary factor contributing to the death.[62]

- A 46-year-old male was found dead after several days of using the bath salt "Drone." The decedent had complained of weakness, difficulty walking, increased falling, nausea and vomiting prior to his death. He had a history of drug use and diabetes. Toxicology results confirmed MDPV in blood and urine. The cause of death was determined to be diabetic ketoacidosis in a setting of MDPV abuse.[63]

- A 40-year-old male was found dead at his home. The decedent was alleged to have been snorting and smoking bath salts. The decedent had HIV and had taken a variety of medications. Toxicology results confirmed MDPV in blood and urine. Death was determined to be attributed to relevant natural causes in a setting of MDPV abuse.[46]

- Rohrig described the case of a 21-year-old who was struck and killed by a van after he ran into oncoming traffic.[64] A witness reported that the decedent was let out of the car on the side of a local interstate after he acted wildly and belligerently after ingesting "bath salts" and smoking "K2" (a synthetic cannabinoid containing product). MDPV was detected in serum samples from the decedent.

---

[61] BL Murray et al., *Death Following Recreational Use of Designer Drug "Bath Salts" Containing 3,4-Methylenedioxypyrovalerone (MDPV)*, 8 J. MED. TOXICOLOGY 69, 69-75(2012).
[62] K Kesha et al., *Methylenedioxypyrovalerone ("Bath Salts") Related Death: Case Report and Review of the Literature*, 58.6 J. FORENSIC TOXICOLOGY 1654, 1654-1659 (2013).
[63] TH Wright et al., *Deaths Involving Methylenedioxypyrovalerone (MDPV) in Upper East Tennessee*, 58.6 J. FORENSIC TOXICOLOGY, 1558, 1558-1562 (2013).
[64] T Rohrig, California Association of Toxicologist(CAT) Proceedings, *Designer Drugs- The Future of Drug Abuse? Pharmacology of Cathinone Analogs AKA "Bath Salts"*. May 5-6, Napa, CA (2011).

- A 30-year-old man who reportedly spent the day snorting bath salts jumped from a second story window of a hotel. He was found dead in a creek near the hotel. MDPV was detected in blood samples from this individual.[65]

- A 25-year-old man was transported to the emergency department after he was found with marked agitation and altered mental status. He presented with elevated blood pressure, pulse rate and temperature. He also suffered from mydriasis, combativeness, and other symptoms. He was treated at the hospital by extubation, and hemodialysis. Urine tested positive for MDPV. He recovered and was released from the hospital on day 18.[66]

- Sadeg *et al.* described a case of a 47-year-old man who was brought to the emergency department by firemen for behavioral changes with delirious thoughts.[67] His wife described the man as restless and soliloquizing for the last three days. At the hospital the patient was suspicious, anxious, and agitated. He suffered an acute episode of delirium with persecution, megalomaniac themes and focused on the feeling of being watched and monitored as well as having the power to remotely control electrical circuits. He was treated with antipsychotics and benzodiazepines. Testing of products purchased by the patient on the Internet and ingested identified MDPV. The patient reported experiencing euphoria, increase energy with restlessness, empathy, and openness. Analysis of serum of patient also identified MDPV. The patient recovered the following day and treatment ceased. However, three weeks after the patient was discharged he took again to craving the MDPV-containing product which led to a new occurrence of psychosis with visual hallucinations.

- Penders and Gestring reported three cases of paranoid psychotic delirium (presenting as paranoid hallucinatory psychosis) following the alleged abuse of "bath salts" containing MDPV.[68] Interestingly, in these three cases of delirium, some memory loss was reported during the time of abuse of the "bath salts."

- Kriikku *et al.* described cases involving drivers suspected of being under the influence of drugs (DUID) in Finland.[69] Blood samples from individuals suspected of DUIDs from August 2009 to August 2010 were screened for the presence of MDPV. Of 3000 samples tested, 259 were found to be positive for MDPV. The concentration of MDPV ranged from 0.020 – 8.4 mg/L (limit of detection is 0.003 mg/L). Although other drugs may have been detected, the authors concluded that MDPV is a significant problem in DUID cases in Finland.

---

[65] JW Spencer et al., *Acute Psychiatric, Cardiopulmonary, and Neurologic Effects of Laboratory-Confirmed Use of Methylenedioxypyrovalerone (MDPV) "Bath Salts"*, 49 CLINICAL TOXICOLOGY (Phila)515, 515–562 (2011).
[66] HA Borek & CP Holstege, *Hyperthermia and Multiorgan Failure After Abuse of "Bath Salts" Containing 3,4-Methylenedioxypyrovalerone*, 60.1 ANNUALS OF EMERGENCY MEDICINE103, 103-105 (2012).
[67] N Sadeg et al., *Case Report of Cathinone-Like Designer Drug Intoxication Psychosis and Addiction with Serum Identification*, 13.1 ADDICTIVE DISORDERS & THEIR TREATMENT 38, 38-43 (2014).
[68] TM Penders & R Gestring, *Excited Delirium Following Use of MDPV: 'Bath Salts'*. 36.2 GEN. HOSPITAL PSYCHIATRY 647, 647-650 (2011).
[69] P Kriikku et al., *New Designer Drug of Abuse: 3,4-Methylenedioxypyrovalerone (MDPV). Findings from Apprehended Drivers in Finland*. 210.1-210.3 FORENSIC SCI. INT'L 195, 195-200 (2011).

- A 47-year-old male with a history of psychoactive substance abuse experienced severe adverse effects after ingesting "bath salts" that contained MDPV.[70] Routine drugs of abuse were not detected in biological specimens from the patient. Adverse effects included terrifying hallucinations, coma, seizure, multi-organ failure and ischemic colitis. His symptoms resolved after treatment.

In summary the scientific, medical, case reports, and law enforcement information details serious adverse health effects directly attributable to the abuse of methylone, mephedrone, or MDPV. These substances have been directly compared to substances listed under the sentencing guidelines as to effect and potency.

Synthetic Cannabinoids

Although the abuse of JWH-018, AM-2201 and other synthetic cannabinoids are a more recent challenge for law enforcement and public health, the design and investigation of many of these substances date back more than 20 years. Synthetic cannabinoids are cannabinoid agonists that target the cannabinoid receptor 1. These substances are functionally similar to THC, the main psychoactive ingredient in marijuana. In 2008, synthetic cannabinoids were detected in herbal smoking blends and many generations have been encountered since the initial finding in an attempt to stay ahead of regulatory controls. According to some reports the intoxication or high produced by synthetic cannabinoids is more intense than that produced by cannabis. The increased affinity of these substances for the cannabinoid receptor relative to THC and the greater activation of the receptor are attributable to the greater potency of these substances relative to marijuana.[71] Thus, an identical amount of JWH-018 or AM-2201 to THC would be expected to show greater intoxication.[72]

JWH-018 and AM-2201 are synthetic cannabinoids and share pharmacological similarities with THC. Serious adverse health effects, as discussed below, are associated with the ingestion of these synthetic cannabinoids. The term "Spice" is commonly used to describe the diverse types of herbal blends that encompass synthetic cannabinoids being laced on plant material for recreational use. Since the emergence of these smokeable herbal product blends, there has been a relatively high incidence of adverse health effects.

These substances are used for their psychoactive properties, and are promoted as "legal" alternatives to marijuana. Synthetic cannabinoids in bulk powder form are smuggled from overseas via common carrier into the United States, and final products for distribution are made in the United States. The powdered forms of JWH-018 or AM-2201 are typically dissolved in solvents (*e.g.*, acetone) before being applied to a plant material or dissolved in a propellant

---

[70] G Gavriilidis et al., *"Bath Salts" Intoxication with Multiorgan Failure and Left-sided Ischemic Colitis: A Case Report.* 19.4 HIPPOKRATIA 363, 363-365. (2015).

[71] BK Atwood et al., *JWH018, a Common Constituent of 'Spice' Herbal Blends, is a Potent and Efficacious Cannabinoid CB1 Receptor Agonist*, 160 BRITISH PHARMACOLOGICAL SOC'Y 585, 585-593 (2010); G Griffin et al., *Evaluation of Cannabinoid Receptor Agonists and Antagonists Using the Guanosine-5'-O-(3-[^{35}S]thio)-triphosphate Binding Assay in Rat Cerebellar Membranes*, 285.2 J. PHARMACOLOGY AND EXPERIMENTAL THERAPEUTICS, 553, 553-560 (1998).

[72] JL Wiley et al., *Hijacking of Basic Research: The Case of Synthetic Cannabinoids*. RTI Press publication No. OP-0007-1111. Research Triangle Park, NC: RTI Press. Retrieved from http://www.rti.org/rtipress.

intended for use in e-cigarette devices. Law enforcement personnel have encountered various application methods including buckets or cement mixers in which plant material and one or more synthetic cannabinoids, such as JWH-018 and/or AM2201, are mixed together, as well as large areas where the plant material is spread out so that a dissolved synthetic cannabinoid can be applied directly.

Adverse health effects following ingestion of JWH-018 have been reported to include short-term memory defects, hypertension, delusions, chest pain, intractable abdominal pain, nausea, vomiting, tachycardia, anxiety, paranoia, auditory and visual hallucinations, seizure, coma and death.[73] Adverse effects following ingestion of AM-2201 have been reported to include convulsions, intractable abdominal pain, nausea, vomiting, confusion, disorientation, psychiatric complications including self-induced lethal trauma and death.[74]

On March 1, 2011, a final order to temporarily place JWH-018 into Schedule I of the CSA was published in the Federal Register (76 FR 11075) upon finding that this substance poses an imminent threat to public safety. On July 9, 2012, JWH-018, AM2201, and 13 other synthetic cannabinoids were permanently placed into Schedule I of the CSA following congressional action (section 1152 of Food and Drug Administration Safety and Innovation Act (FDASIA)). The FDASIA also amended the CSA by adding the term "cannabimimetic agents" which was defined to include substances within defined structural classes that are demonstrated by binding studies and functional assays to be cannabinoid receptor type 1 (CB1 receptor) agonists.

The data available and reviewed for JWH–018 and AM-2201 indicate that these synthetic cannabinoids have a high potential for abuse, no currently accepted medical use in treatment in the United States and lack an accepted safety for use under medical supervision.

JWH-018

JWH-018 is a synthetic cannabinoid of the indole-derived cannabinoids and was one of the initial synthetic cannabinoids identified in the smokable herbal products. The synthesis and evaluation of JWH-018 had been published in the scientific literature many years prior to discovery of the substance on plant material. Early clinical reports documenting JWH-018 abuse note patients presenting with symptoms atypical of marijuana use, noting extreme agitation, syncope, tachycardia, and visual and auditory hallucinations.[75]

[73] SMR Gurney et al., *Pharmacology, Toxicology, and Adverse Effects of Synthetic Cannabinoid Drugs*, 26.1 FORENSIC SCI. REV., 54, 54-78 (2014).
[74] S Gurney et al., *Pharmacology, Toxicology, and Adverse Effects of Synthetic Cannabinoid Drugs*, 26.1 FORENSIC SCI. REV. 53, 54-78 (2014); A. Patton et al., *K2 Toxicity: Fatal Case of Psychiatric Complications Following AM2201 Exposure*, 58.6 J. FORENSIC SCI. 1676, 1676-1680 (2013).
[75] D Vearrier & KC Osterhoudt, *A Teenager With Agitation: Higher Than She Should Have Climbed*, 26 PEDIATRIC EMERGENCY CARE 462, 462–465 (2010); H Muller et al., *The Synthetic Cannabinoid Spice as a Trigger for an Acute Exacerbation of Cannabis Induced Recurrent Psychotic Episodes*, 118 SCHIZOPHRENIA RES. 309, 309–310 (2010); S Every-Palmer, *Warning: Legal Synthetic Cannabinoid-Receptor Agonists Such As JWH-018 May Precipitate Psychosis in Vulnerable Individuals*, 105 ADDICTION 1859, 1859–1860 (2010); AB Schneir et al., *"Spice" Girls: Synthetic Cannabinoid Intoxication*, 40.3 J. EMERGENCY MED. 296, 296-299 (2010).

Scientific Evidence of the Substance's Pharmacological Effect

The effect of the acute administration of JWH-018 (0.01-6 mg/kg i.p.) on sensorimotor function in male CD-1 mice was compared to those effects caused by the administration of THC (0.01-6 mg/kg i.p.).[76] JWH-018 inhibited sensorimotor responses at the lower doses (0.01-0.1 mg/kg), reduced spontaneous locomotion at intermediate to high doses (1-6 mg/kg) and induced convulsions, myoclonia and hyperreflexia at high dose (6 mg/kg). THC reduced sensorimotor responses in mice but it did not inhibit spontaneous locomotion and it did not induce neurological alterations. JWH-018 was more potent than THC in this study and the greater activity could be due to the higher affinity at the CB1 receptor.

Cannabinoid agonists elicit a characteristic cluster of effects in laboratory animals. This cluster of classical endpoints of analgesia, hypothermia, catalepsy, and locomotor suppression is known as the cannabinoid tetrad and is a classic test. JWH-018 elicits characteristic tetrad effects in mice after intraperitoneal injection.[77] Wiley and colleagues found JWH-018 to be 2.5 times more potent than THC in the tetrad battery.[78] In another tetrad study, JWH-018 was found to be more potent than THC by inhalation and intraperitoneal injection.[79] These results demonstrate that JWH-018 elicits a THC-like profile in a test battery in mice and would be likely to produce cannabimimetic discriminative stimulus effects in rodents, confirmed below, and would be predicted to have marijuana-like effects in humans. JWH-018 displayed greater potency than THC in the three studies detailed above. Drug discriminative studies selective for cannabinoid agonism is a powerful tool comparing effects of cannabinoids and is highly selective for CB1 receptor. The results are highly predictive of subjective effects for cannabis.[80] This is important for it would be inappropriate to dose humans with substances such as JWH-018 in the absence of safety evaluations. Data from published drug discrimination studies indicate that JWH-018 is similar to THC in its discriminative stimulus effects and it substitutes fully for the discriminative stimulus effects of THC in animals trained to discriminate THC from its vehicle.[81] This study reported potencies (ED_{50}) of 0.18 mg/kg and 0.56 mg/kg for JWH-018 and THC, respectively. Thus JWH-018 is approximately three times more potent than THC in this assay. Jarbe *et al.* found JWH-018 to be approximately 8 times more potent than THC in rats.[82] In monkeys, the ED_{50} values were reported as 0.013 mg/kg for JWH-018 and 0.044 for THC.[83]

---

[76] A Ossato et al., *JWH-018 Impairs Sensorimotor Functions in Mice*, 300 NEUROSCIENCE 174, 174-188 (2015).
[77] LK Brents et al., *Monohydroxylated Metabolites of the K2 Synthetic Cannabinoid JWH-073 Retain Intermediate to High Cannabinoid 1 Receptor (CB1R) Affinity and Exhibit Neutral Antagonist to Partial Agonist Activity*, 83.7 BIOCHEMISTRY AND PHARMACOLOGY 952, 952–961 (2012).
[78] JL Wiley et al., *1-Pentyl-3-Phenylacetylindoles and JWH-018 Share In Vivo Cannabinoid Profiles in Mice*, 123.1-123.3 DRUG AND ALCOHOL DEPENDENCE 148, 148–153 (2012).
[79] R Marshell et al., *In Vivo Effects of Synthetic Cannabinoids JWH-018 and JWH-073 and Phytocannabinoid Δ^9-THC in Mice: Inhalation Versus Intraperitoneal Injection*, 124 PHARMACOLOGY BIOCHEMISTRY AND BEHAVIOR 40, 40-47 (2014).
[80] RL Balaster & WR Prescott, *Δ^9-Tetrahydrocannabinol Discrimination in Rats as a Model for Cannabis Intoxication*, 16 NEUROSCIENCE AND BIOBEHAVIORAL REV. 55, 55-62 (1992).
[81] MB Gatch & MJ Forester, *Δ^9-Tetrahydrocannabinol-Like Discriminative Stimulus Effects of Compounds Commonly Found in K2/Spice, 8* BEHAVIORAL PHARMACOLOGY 750, 750-757 (2014).
[82] Jarbe et al., *Cannabinergic Aminoalkylindoles, Including AM678=JWH018 Found in 'Spice', Examined Using Drug (Δ9-THC) Discrimination for Rats*, 22.5-22.6 BEHAVIORAL PHARMACOLOGY 498, 498–507 (2011).
[83] BC Ginsburg et al., *JWH-018 and JWH-073: Δ^9-Tetrahydrocannabinol-Like Discriminative Stimulus Effects in Monkeys*, 340.1 J. PHARMACOLOGY AND EXPERIMENTAL THERAPEUTICS 37, 37-45 (2012).

Adverse Effects/Deaths Involving JWH-018

Adverse health effects following ingestion of JWH-018 (as confirmed by toxicology results) have included: short-term memory defects, hypertension, delusions, chest pain, intractable abdominal pain, nausea, vomiting, tachycardia, anxiety, paranoia, auditory and visual hallucinations, seizure, coma and death.[84]

JWH-018 was confirmed in 8 of 29 synthetic cannabinoid presentations in response to recreational use.[85] The acute adverse reactions displayed included restlessness/agitation, changes in perception/hallucinations, vertigo, somnolence, anesthesia/paraesthesis, shivering/shaking, tachycardia, other electrocardiographic changes, hypertension, thoratic pain, nausea/vomiting, mydriasis, and conjunctival hyperaemia. Seizures developed in 1 of the 8 JWH-018 patients.

- According to the data gathered by DEA, in September 2011, a 19-year-old male complained of cramping and vision changes, and was transported to a local emergency facility for further assessment. The victim was admitted but ultimately died four days later. Upon autopsy, postmortem analysis demonstrated extensive multi-organ failure. Postmortem toxicology detected JWH-018N, a metabolite of JWH-018. The cause of death was determined to be excited delirium which was associated with drug toxicity. The manner of death was ruled accidental.

- In a case report published by Wikstrom *et al.*, a 26-year-old male ingested multiple synthetic substances, ultimately resulting in his death.[86] Postmortem toxicology results obtained during autopsy revealed a high concentration of methoxetamine (MXE), along with three different synthetic cannabinoids (AM694, AM2201 and JWH-018). Authors stated that the high MXE concentration pointed to an acute fatal intoxication with MXE; however, the presence of the three synthetic cannabinoids may have contributed to the death.

NFLIS reports for JWH-018

According to forensic laboratory data as reported by the National Forensic Information Laboratory System[87,88] (NFLIS), JWH-018 was first encountered by law enforcement in August

[84] SMR Gurney et al., *Pharmacology, Toxicology, and Adverse Effects of Synthetic Cannabinoid Drugs*, 26.1 FORENSIC SCI. REV. 54, 54-78 (2014).
[85] M Hermanns-Clausen et al., *Acute Toxicity Due to the Confirmed Consumption of Synthetic Cannabinoids: Clinical and Laboratory Findings*, 108.3 ADDICTION 1-11 (2012).
[86] M Wikstrom et al., *An Accidental Fatal Intoxication with Methoxetamine*, 37.1 J. ANALYTICAL TOXICOLOGY PSYCHOPHARMACOLOGY 43, 43-46 (2013).
[87] The NFLIS is a program of the DEA, Diversion Control Division. NFLIS systematically collects drug identification results and associated information from drug cases submitted to and analyzed by Federal, State and local forensic laboratories. NFLIS represents an important resource in monitoring illicit drug abuse and trafficking, including the diversion of legally manufactured pharmaceuticals into illegal markets. NFLIS is a comprehensive information system that includes data from forensic laboratories that handle approximately 98% of an estimated nearly 1.0 million distinct annual State and local drug analysis cases. NFLIS includes drug chemistry results from completed analyses only.
[88] While NFLIS data is not direct evidence of abuse, it can lead to an inference that a drug has been diverted and abused. See 76 Fed. Reg. 77330, 77332, (Dec. 12, 2011).

2009. Through January 2017, NFLIS has reported 7,144 law enforcement encounters involving JWH-018 (query date February 27, 2017, Federal, State, and local laboratories).

Summary JWH-018

JWH-018 is comparable pharmacologically to the Schedule I substance THC. JWH-018 binds to actives the CB1 receptor, the same receptor as THC. In standard behavioral studies, JWH-018 is at least three times more potent than THC. It was not found to be less potent than THC in any study. Ginsburg and colleagues stated that JWH-018 has abuse liability similar to THC and possibly greater and that anecdotal reports of intoxication suggest alternative sites of action.[89] Further, the short duration and increased efficacy of JWH-018 could lead to more frequent and habitual use.[47]

AM-2201

AM-2201 is a synthetic cannabinoid of the indole-derived cannabinoids and was encountered around the time JWH-018 was temporarily controlled by the DEA. AM-2201 is similar in structure to JWH-018, differing by the addition of a single fluorine atom. Information regarding AM-2201 was initially published in the patent literature many years prior to the encounter of the substance by law enforcement. Early clinical reports documenting the abuse of AM-2201 note patients present to emergency departments with a host of symptoms many of which are atypical of marijuana use, noting extreme agitation, syncope, tachycardia, and visual and auditory hallucinations.[90]

Scientific Evidence of the Substance's Pharmacological Effect

Data from a published drug discrimination studies indicate that AM-2201 is similar to THC in its discriminative stimulus effects and it substitutes fully for the discriminative stimulus effects of THC in animals trained to discriminate THC from its vehicle.[91] This study reported potencies (ED_{50}) of 0.11 mg/kg and 0.56 mg/kg for AM-2201 and THC, respectively. Thus AM2201 is approximately five times more potent than THC in this assay.

Adverse Effects/Deaths Involving AM-2201

[89] BC Ginsburg et al., *JWH-018 and JWH-073: Δ^9-Tetrahydrocannabinol-Like Discriminative Stimulus Effects in Monkeys*, 340.1 J. PHARMACOLOGY AND EXPERIMENTAL THERAPEUTICS 37, 37-45 (2012).
[90] D Vearrier & KC Osterhoudt, , 26 PEDIATRIC EMERGENCY CARE462, 462–465 (2010); H Muller *et al*., *The Synthetic Cannabinoid Spice as a Trigger for an Acute Exacerbation of Cannabis Induced Recurrent Psychotic Episodes*, 118 SCHIZOPHRENIA RES.309, 309–310 (2010); S Every-Palmer, *Warning: Legal Synthetic Cannabinoid-Receptor Agonists Such As JWH-018 May Precipitate Psychosis in Vulnerable Individuals*, 105 ADDICTION 1859, 1859–1860 (2010); AB Schneir et al., *"Spice" Girls: Synthetic Cannabinoid Intoxication*, 40.3 J. EMERGENCY MED. 296, 296-299 (2010).
[91] MB Gatch & MJ Forester, *Δ^9-Tetrahydrocannabinol-Like Discriminative Stimulus Effects of Compounds Commonly Found in K2/Spice*, 8 BEHAVIORAL PHARMACOLOGY 750, 750-757 (2014).

Adverse effects following ingestion of AM-2201 (as confirmed by toxicology results) have included: convulsions, intractable abdominal pain, nausea, vomiting, confusion, disorientation, psychiatric complications including self-induced lethal trauma and death.[92]

- In August 2011, a 23-year-old male suffered self-inflicted lethal trauma in the form of sharp-force neck wounds following ingesting a synthetic cannabinoid. A high concentration of AM-2201 was found in both postmortem blood and evidence collected.[93]

- According to the data gathered by DEA, in February 2012, a 26-year-old male was found dead in his residence. He had a history of abusing natural and synthetic cannabinoids. The autopsy was essentially negative, however the comprehensive postmortem toxicology analysis revealed presence of three synthetic cannabinoids in the blood (AM-2201, JWH-122 and JWH-210), results further confirmed by an outside laboratory. The cause of death is ascribed to "sudden cardiac death associated with the use of synthetic cannabinoids. The manner of death is classified as accidental.

- According to the data gathered by DEA, in March 2012, a 16-year-old male was found dead in a hot tub at his parent's residence. The medical examiner concluded that the young man was intoxicated by the synthetic cannabinoid AM-2201 at the time of his death. Results of toxicology testing for both the decedent's blood and evidence collected were positive for AM-2201. Detailed blood toxicological tests revealed no additional therapeutic or illicit drugs that could have caused or contributed to his death. A full autopsy showed no evidence of natural diseases or significant traumatic injuries. The manner of death was classified as accidental.

- In a case report published by Wikstrom *et al.*, a 26-year-old male ingested multiple synthetic substances, ultimately resulting in his death.[94] Postmortem toxicology results obtained during autopsy revealed a high concentration of methoxetamine (MXE), along with three synthetic cannabinoids (AM-694, AM-2201 and JWH-018). Authors stated that the high MXE concentration pointed to an acute fatal intoxication with MXE; however, the presence of the three synthetic cannabinoids may have contributed to the death.

- A 19-year-old male in his normal state of health had a witnessed generalized 1- to 2-min convulsion while smoking a product "Happy Tiger Incense."[95] He vomited and had second generalized convulsions during transport. On admission to the emergency department, he had blood pressure 177/82 mm Hg, heart rate 84 beats/min. JWH-018, JWH-081, JWH-250, and AM-2201 were identified in the product.

---

[92] SMR Gurney et al., *Pharmacology, Toxicology, and Adverse Effects of Synthetic Cannabinoid Drugs*, 26.1 FORENSIC SCI. REV. 53, 53-78 (2014); AL Patton et al., *K2 Toxicity: Fatal Case of Psychiatric Complications Following AM2201 Exposure*, 58.6 J. FORENSIC SCIENCES 1676, 1676-1680 (2013).

[93] AL Patton et al., *K2 Toxicity: Fatal Case of Psychiatric Complications Following AM2201 Exposure*, 58.6 J. FORENSIC SCI., 1776, 1676-1680 (2013).

[94] M Wikstrom et al., *An Accidental Fatal Intoxication with Methoxetamine*, 37.1 J. ANALYTICAL TOXICOLOGY PSYCHOPHARMACOLOGY 43, 43-46 (2013).

[95] AB Schnier & T Baumbacher, *Convulsions Associated with the Use of a Synthetic Cannabinoid Product*, 8 J. MED.L TOXICOLOGY 62, 62-64 (2012).

- A 20-year-old male smoked the product "Black Mamba" and rapidly after smoking, he had a generalised self-terminating tonic-clonic convulsion.[96] After 2 hours of observation in the Emergency Department (ED), the patient self-discharged against medical advice. Analysis of urine detected metabolites of AM-2201; no other drugs were detected on extensive analytic screening.

NFLIS reports for AM-2201

According to forensic laboratory data as reported by the National Forensic Information Laboratory System (NFLIS), AM-2201 was first encountered by law enforcement in February 2010. Through May 2015, NFLIS has reported 24,165 law enforcement encounters involving AM-2201 (query date February 27, 2017, Federal, State, and local laboratories). In 2013, AM-2201 was the most commonly reported synthetic cannabinoid in drug seizures and was the eighth most encountered substance by law enforcement. It ranked above common substances of abuse such as amphetamine at #11 and PCP at #19 of all drugs reported by state and local forensic labs.

Summary AM-2201

AM-2201 is comparable pharmacologically to the Schedule I substance THC. AM-2201 binds to actives the CB1 receptor, the same receptor as THC. In standard behavioral studies, AM-2201 is at least 5-times more potent than THC. It was not found to be less potent than THC in any study.

In summary, pharmacological studies and clinical reports detail the drug effects of JWH-018 and AM-2201. Animal studies are directly compared to THC and demonstrate an increased potency of JWH-018 and AM-2201 relative to THC. Additionally, serious adverse effects including coma, seizures and death following use of products containing JWH-018 and/or AM-2201 have been documented and law enforcement has detailed information regarding the trafficking and manufacture of the substances and their respective products.

Methylenedioxymethamphetamine

Methylenedioxymethamphetamine (MDMA) is a Schedule I controlled substance, meaning it has a high potential for abuse and no approved medical use. It is well established that MDMA has powerful pharmacological effects and is being abused. The substance has the capacity to cause lasting physical harm and continues to be a threat to public health and safety.[97] As a result of the intense euphoria common to MDMA, there is depletion of neurotransmitters resulting in depression and common to other drugs of abuse, MDMA triggers substance induced anxiety, panic, psychosis, and depression.

The Sentencing Commission's sentencing guidelines for MDMA, originally based on research that demonstrated neurotoxicity in users, has been strengthened since 2001 by ongoing

[96] D McQuade et al., *First European Case of Convulsions Related to Analytically Confirmed Use of the Synthetic Cannabinoid Receptor Agonist AM-2201*, 69.3 EUROPEAN J. CLINICAL PHARMACOLOGY 373, 373-376 (2013).
[97] AC Parrott, *MDMA is Certainly Damaging after 25 Years of Empirical Research: a Reply and Refutation of Doblin et al*, 29.2 HUMAN PSYCHOPHARMACOLOGY 109, 109-119 (2014).

research and publications utilizing updated and more precise measurements which repeatedly conclude that MDMA, even while taken in low doses, is neurotoxic. The neurochemistry and adverse health effects of MDMA have not changed. The substance continues to be both reinforcing and a catalyst for neurological disorders. There is a misbelief among users that the drug is safe even amidst the reports of severe acute toxicity and deaths. Particularly concerning is the rise in MDMA use by teenagers. The number of 10th and 12th grade students that have used MDMA over the past year is approaching the highest levels seen in the past decade, while over the same time period, there has been a dramatic drop in students in grades 8, 10 and 12 who feel there is a "great risk" in using MDMA once or twice, demonstrating that the perception that MDMA is a safe drug is intensifying.[98]

As described by the National Institute on Drug Abuse (NIDA), MDMA is a synthetic, psychoactive drug that is chemically similar to the stimulant methamphetamine and the hallucinogen mescaline. MDMA is a powerful recreational drug of abuse resulting in toxic outcomes to serotonin neurons within the cortex and the hippocampus, amongst other areas.[99] The desired effects of MDMA have included increased energy, euphoria and positive social and emotional feelings, accompanying these effects are a host of harms to include potential hypertension (increased blood pressure), hyperthermia (increased body temperature) and hyponatremia (electrolyte disturbance resulting in low levels of sodium) exacerbated by antidiuresis (reduced urine volume). There have been a number of peer-reviewed published studies clearly demonstrating the neurotoxicity of MDMA, especially in the form of a decrease in serotonin transporter (SERT) density and binding following MDMA use.[100] In addition to imaging studies confirming that MDMA exposure can lead to neurotoxicity, multiple recent studies have demonstrated the negative effects of MDMA use on memory. Results of clinical testing of MDMA users have demonstrated the following: (1) abnormal function of the hippocampus during memory function tests;[101] (2) significantly worse performance of male MDMA users on the tasks that correlate to cognitive flexibility and on the combined executive function task;[102] (3) using fMRI, MDMA was shown to be associated with reduced associative memory performance;[103] (4) a recently published meta-analysis of multiple studies regarding MDMA users reduced the outcomes to a single common denominator to see the average effect and concluded that there was a significant decrement in the MDMA user as compared to control subjects regarding verbal memory;[104] and (5) cortex deficiencies during a word recognition task

---

[98] National Press Release, LD Johnston et al., *Marijuana Use Continues to Rise Among U.S. Teens, While Alcohol Use Hits Historic Lows*, University of Michigan News Service, Ann Arbor, MI (December 14, 2011), *available at* http://www.monitoringthefuture.org/press.html (last visited Mar. 2, 2017).

[99] SJ Kish et al., *Decreased Cerebral Cortical Serotonin Transporter Binding in Ecstasy Users: a Positron Emission Tomography/[(11)C]DASB and Structural Brain Imaging Study*, 133 BRAIN, 1779, 1779-1797 (2010).

[100] UD McCann et al., *Positron Emission Tomographic Evidence of Toxic Effect of MDMA ("Ecstasy") on Brain Serotonin Neurons in Human Beings*, 352.9138 LANCET 1433, 1433-1437 (1998); RL Cowan, *Neuroimaging Research in Human MDMA Users: a Review,189.4* PSYCHOPHARMACOLOGY (BERL) 539, 539-556 (2007).

[101] LK Jacobsen et al., *Preliminary Evidence of Hippocampal Dysfunction in Adolescent MDMA ("Ecstasy") Users: Possible Relationship to Neurotoxic Effects*, PSYCHOPHARMACOLOGY (BERL)173, 3-4, 383-90 (2004).

[102] NA von Geusau et al., 175.3 *Impaired Executive Function in Male MDMA ("ecstasy") Users*, PSYCHOPHARMACOLOGY (BERL) 331, 331-41 (2004).

[103] G Jager et al., *Assessment of Cognitive Brain Function in Ecstasy Users and Contributions of Other Drugs of Abuse: Results From an FMRI Study*, 33.2 NEUROPSYCHOPHARMACOLOGY 247, 247-258 (2008).

[104] G Rogers et al., *The Harmful Health Effects of Recreational Ecstasy: a Systematic Review of Observational Evidence*, 13.6 HEALTH TECH. ASSESSMENT xii, iii-iv, ix-xii, 1-315(2009).

in MDMA users.[105] Lastly, in an even more compelling argument that MDMA exposure can lead to long-lasting neurotoxicity, Morgan *et al.* looked at verbal memory between current and former MDMA users, as well as polydrug users and control volunteers with no prior drug use history, and demonstrated a deficiency in verbal memory in those users who were abstinent from MDMA use on average for two years prior to testing.[106]

Clinical case reports document that regular MDMA use can be associated with chronic psychiatric symptoms after cessation of drug use. In addition to neurocognitive and neurobehavioral deficits linked to MDMA's toxicity, serious cardiovascular and respiratory complications and liver damage have been reported in connection with MDMA use. A case series published in the Journal of Intensive Care Medicine described twelve patients that presented to the emergency department with MDMA toxicity resulting in 4 patients with permanent neurological, musculoskeletal and/or renal deficits and 2 deaths, all directly resultant from MDMA ingestion.[107] Other overdose events have been reported and some with tragic outcomes.[108]

Similar to other drugs of abuse, studies demonstrate MDMA dependence is associated with intensity and lifetime use.[109] MDMA-associated overdoses commonly occur with polysubstance use, possibly used to enhance the effects of the drug. In the absence of national data for MDMA overdose deaths, the Florida Department of Law Enforcement maintains a database for drug-related deaths in Florida. From 2003 to 2010, there were a total of 388 MDMA-related deaths and MDMA was implicated as the cause of death in 86 of these deaths. This remains especially concerning as MDMA pills have increased in the amount of MDMA they contain in recent years.[110]

MDMA remains a dangerous drug of concern and the short- and long-term adverse health effects are well documented. DEA continues to encounter MDMA in our investigations. Also, morbidity and mortality information continues to be collected connected to MDMA abuse. MDMA is not a benign drug, as some suggest.

---

[105] AP Burgess et al., *Event Related Potential (ERP) Evidence for Selective Impairment of Verbal Recollection in Abstinent Recreational Methylenedioxymethamphetamine ("Ecstasy")/Polydrug Users*, 216.4 PSYCHOPHARMACOLOGY (BERL) 545, 545-556 (2011).

[106] MJ Morgan et al., *Ecstasy (MDMA): Are the Psychological Problems Associated With Its Use Reversed By Prolonged Abstinence?*, 159.3 PSYCHOPHARMACOLOGY (BERL) 294, 294-303 (2002).

[107] P Armenian et al., *Multiple MDMA (Ecstasy) Overdoses at a Rave Event: A Case Series*, 28.4 J, INTENSIVE CARE MED. 252, 252-258 (2012).

[108] Morbidity and Mortality Weekly Report, *Ecstasy Overdoses at a New Year's Eve Rave – Los Angeles, CA, 2010*. CENTER FOR DISEASE CONTROL 59, 22, 677-681 (June 11, 2010); Morbidity and Mortality Weekly Report, *Illness and Deaths Among Persons Attending an Electronic Dance Music Festival – New York City, 2013*. CENTER FOR DISEASE CONTROL 63, 50, 1195-1198 (December 19, 2014); CM Milroy, *"Ecstasy" Associated Deaths: What is the Fatal Concentration? Analysis of a Case Series*, 7.3 FORENSIC SCI. MED. AND PATHOLOGY 248, 248-252 (2011); F Schifano, *A Bitter Pill. Overview of Ecstasy (MDMA, MDA) Related Fatalities*, 173 PSYCHOPHARMACOLOGY (BERL)242, 242-248 (2004).

[109] N Bruno & PP Battaglini, *Integrating Perception and Action Through Cognitive Neuropsychology (Broadly Conceived)*, 25 COGNITIVE NEUROPSYCHOLOGY 5, 5-7, (2008); JW Hopper et al., *Incidence and Patterns of Polydrug Use and Craving for Ecstasy in Regular Ecstasy Users: an Ecological Momentary Assessment Study*, 83.3 DRUG AND ALCOHOL DEPENDENCE 221, 221-235 (2006).

[110] *Recent Changes in Europe's MDMA/Ecstasy Market*, EUROPEAN MONITORING CENTRE FOR DRUGS AND DRUG ADDICTION, (EMCCDA Rapid communication, Publication Office of the E.U., Luxembourg), April 2016.

- - -

Thank you for the opportunity to share the views of the Department of Justice. We look forward to working with the Commission on this important issue.

Gregory B. Dudley, Ph.D.
Eberly Family Distinguished Professor
Chair, C. Eugene Bennett Department of Chemistry
West Virginia University

Dr. Dudley is the Eberly Family Distinguished Professor and Chair of the C. Eugene Bennett Department of Chemistry at West Virginia University since 2016. Previously, he was on the faculty in the Department of Chemistry and Biochemistry at the Florida State University (FSU) from 2002–2016, during which time he also served (first informally, then formally) on the Graduate Faculty in the College of Pharmacy and Pharmaceutical Sciences at Florida A&M University in Tallahassee, FL. In addition to his numerous scientific publications, Dr. Dudley has provided expert testimony in many federal and state court cases involving synthetic controlled substances.

Dr. Dudley received a Bachelor of Arts in chemistry from Florida State University in 1995 and a Ph.D. in organic chemistry from the Massachusetts Institute of Technology in 2000. After leaving MIT, he was an NIH Research Fellow in the Molecular Pharmacology and Chemistry program at the Memorial Sloan–Kettering Cancer Center (MSKCC) in New York from 2000–2002.

OPINION TESTIMONY BEFORE THE US SENTENCING COMMISSION

Gregory B. Dudley, Ph.D.

Introduction

In this statement, I provide personal opinions and recommendations on various ways to improve consistency, clarity, and coverage in the Sentencing Guidelines. I address several points, as highlighted in the outline below. These opinions are informed by the scientific literature, careful review of the current Sentencing Guidelines, and analysis and observations from having served as an expert witness at sentencing hearings over the past few years. The Sentencing Guidelines are generally logical and internally consistent in the structured guidance they provide for sentencing in cases involving drug-related offenses. However, there are specific areas in which the internal consistency and/or clarity can be improved, as well as additional coverage that is made necessary by emerging designer drugs. I focus my attention on a few of these areas. Specific recommendations include:

1. Remove inconsistencies and perceived ambiguities; provide disambiguation instruction
    a. THC vs. marijuana
    b. Synthetic cannabinoid substance vs. synthetic marijuana
    c. What if two or more substances can be identified as the "most closely related"?
2. Add representative new designer drugs (synthetic cannabinoids and cathinones)
    a. Synthetic cannabinoids: JWH-018 and AB-FUBINACA
    b. Synthetic cathinones: Methylone, MDPV, alpha-PVP
3. Reconsider the "marihuana equivalency" standard

Summary of proposed revisions (Executive Summary)

In conjunction with opinions and recommendations outlined above and discussed herein, I propose the following specific changes to the Sentencing Guidelines:

Under Application Note 6, addition of the italicized text is proposed:

"In the case of a controlled substance that is not specifically referenced in this guideline, determine the base offense level using the marihuana equivalency of the most closely related controlled substance referenced in this guideline. *If an unlisted substance is closely related to two or more listed substances, then the Rule of Lenity shall apply, and the lowest marijuana equivalency of the closely related substances shall be applied to the unlisted substance.* In determining the most closely related controlled substance, the court shall, to the extent practicable, consider…"

Under Cocaine and Other Schedule I and II Stimulants (and their immediate precursors)*, I propose the following additions:*

- *1 gm of 3,4-Methylenedioxymethcathinone/Methylone = 100 gm of marijuana*
- *1 gm of α-pyrrolidinovalerophenone/alpha-PVP = 100 gm of marijuana*
- *1 gm of 3,4-Methylenedioxy-α-pyrrolidinovalerophenone/MDPV = 40 gm of marijuana*
- *1 gm of Other Synthetic Cathinone Substances (unless covered elsewhere in these Guidelines) = 100 gm of marijuana*

Under Schedule I Marijuana *and other Cannabinoids (note the broader classification to include other cannabinoids) I propose the following revisions:*

- 1 gm of Marijuana/Cannabis, granulated, powdered, etc. = 1 gm of marijuana
- ~~1 gm of Hashish Oil = 50 gm of marijuana~~
- 1 gm of Cannabis Resin or Hashish = 5 gm of marijuana
- *1 gm of Tetrahydrocannabinol (natural or synthetic) = 7 gm of marijuana*
- *1 gm of Synthetic Marijuana ("Spice", "fake pot" etc.; a smokeable mixture comprising plant material and a Schedule I or II synthetic cannabinoid substance) = 1 gm of marijuana*
- *1 gm of JWH-018, a synthetic cannabinoid substance = 14 gm of marijuana*
- *1 gm of AB-FUBINACA, a synthetic cannabinoid substance = 14 gm of marijuana*
- *1 gm of Synthetic Cannabinoid Substance (unless otherwise listed, when possessed for the purpose of making synthetic marijuana) = 14 gm of marijuana*

1. Remove perceived ambiguities and inconsistencies; provide disambiguation instruction.

The Guidelines should provide clear and unambiguous guidance on a sentencing structure that promotes logical and consistent sentences. Inconsistencies and logical disconnects translate into increased risk of unnecessary sentencing disparities.

1a. THC vs marijuana: *The Drug Equivalency of THC should be 1:7, to reflect better the amount of THC in actual marijuana*. The current marijuana equivalency of THC is inconsistent with the amount of THC in marijuana. Illicit marijuana today is commonly ≥12% THC by weight. Thus, 1 gram of THC is contained in as little as 7-8 grams of marijuana. However, the Drug Equivalency Tables identify 1 gram of THC as equivalent to 167 grams of marijuana. The amount of THC often found in only 7-8 grams of marijuana is thus treated as the equivalent of 167 grams of marijuana. The arbitrarily high marijuana equivalency of THC has created problems when considering sentences for cannabinoid substances that can be ambiguously compared to either THC or marijuana.

There are other pairs of substances in which an active ingredient and its natural source are treated consistently. Just like THC is the active ingredient in marijuana, psilocin and psilocybin are active ingredients in hallucinogenic mushrooms. Likewise, mescaline is the active ingredient in peyote. In these sets of substances, the marijuana equivalencies of the pure active ingredient and the source material scale roughly according to the doses. For example, psilocin and psilocybin each has a marijuana equivalency of 1:500 and a standard dose of 10 mg. The marijuana equivalencies of dry and wet hallucinogenic mushrooms are 1:1 and 1:0.1, respectively, with standard doses of 5 grams and 50 grams. Thus, one could start with 50 grams of wet mushrooms, dry it down to 5 grams of dry mushrooms, and then extract out ca. 10 mg of psilocin and/or psilocybin. (These ballpark numbers chosen based on the dosage chart in the Sentencing Guidelines are consistent with the actual range of concentrations found in the mushroom.) At any point in the process, the marijuana equivalency of the substance in question would be 5 grams of marijuana. However, one could start with 5 grams of actual marijuana, extract out <1 gram of THC, and in so doing increase the marijuana equivalency to >100 grams of marijuana. In other words, 5 grams of marijuana has the potential to equal >100 grams of marijuana if one extracts the active ingredient.

If THC is adjusted as proposed, then the marijuana equivalency of Hashish Oil (1:50) should also be adjusted. I suggest removing Hashish Oil as a specific line item and allow it to be treated as a "*mixture or substance containing a detectable quantity of* [THC]"; marijuana equivalency = 1:7. Thus, Hashish Oil would be treated as pure concentrated THC.

If one treats marijuana itself as a "*mixture or substance containing a detectable quantity of* [THC]", then 5 grams of marijuana could be treated as 5 grams of THC, and 5 grams of THC equals 835 grams of marijuana using the 1:167 ratio. Confusion surrounding the statement that "the weight of a controlled substance set forth in the table refers to the entire weight of any mixture or substance containing a detectable amount of the controlled substance" is addressed in the next section.

1b. Synthetic cannabinoid substance vs. synthetic marijuana. "Synthetic marijuana" is a mixture or substance containing plant material and a detectable quantity of a synthetic cannabinoid substance that is intended for smoking as an alternative to marijuana. It is reasonable and logical that a substance intended to mimic marijuana should be assigned a marijuana equivalency ratio of 1:1.

According to the DEA, "synthetic marijuana" is generally prepared by mixing 1 part of a synthetic cannabinoid substance with 13 parts of an inert plant material. Therefore, 1 gram of a pure synthetic cannabinoid substance can be (and perhaps typically is) used to produce 14 grams of synthetic marijuana. If the "object of the attempt" is to produce 14 grams of synthetic marijuana from 1 gram of synthetic cannabinoid substance, then the appropriate marijuana equivalency ratio for a pure synthetic cannabinoid substance is 1:14. In other words, if the active ingredient of synthetic marijuana represents $1/14^{th}$ of the total weight, then the marijuana equivalency of various synthetic cannabinoid substances should be 1:14.

There should be separate listings for synthetic marijuana and for the specific synthetic cannabinoid substances, just as there are separate listings for THC and marijuana, for mescaline and peyote, and for psilocin and psilocybin and hallucinogenic mushrooms. Some courts have treated synthetic marijuana as if it were pure THC (i.e., a "*mixture or substance containing a detectable quantity of* [synthetic cannabinoid substance]"), resulting in penalties based largely on the weight of the inert plant carrier material. Other courts have focused on the amount of the pure synthetic cannabinoid substances involved. In my opinion, reasonable and consistent penalties should focus on the amount of the controlled substance, not the inert plant carrier material.

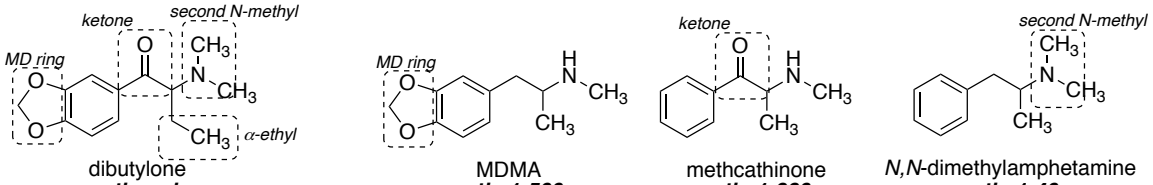
The Department of Justice recommends a 4-fold increase in penalty for synthetic cannabinoids relative to THC. In my efforts to craft an internally consistent and logical set of marijuana equivalencies for various cannabinoid substances, I effectively recommend a 2-fold increase in penalty for synthetic cannabinoids relative to THC — the marijuana equivalency of the synthetic cannabinoids should be 1:14, whereas THC should be 1:7. Note that based on current estimates, the amount of the active synthetic cannabinoid substance in synthetic marijuana ($1/14^{th}$; or about 7%) is less than the amount of THC in actual marijuana by roughly a factor of 2. Thus, assigning synthetic marijuana a marijuana equivalency ratio of 1:1 also captures the approximately 2-fold increase in penalty for synthetic cannabinoids relative to THC.

I recommend that the active ingredients of synthetic marijuana (e.g., JWH-018, AM-2201, and/or other synthetic cannabinoid substance) should be categorically listed with a marijuana equivalency of 1:14. Specific examples of synthetic cannabinoid substances should be provided to avoid confusion and to convey the intent of the categorical listing. As discussed later, I suggest listing JWH-018 and AB-FUBINACA, along with a categorical listing of synthetic cannabinoid substances.

I suggest that "synthetic marijuana" be listed in the Guidelines and defined as "a smokeable mixture comprising plant material and a Schedule I or II synthetic cannabinoid substance". Synthetic marijuana, which is intended to mimic the effects of actual marijuana, should be assigned a marijuana equivalency of 1:1. There is evidence to suggest that some of the synthetic cannabinoids are more potent than THC, but this potency is offset by preparations of synthetic marijuana with lower levels of active ingredient (assuming the DEA is correct in their statement on the general preparation).

Another way to achieve the same outcome is to list synthetic cannabinoids twice: once when found in smokeable form mixed with plant material (e.g., JWH-018, smokeable; marijuana equivalency 1:1), and again when found in pure form (e.g., JWH-018, actual; marijuana equivalency 1:14) to denote the molecular substance prior to production of the smokeable product.

1c. What if two or more substances can be identified as the "most closely related"? Application Note 6 in the Guidelines reads, "In the case of a controlled substance that is not specifically referenced in this guideline, determine the base offense level using the marihuana equivalency of the most closely related controlled substance referenced in this guideline." However, "most closely related" can be ambiguous. If two or more substances could reasonably be identified as the "most closely related controlled substance", then the Rule of Lenity should apply. One example is synthetic marijuana, which can be compared to either THC or marijuana. Another example is dibutylone, below.



The synthetic cathinone substance dibutylone is similarly comparable in chemical structure to MDMA, dimethylamphetamine, and methcathinone. Like dibutylone, all three of these listed substances have stimulant properties, and they share elements of the phenethylamine core, with each sharing an additional structural feature in common: the MD ring (MDMA), the dimethylamino (dimethylamphetamine), or the beta-ketone (methcathinone). At the present time, there is no reasonable, reliable, and consistent way to determine which substance is most similar to dibutylone.

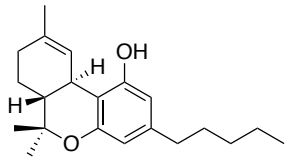
The Department of Justice references MDMA as the most closely related substance to dibutylone, although I contend that MDMA is least closely related of these three choices, because I subjectively consider the ketone and dimethylamino functional groups to be more important structural features than the MD ring. In my opinion, dimethylamphetamine and methcathinone are similarly related to dibutylone in terms of chemical structure; the ketone and dimethylamino are similarly important in my estimation. The Rule of Lenity resolves the dilemma over which of these two most closely related substances to choose. (Another example is that of ethylone, which has been compared to MDEA and to methcathinone, and there is ambiguity as to which is a better comparison.)

I suggest that the following directive be added to Application Note 6 of the Guidelines: "*If an unlisted substance is closely related to two or more listed substances, then the Rule of Lenity shall apply, and the lowest marijuana equivalency of the closely related substances shall be applied to the unlisted substance.*"

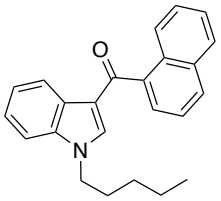
2. Add representative new designer drugs (synthetic cannabinoids and cathinones).

New designer drugs including synthetic cannabinoid substances and synthetic cathinones have been added to the list of controlled substances, and they should also be added—specifically and/or categorically—to the Drug Equivalency Tables in the Sentencing Guidelines.

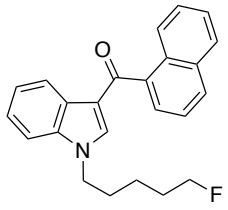
2a. Synthetic cannabinoids: JWH-018 and AB-FUBINACA. The Department of Justice suggests adding two synthetic cannabinoid substances — JWH-018 and AM-2201 — to the Drug Equivalency Tables. I agree with the proposed addition of JWH-018, and I suggest adding AB-FUBINACA (as opposed to AM-2201) as the second substance. There is a wide range of synthetic cannabinoid substances being used to produce "synthetic marijuana" in the emerging designer drug market. These substances should be treated categorically to the extent possible, but their diverse structures and properties require a thoughtful selection to provide unambiguous categorical coverage.



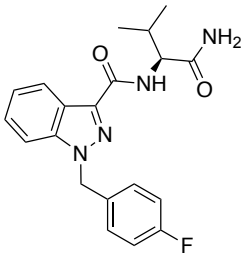
Δ^9-THC



JWH-018



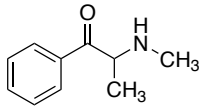
AM-2201



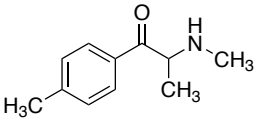
AB-FUBINACA

The categorical listing of "synthetic cannabinoids for the purpose of making synthetic marijuana" should be added to the Guidelines and assigned a marijuana equivalency of 1:14. (See section 1b above for the rationale as to why 1:14 is the appropriate ratio.) Examples of synthetic cannabinoids include JWH-018 and AB-FUBINACA. JWH-018 is arguably first and foremost among the synthetic cannabinoid substances; it is a logical choice to be listed in the Guidelines. The Department of Justice suggests listing AM-2201 as well. However, AM-2201 is "substantially similar" in chemical structure to JWH-018, and there is not much additional benefit to listing a second substance that is "substantially similar" to the first. In contrast, AB-FUBINACA diverges significantly from JWH-018. Providing AB-FUBINACA as the second example makes clear that coverage includes indoles and indazoles with different types of substituents at both the 1- and 3- positions. JWH-018 and AM-2201 define a very narrow range of structures because they themselves are so similar in structure.

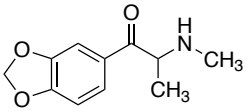
2c. Synthetic cathinones: Methylone, MDPV, alpha-PVP. The Department of Justice suggests adding three synthetic cathinone substances — methylone, mephedrone, and MDPV — to the Drug Equivalency Tables. Mephedrone need not be a high priority, in my opinion, because mephedrone is substantially similar in structure to methcathinone. Instead of mephedrone, I encourage the Commission to provide explicit sentencing guidance on alpha-PVP (aka "Flakka"). alpha-PVP is substantially similar in structure to pyrovalerone (a Schedule V substance), but alpha-PVP is now notorious as a stimulant drug of abuse.



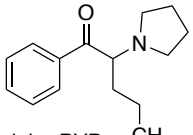
methcathinone



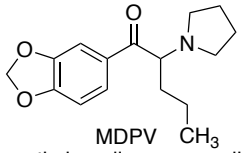
mephedrone
(4-methylmethcathinone)



methylone
(3,4-methylenedioxy-
methcathinone)



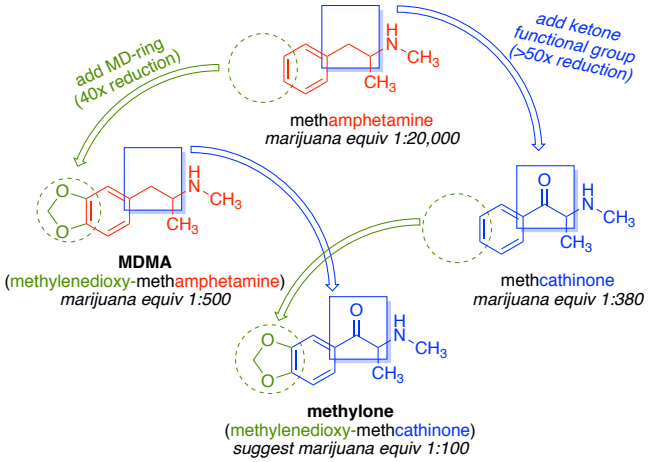
alpha-PVP
(α-pyrrolidino-
valerophenone)



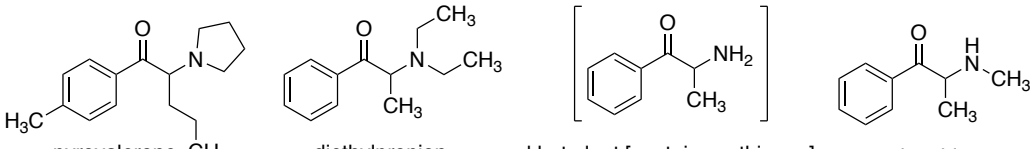
MDPV
(3,4-methylenedioxy-α-pyrrolidino-
valerophenone)

I suggest adding methylone and alpha-PVP to the Guidelines, each with a marijuana equivalency of 1:100. I suggest adding MDPV, the methylenedioxy- derivative of alpha-PVP, with an equivalency of 1:40. These new listings can then reasonably be extrapolated to other cathinone derivatives. In case other emerging synthetic cathinones cannot easily be related to one of these three listed substances, I propose to list "*Other Synthetic Cathinone Substances (unless covered elsewhere in these Guidelines)*" categorically with a marijuana equivalency of 1:100.

Listing these cathinone derivatives lower than methcathinone is consistent with amphetamine derivatives being listed lower than methamphetamine. N,N-dimethylamphetamine is listed at 1:40, and methylenedioxy-methamphetamine (MDMA) is listed at 1:500 (which itself may be too high), both of which are significant downward departures from pure methamphetamine (1:20,000; see graphic at right). Likewise, N,N-dialkyl-cathinones (like MDPV and alpha-PVP) and methylenedioxy-cathinones (like methylone and MDPV) should be listed at a reduced ratio relative to methcathinone.



cathinone substances covered in the current Guidelines:



pyrovalerone
Schedule V
ratio 1:0.00625 (160:1)

diethylpropion
Schedule IV
ratio 1:0.00625 (160:1)

khat plant [contains cathinone]
Schedule I
ratio 1:0.01 (100:1)

methcathinone
Schedule I
ratio 1:380

The Department of Justice is advocating for higher marijuana equivalencies for synthetic cathinones than what I suggest. They recommend marijuana equivalencies that are greater than or equal to that of methcathinone, but methcathinone is an outlier among cathinone substances referenced in the Guidelines. The Guidelines provide categorical recommendations for the cathinone substances diethylpropion (Schedule IV) and pyrovalerone (Schedule V): 160 gm of a Schedule IV/V substance = 1 gm of marijuana. Cathinone itself is found in the khat plant, which is assigned a marijuana equivalency of 1:0.01. Methcathinone, at 1:380, is the most severely punished cathinone referenced in the Sentencing Guidelines by a wide margin. Listing new cathinone derivatives with marijuana equivalencies lower than for methcathinone would maintain this trend, which is also consistent with what is seen among amphetamine derivatives (with methamphetamine at the high end).

3. Reconsider the "marihuana equivalency" standard

The Department of Justice suggests replacing the "marijuana equivalency" standard with a points system. This is a good idea, both because of the confusion they reference and because marijuana is an ambiguous, moving target. Marijuana is a heterogeneous mixture — different batches contain different amounts of the primary active ingredient, THC. THC itself is listed in both Schedules I and III, and societal attitudes towards both marijuana and THC are in flux.

I thank the Commission for allowing me the opportunity to offer these opinions, and I thank them in advance for considering my opinions in their future deliberations.

Rick Doblin, Ph.D.
Founder and Executive Director
Multidisciplinary Association for Psychedelic Studies
Santa Cruz, California

Dr. Doblin founded Multidisciplinary Association for Psychedelic Studies (MAPS) in 1986. His professional goal is to help develop legal contexts for the beneficial uses of psychedelics and marijuana, primarily as prescription medicines but also for personal growth for otherwise healthy people, and eventually to become a legally licensed psychedelic therapist. Under Dr. Doblin's leadership, MAPS is currently funding clinical trials of MDMA as a tool to assist psychotherapy for the treatment of posttraumatic stress disorder (PTSD) as part of a plan to make MDMA into a Food and Drug Administration-approved prescription medicine by 2021.

Dr. Doblin received his undergraduate degree from New College of Florida and his Ph.D. in Public Policy from Harvard's Kennedy School of Government, where he wrote his dissertation on the regulation of the medical uses of psychedelics and marijuana and his Master's thesis on a survey of oncologists about smoked marijuana vs. the oral THC pill in nausea control for cancer patients.

Rick Doblin, Ph.D., Testimony to US Sentencing Commission Re: MDMA

Prepared in collaboration with Ismail L. Ali, JD, and Natalie Lyla Ginsberg, MSW

Table of Contents

I. The Creation & Criminalization of MDMA 2
a. Origin of MDMA 2
b. History of Criminalization 3
II. The MDMA Sentencing Guideline Lacks an Empirical Basis 5
a. Two federal courts have found the 2001 MDMA Sentencing Guideline to be excessive. 5
b. As successfully argued by the ACLU, the present MDMA Sentencing Guideline is based on inaccurate science that exaggerated risks. 6
c. Most commonly-cited MDMA neurotoxicity studies are misleading. 10
III. MDMA's Robust Prosocial Capacity and Low Risk Profile 11
a. MDMA's Risk Profile 11
b. MDMA literature reviews highlight MDMA's prosocial capacities 12
c. MAPS has sponsored and published FDA-approved drug development studies demonstrating the healing capacity of MDMA-assisted psychotherapy 14
d. Highlights of Non-MAPS MDMA Research 15
e. Non-clinical MDMA use can produce self-healing. 16
IV. Conclusion 18
V. Appendices 19

I. Introduction

For the last 35 years, from 1982 when I first learned about MDMA to 1986 when I founded the non-profit research and educational organization, the Multidisciplinary Association for Psychedelic Studies (MAPS), my life has been focused around understanding the therapeutic potential of MDMA and developing MDMA-assisted psychotherapy into an FDA-approved treatment available by prescription. In 2001, I testified before the USSC regarding MDMA, only to see the penalties increased based on risk estimates that seemed excessive at the time; subsequent research ultimately demonstrated a lower risk profile. I'm deeply grateful for this new opportunity sixteen years later to present this written and oral testimony to the USSC to aid in its deliberations reviewing the current sentencing guidelines.

II. The Creation & Criminalization of MDMA

a. Origin of MDMA

MDMA was discovered and patented by the German pharmaceutical company Merck in 1912. MDMA was manufactured as part of a series of chemical intermediates. Merck's goal was to create a new chemical pathway to avoid a competitor's patent in an effort to develop a medicine for uncontrolled bleeding. Merck first tested MDMA in animals in 1927 and found nothing of interest, and never tested MDMA in humans. MDMA is now off-patent.[1]

In 1953-54, MDMA was one of eight compounds studied in animals with funding from the US Army Chemical Center. This research was declassified in 1969 and published in 1972. In 1967, a biochemist formerly employed by Dow Chemical named Alexander Shulgin re-synthesized MDMA after being introduced to the substance at a conference. He provided initial reports of its pharmacology, with 80 mg to 160 mg required to produce desired subjective effects in humans.[2] MDMA was found to robustly influence human emotional status in a unique way without adversely affecting physiological functions or perception, such as visual perception or cognition.[3]

After being rediscovered, MDMA was used as an adjunct to psychotherapy. In 1977, Shulgin introduced a psychologist named Leo Zeff to MDMA. At the time, MDMA was a legal compound only known to a small group of psychopharmacologists. Zeff incorporated MDMA into his psychotherapy practice and ultimately shared MDMA widely with therapists across the country, introducing the substance to hundreds of therapists over the course of years.[4] As reported

[1] Ronald Freudenmann, *et al.*, *The origin of MDMA (ecstasy) revisited: the true story reconstructed from the original documents*, 101(9) Addiction 1241 (2006).
[2] Shulgin, Alexander & Anne, *Pihkal: A Chemical Love Story*, Transform Press (1991), 69. ISBN: 0-9630096-0-5.
[3] MDMA Investigator's Brochure, 8th Ed. (30 March 2016) ("IB") at 10 (citations removed) [Appendix A].
[4] *Id*.

by the National Institute on Drug Abuse (NIDA) website, some MDMA therapists at the time even called MDMA "penicillin for the soul" because it was perceived to enhance communication in patient sessions and reportedly allowed users to achieve insights about their problems.[5] Chemists and therapists distributing the legal compound hoped to make a meaningful contribution to people's psychological health. Dozens of known therapeutic uses of MDMA are recorded in the public domain so use patents are not available.

Based on my conversations in the early to mid-1980s with MDMA therapists and with chemists producing MDMA for therapists, I estimate about half a million doses of legal MDMA were distributed from the late 1970s to 1984 for use in therapeutic and personal growth settings, without attracting attention of the police. However, in the early 1980s, MDMA began to be marketed outside of therapeutic contexts by entrepreneurs who rebranded MDMA as "Ecstasy" in the club scenes in Dallas, Los Angeles and elsewhere. This campaign initiated recreational use.[6] It was apparent to those using MDMA in therapeutic contexts that the recreational use of MDMA was going to lead to the criminalization of MDMA for all uses, since at the time Nancy Reagan was simultaneously re-escalating the United States' "war on drugs." In 1984, Senator Lloyd Bentsen of Texas requested that the DEA schedule and criminalize MDMA, starting in motion the ending of MDMA's status as a legal substance.

b. History of Criminalization

The DEA first proposed to place MDMA in Schedule I in July of 1984.[7] In response, with the help of pro-bono legal services, I helped organize a group of psychiatrists and psychotherapists to request DEA Administrative Law Judge (ALJ) hearings seeking to maintain MDMA's legal medical use. These hearings were granted and began in early 1985. In the midst of the DEA hearings, which generated media attention that was generally positive about the effects of MDMA, DEA's Acting Administrator John Lawn placed MDMA on Schedule I using emergency scheduling powers, based on a perception of a "continuing and apparently increasing number [of people] being exposed to MDMA, its potential neurotoxicity and the lack of accepted medical use or established safety for use of MDMA."[8]

In 1986, the World Health Organization (WHO) of the United Nations followed the United States' criminalization process, placing MDMA in Schedule I. However, Dr. Paul Grof, the chairman of WHO's Expert Committee on Drug Dependence that reviewed the data on MDMA, voted against the recommendation for criminalization due to concerns that premature scheduling could negatively impact research into MDMA's risks and benefits. The only scientific evidence referenced by the Expert Committee as the basis of the scheduling recommendation was research on a related but different compound, MDA, administered to rats in frequent and high doses. The

[5] A Brief History of MDMA. NIDA. Found at: https://www.drugabuse.gov/publications/research-reports/mdma-ecstasy-abuse/brief-history-mdma.
[6] *Id.*
[7] 49 Fed. Reg. 30210-30212 (July 27, 1984).
[8] DEA Press Release on Emergency Scheduling. May 31, 1985. Found at: http://www.maps.org/research-archive/dea-mdma/pdf/0180.PDF.

World Health Organization (WHO) noted that there was insufficient data to draw strong conclusions: "No data are available concerning [MDMA's] clinical abuse liability, nature and magnitude of associated public health or social problems."[9] The WHO Expert Committee on Drug Dependence, despite its chairman's objections, determined that there was inadequate research supporting MDMA's therapeutic use,[10] though it had been used therapeutically, outside of research, for over a decade. However, the Committee noted in its report that it was impressed by the non-clinical reports of MDMA and urged countries to pursue further research.[11]

In May 1986, after two years of hearings, DEA ALJ Francis Young recommended *against* placing MDMA on Schedule I. He disagreed with the DEA's claim that FDA approval of a drug was "binding on the medical profession which respect to what is, or is not, accepted medical… use."[12] Specifically, he acknowledged that the nonexistence of a New Drug Application (NDA) did not preclude the drug from having medical use.[13] The Opinion also acknowledged MDMA's past use in therapy, and recommended that MDMA be placed in Schedule III.

Despite the weight of the evidence undermining MDMA's placement in Schedule I, and the fact that the DEA had acted outside of its authority when it Emergency Scheduled MDMA, Lawn overruled ALJ Young and classified MDMA as Schedule I in October of 1986.[14]

In 1987, Dr. Lester Grinspoon, a psychiatrist on the faculty of Harvard Medical School, sued the DEA on the grounds that DEA had ignored MDMA's medical use, and the federal court agreed, finding Lawn's ruling "unpersuasive."[15] This decision vacated MDMA's schedule I status. A month later, DEA Administrator Lawn intervened *again* and reverted MDMA to its Schedule I placement, dismissing the expert testimony of psychiatrists discussing over 200 cases of MDMA-assisted psychotherapy because they were not published in medical journals.

It is notable that subsequent to the first emergency placement, the DEA arrested several individuals for MDMA distribution. The DEA claimed that its emergency scheduling authority was derived from the Comprehensive Crime Control Act (CCCA), which Congress passed in 1984. The CCCA granted the Attorney General powers to temporarily schedule drugs without following regular procedures when there was imminent risk to public health. However, the Attorney General

---

[9] World Health Organization, *22nd report of the Expert Committee on Drug Dependence*, Technical Report Series (1985) at 25. Found at: http://apps.who.int/iris/bitstream/10665/39635/1/WHO_TRS_729.pdf.
[10] *Id.*
[11] *Id.* at 26 (Despite insufficient methodologically sound data to reliably comment on MDMA's purported therapeutic usefulness, the report stated that "There was...sufficient interest expressed to recommend that investigations be encouraged to follow up these preliminary findings. To that end, the Expert Committee urged countries to use the provisions of article 7 of the Convention on Psychotropic Substances to facilitate research on this interesting substance.")
[12] In the matter of MDMA Scheduling, Docket No. 84-48 (Dec. 2, 2014).
[13] Young stated: "If this is the criterion, 'accepted safety' for use by physicians is reduced to being determined by… a businessman's or corporation's determination of the economic feasibility of mass production. Congress has not given the slightest hint of an intention to rely here on such judgments. That would, however, be the bottom line result of the Agency's position in many cases.... It ignores the reality that commercial pharmaceutical manufacturers base their production decisions on economic considerations. If they are commercially manufacturing a product, they have, no doubt, concluded that the pharmaceutical can be safely used. But the converse is not necessarily true." *Id.*
[14] 51 Fed. Reg. 198, 36552 (October 14, 1986).
[15] *Grinspoon v. DEA*, 828 F.2d 881 (1st Cir., 1987).

had never formally sub-delegated these "emergency scheduling" powers to the DEA. In 1988, three individuals who had pled guilty to distribution of MDMA challenged the emergency scheduling procedure. Based in part on the discrepancies in amount of due process required for the two scheduling procedures, the US Court of Appeals for the Ninth Circuit ruled that DEA's emergency scheduling of MDMA was illegal, freeing the arrested individuals on procedural grounds.[9]

III. The MDMA Sentencing Guideline Lacks An Empirical Basis.

a. Two federal courts have found the 2001 MDMA Sentencing Guidelines to be excessive.

In 2011, at sentencing in two separate federal MDMA trafficking cases, Hon. William Pauley III from the Southern District of New York and Hon. Ricardo S. Martinez from the Western District of Washington, both chose to vary downward from the MDMA Guideline range. In collaboration with MAPS,[16] ACLU attorneys Jay Rorty and Scott Michelman argued that because the MDMA guideline was based on now-discredited science, it lacked an empirical basis and thus need not be adhered to.[17] The courts agreed, acknowledging the 2001 Sentencing Commission's reliance on exaggerated, scientifically unsound perceptions of MDMA's harmfulness.

When sentencing the defendant in *US v. McCarthy*, Judge Pauley adopted an MDMA-to-marijuana ratio of 200:1, higher than the pre-2001 ratio of 35:1 but lower than the present ratio of 500:1.[18] In his Opinion, Judge Pauley concluded that MDMA is not in fact more harmful than cocaine (as concluded by the Sentencing Commission in 2001), but also that it is not as harmful as marijuana.[19] Specifically, he noted that failing to recognize the totality of cocaine's effects, which "render it significantly more harmful than MDMA," led to an imbalanced analysis which did not include multiple factors that could have led to a lighter sentencing determination.[20] In addition, Judge Pauley concluded that the Commission's analysis of MDMA's actual negative impacts - which focused on neurotoxicity alone - was "selective and incomplete."[21]

In *US v. Phan*, the court was not considering imposing a sentence above 36 months, already lower than the 41- to 188-month range which was otherwise possible given the pre-2001 Guideline.[22] However, despite already planning on a downward deviation from the Guideline,

[16] MAPS/ACLU Sentencing Press Release [Appendix D]
[17] *US v. Phan* (W.D. WA 2011), Supplemental Sentencing Memorandum ("*Phan* memo") at 8 [Appendix B].
[18] *US v. McCarthy* (S.D. NY 2011), Memorandum and Order ("*McCarthy* order") at 8 [Appendix C].
[19] *Id*. at 8.
[20] *Id*. at 7.
[21] *Id.* at 5.
[22] *US v. Phan* (W.D. WA 2011), Sentencing Hearing Transcript at 4-5 ("If this court were to treat MDMA as equivalent to marijuana on a ratio of one-to-one, then the resulting level in this case would start at 20. With the appropriate adjustments as set out in the presentence report that's prepared by probation, the end result would be a level 22. This defendant falls in a criminal history category one. His resulting range would then be 41 to 51 months.

Judge Martinez nonetheless acknowledged the need to re-evaluate the guideline ranges in the face of new experience and knowledge.[23] Ultimately, Judge Martinez noted:

> The exact question of whether or not this court believes that there is a problem with the current MDMA guideline I think is before this court, and I believe the answer is, yes, there is. Based on everything that I have seen that was presented here, based on the arguments that were made in the Southern District of New York [*US v. McCarthy*], I think it's imperative that the Sentencing Guideline Commission address this issue, just like they did with disparity between crack and powder cocaine.[24]

b. As successfully argued by the ACLU, the present MDMA Sentencing Guideline is based on inaccurate science.

The sentencing memo submitted to the court in *US v. Phan* provides a thorough overview and rebuttal of the now-discredited science relied on to form the 2001 MDMA Guideline.[25] The memo notes that the Commission's scientific evidence exhibited a number of problems including inadequate controls, inappropriate doses, non-replicable studies, and most notably, research by a researcher who later retracted another study claiming that MDMA caused Parkinson's because the study mistakenly used *d-methamphetamine,* an entirely different compound than the purported MDMA.[26] The *Phan* memo states:

> Specifically, when considering the guidelines for MDMA, the Commission's 'empirical data' included case studies of individuals who were heavy users of other drugs; studies in which animals were administered doses that we now know are exponentially larger relative to their size than doses human beings ingest; a website that the Commission itself noted was not scientific; and the work of a

---

If the court were instead to use the ratio of 35-to-one, because that was my understanding of the pre-2001 -- the ratio that was used prior to the 2001 amendments to the current MDMA guidelines, then the resulting guideline range for this defendant, Mr. Phan, would be level 34 and call for a range of 151 to 188 months.").

[23] *Id*. at 6-7. ("I think the fact that the Ninth Circuit has explained that district judges are at liberty to reject any guidelines on policy grounds, and the Ninth Circuit has also held that it would be error to attach a presumption of reasonableness to the guideline range, in view of all that, the court is not required to embrace any particular alternative ratio, and this court will not do so in this situation for a variety of reasons. One, I will not do it because it's not necessary in this case in order for the court to impose a sentence that is sufficient, but not more than necessary to accomplish the reasonable objectives of sentencing. But I do it for another reason that's even more important. The court agrees that there may very well be problems with the MDMA guidelines as currently constructed. As we learn more about the effects of certain drugs on humans, especially after years of experience with those drugs and especially as more designer drugs come into play, it obviously makes logical sense to go back and re-evaluate all the guideline ranges.")

[24] *Phan* memo at 7-8.

[25] *Id.* at 15.

[26] *Id.*

> researcher who subsequently retracted multiple MDMA studies because he was testing the wrong chemical compound.[27]

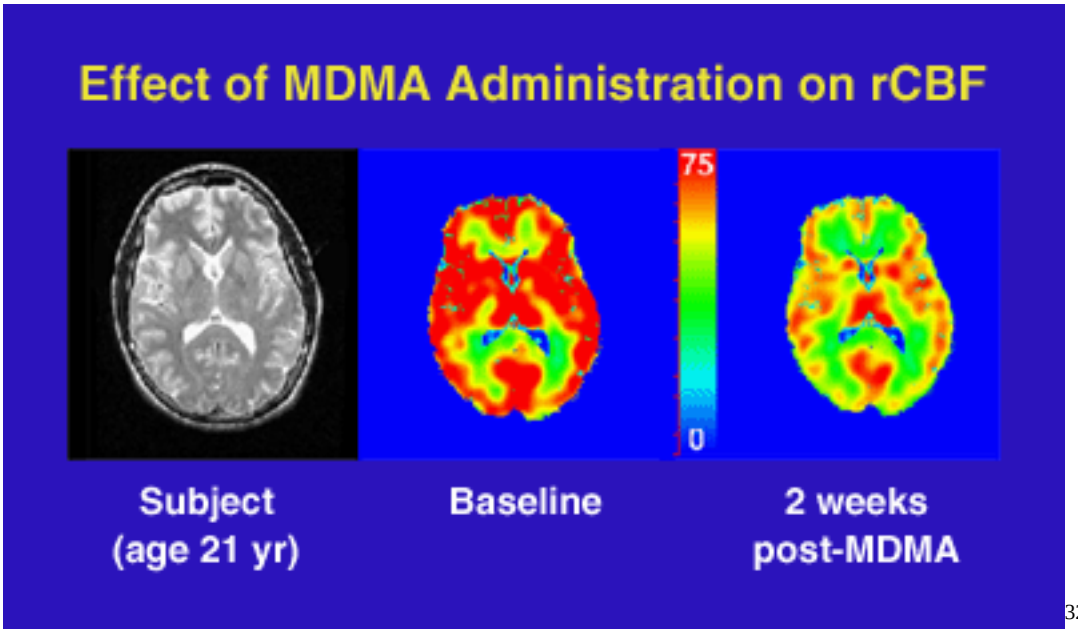
It is also notable that the *Phan* memo compared the discrepancy between fact and reality of MDMA's harmfulness to the discrepancy regarding the crack cocaine guideline at issue in *US v. Kimbrough.*[28] In other words, the Commission's formulation of the Guideline for MDMA sentences, similar to its original formulation for crack cocaine, is based on alarmist and now discredited studies.

In 2004 I published a rebuttal to a number of arguments and studies used to justify MDMA's continued criminalization, including studies used to the 2001 guidelines.[29] For example, then-NIDA Director Alan Leshner's 2001 Senate Subcommittee on Government Affairs testimony was incredibly misleading; Leshner led the Senators to believe that MDMA caused permanent changes in cerebral blood flow, but in fact, the changes were both temporary and of no clinical consequence. As I explain in my 2004 rebuttal in more detail:

> Testimony that then-NIDA Director Alan Leshner gave on July 30, 2001 to the Senate Subcommittee on Government Affairs, illustrated with a large poster purporting to show that MDMA negatively affects (reduces) cerebral blood flow, was clearly misleading. The poster [below, 31] showed a healthy-looking brain with what was represented as normal cerebral blood flow, with this image labeled "Baseline." For comparison purposes, the poster also contained a second brain scan image of the same subject with reduced cerebral blood flow. This image was labeled "Two weeks post-MDMA." What Leshner didn't tell the Senators is that the scans were drawn from a study that showed no difference between Ecstasy users (N=21) and controls (N=21) in cerebral blood flow (Chang et al. 2000).[30]
>
> The images Leshner used in his Senate testimony came from one of the subset (N=10) of the Ecstasy users in the larger study who participated in Dr. Grob's Phase I MDMA safety study. These ten subjects were scanned at baseline, like the other eleven Ecstasy-using subjects in Dr. Chang's research. They were then scanned again after receiving two doses of MDMA administered in the context of Dr. Grob's study, at time points ranging from two weeks to 2-3 months after the last dose of MDMA. Subjects scanned two weeks after MDMA showed a temporary reduction in cerebral blood

[27] *Id.*
[28] *Id.* at 8-10.
[29] Doblin, Rick, *Exaggerating MDMA's risks to justify a prohibitionist policy*, MAPS Research Archive (January 16, 2004) ("Doblin 2004"). Found at: http://www.maps.org/research-archive/mdma/rd011604.html.
[30] Chang, et. al., *Effect of ecstasy 3,4-methylenedioxymethamphetamine / MDMA on cerebral blood flow: a co-registered x SPECT and MRI study*, Psychiatry Research: Neuroimaging Section 98 (2000), 15-28.

flow while subjects scanned from 2-3 months after MDMA showed a return to baseline. The impression Leshner left the Senators was that MDMA caused permanent changes in cerebral blood flow when the changes were both temporary and of no clinical consequence.[31]

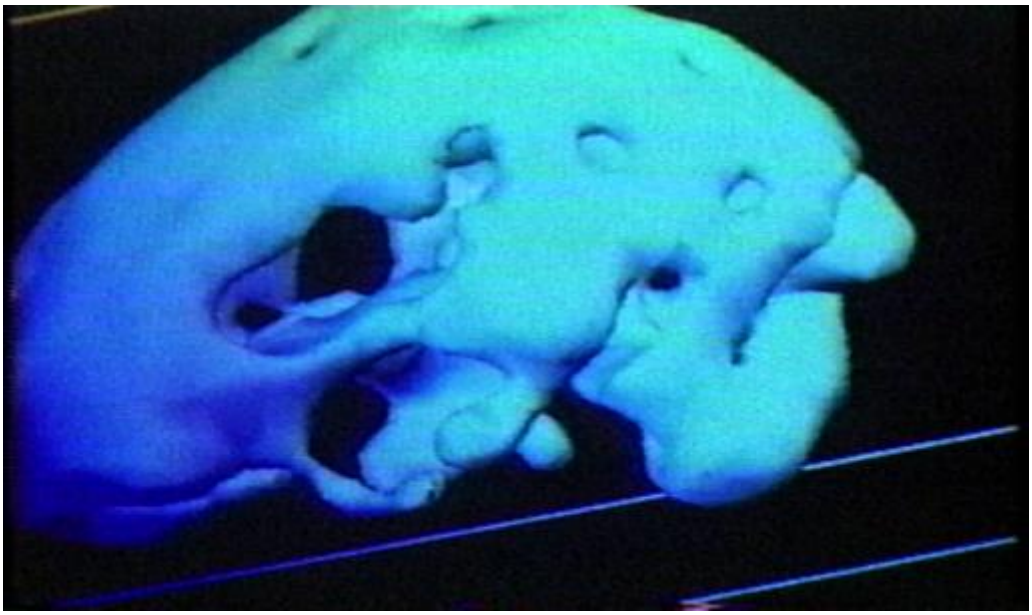


[32]

Ironically, Leshner didn't realize that in order to participate in the Phase 1 study and receive MDMA, FDA required subjects to have already had substantial exposure to MDMA. On average, the subjects in Dr. Chang's study had an exposure to MDMA of 211 times. Thus, the healthy-looking brain that Leshner showed to the Senators to contrast with the image of the same brain two weeks post-MDMA was actually the brain of a heavy MDMA user at baseline! If he had fully understood the science underlying the images he showed to the Senator, Leshner should have reported that the baseline image dramatically illustrated that MDMA caused no persisting long-term differences in cerebral blood flow as compared to the non-MDMA using controls. Instead, he used the image to convey an impression of the dangers of MDMA at odds with what the study actually demonstrated.

[31] Leshner, Alan, Hearing Before the Senate Subcommittee on Governmental Affairs - "Ecstasy Abuse and Control" Statement for the Record (July 30, 2001). Found at: http://www.drugabuse.gov/Testimony/7-30-01Testimony.html.

[32] Image originally found at: https://archives.drugabuse.gov/Testimony/7-30-01Testimony.html.



My rebuttal also addressed the misleading and alarmist myth that MDMA causes "holes" in user's brains. I wrote:

> Frightening and disturbing images of the brain of an MDMA user that showed explicit holes in the brain [above] that were claimed to have been caused by MDMA have been shown on an MTV special documentary about Ecstasy, as well as on an Oprah Winfrey show. These images were graphically manipulated to represent areas of lower cerebral blood flow as holes and are completely fraudulent. According to a March 2001 educational program about drugs aimed at young people that NIDA helped create, Alan Leshner stated, "We've heard people talk about Ecstasy causing holes in the brain and of course that's a bit of an exaggeration, but there is a core truth to it."[33]

The *Phan* memo provides another example of similarly problematic science: a leading MDMA neurotoxicity researcher, with federal funding from NIDA, published numerous retractions after admitting to mistakenly researching methamphetamine, not MDMA. The *Phan* memo explains:

> The Commission also relied on several studies that were not able to be replicated, or scientists whose work was fraught with methodological problems. For instance, Dr. George Ricaurte, cited and relied upon as '[a] leading researcher in MDMA toxicity studies' in the Commission's 2001 report to Congress, had to

[33] Doblin 2004.

> retract multiple studies after it was discovered that they had not been done with MDMA, but with mislabeled vials of methamphetamine. After this error came to light, in 2003 the journal Science retracted a Ricaurte study purporting to show that a single dose of MDMA could cause brain injury. The mislabeled vials corrupted several of Ricaurte's other studies, as well, and he was forced to withdraw four other papers. Even scientists Ricaurte named in defense of his work were quoted in the New York Times as saying that "some of his best-known work has nonetheless been 'sloppy' or 'not as methodologically rigorous as you might want."[34]

From 1989-2002, Drs. Ricaurte and McCann received federal grants totaling over $14.6 million dollars for MDMA and MDMA-related research.[35]

At my USSC testimony in March 2001, I opposed increasing penalties for MDMA for two primary reasons. The first was that enhanced penalties would increase difficulties in obtaining FDA and DEA permissions to conduct legitimate scientific research into the risks and benefits of the therapeutic use of MDMA as an adjunct to psychotherapy. The second, which is particularly relevant to this testimony, is that MDMA's risks have been greatly exaggerated, particularly the risk of serious functional or behavioral consequences from MDMA neurotoxicity.

USSC's sharp increase in mandatory minimum sentences for MDMA crimes in 2001, from a 35:1 to a 500:1 marijuana-to-MDMA ratio, reflects the hysteria, not the science, much like the circumstances responsible for MDMA's criminalization in the first place. Today, even more data is available to rebut the exaggerated claims of the past.

c. Most commonly cited MDMA neurotoxicity studies are misleading.

Animal studies that demonstrated MDMA to be neurotoxic were using extremely high doses of MDMA, not at all comparable to doses commonly used in humans. These studies administered multiple doses 50 to 100 times higher than doses used in human clinical trials, if appropriate allometric scaling is used between species. Serotonergic toxicity has not been found with doses close to the range used in clinical and recreational use.[35] However, as the MAPS Investigator's Brochure, a literature review of over 600 relevant MDMA studies, writes:

> Repeated very high doses of MDMA in animals reduce total serotonin levels in the brain, impair transport of serotonin, and cause psychobehavioral changes such as increased anxiety...However, the majority of these studies employed large doses of MDMA that overestimated human-equivalent doses, with findings now clearly indicating that doses used in nearly all rat and most primate studies

[34] *Phan* memo at 18 (citations omitted).
[35] Jerome, Ilsa, Ph.D., *NIDA and NCRR Funding for Ricaurte and McCann 1989-2003*, MAPS (2004). Found at: http://www.maps.org/research-archive/mdma/ricaurtefunding.pdf.

> are inappropriately high for comparison to use in clinical settings and are more pertinent toxicological effects of MDMA.[36]

In addition, the "timebomb" theory of MDMA neurotoxicity was premised on the belief that MDMA neurotoxicity was indeed harmful; but not because of MDMA's acute or short-term effects, but rather for effects that some predicted would only show up later in life, perhaps 25 years from when the MDMA was actually being used. However, more than 25 years have passed since those claims were made and we can see now that those fears have not been actualized.

III. MDMA's Robust Prosocial Capacity and Low Risk Profile

a. MDMA's Risk Profile

Analysis and research compiled in MAPS Investigator's Brochure suggests that MDMA's physiological effects are mild when consumed at common recreational and therapeutic doses, and "likely to be well tolerated by healthy individuals."[36] These physiological impacts rarely reach "elevations that exceed those seen after moderate exercise."[37] Negative effects include "lack of appetite, insomnia, dizziness, tight jaw or bruxism, difficulty concentrating, headache, impaired gait or balance, muscle tension, ruminations, feeling cold, and thirst," as well as a mild immunosuppressant effect.[38]

However, MDMA combined with aerobic dancing, a hot crowded environment and not drinking enough water, can become a lethal mix, sometimes resulting in heatstroke. A standard dose of MDMA raises body temperature about one degree, and also inhibits the body's natural thermoregulation, increasing likelihood of heatstroke. Heatstrokes can be easily avoided with the implementation of basic harm reduction measures like access to free water or "cool down rooms." Very rarely, Ecstasy users drink too much water and die from hyponatremia, preventable by substituting drinks with electrolites like Gatorade or fruit juices instead of water.

Black-market MDMA possesses a higher risk profile than responsibly-dosed, pure MDMA. The risks of consuming illicit MDMA include: taking MDMA in an unsafe physical or psychological setting, insufficient knowledge about MDMA, insufficient access to basic harm reduction measures, ingesting a more dangerous substance that is sold as (but is not actually) MDMA, and risks associated with contact with law enforcement. *These risks, however, are all the result of MDMA's criminalization, not MDMA itself.*

MAPS has developed an expertize in minimizing the harms of problematic use of psychedelic substances. MAPS sponsors a program called the Zendo Project, which supports

[36] IB (*supra* note 3) at 9.
[37] *Id.*
[38] *Id.*

medical and emergency teams at large festivals and events across the United States and the world by working with people having difficult psychedelic experiences, commonly known as "bad trips." Instead of being arrested by police or tranquilized by medical staff unfamiliar with psychedelic experiences, the Zendo Project provides a supportive space and peer-counselors specially trained to de-escalate challenging psychedelic experiences, and ultimately transform them into valuable healing and growing opportunities. The Zendo Project has supported almost 2,000 people[39] through difficult psychedelic experiences. Notably, MDMA produces far fewer difficult psychological experiences than substances such as LSD, despite MDMA being more popular. At Burning Man, a festival that hosts 70,000 attendees for a week in the Nevada desert, approximately 6% of Zendo's drug-related intakes in 2016 were related to MDMA.

MDMA is not and has never been the dangerous drug it was once made out to be. Emergency room statistics from 2011 - the most recent publicly available data - show that MDMA-related emergency department visits only amounted to only 1.8% of drug or alcohol-related visits that year.[40] A majority of these visits were inspired by acute psychological distress, and most cases were resolved after supportive care.[41] Further, between 2013 and 2016, the rate of MDMA use in young people has decreased.[42] The social harm from MDMA use is small, and although its use does come with certain risks, they can be significantly mitigated or eliminated with education, harm reduction, and decriminalization.

b. MDMA literature reviews highlight MDMA's prosocial capacities.

In July 2016, the peer-reviewed scientific journal Cell published a commentary about current research into the use of MDMA as a probe for social behaviors and as an adjunct to psychotherapy. The article, authored by neuroscientists Boris Heifets, M.D., Ph.D., and Robert Malenka, M.D., Ph.D., of Stanford University, summarizes current knowledge about MDMA's mechanism of action, highlighting its ability to catalyze prosocial, empathogenic effects. The authors of the Cell article write:

> Here, we argue for the importance of using all the available tools of modern basic and clinical neuroscience research to maps MDMA's mechanism of action in the brain.
>
> [...]
>
> While such pragmatic clinical studies will certainly be important, we are equally excited about the utility of MDMA as a unique and relatively simple manipulation that can be used to probe the neural

[39] Since 2012, the Zendo Project has assisted 1,986 guests and trained approximately 1,166 volunteers, and trained hundreds more in the principles of psychedelic peer counseling.
[40] Drug Abuse Warning Network, *2011: National Estimates of Drug-Related Emergency Department Visits*. HHS (2011). Found at: http://archive.samhsa.gov/data/2k13/DAWN2k11ED/DAWN2k11ED.htm.
[41] IB (*supra* note 3) at 32.
[42] *Monitoring the Future Study: Trends in Prevalence of Various Drugs*. NIDA (2013-2016). Found at: https://www.drugabuse.gov/trends-statistics/monitoring-future/monitoring-future-study-trends-in-prevalence-various-drugs

> basis of prosocial behaviors in a wide range of species.
>
> [...]
>
> As a probe of brain function, [MDMA] is a remarkably simple but powerful tool that can be used to advance our understanding of the neural basis of empathy, social reward, and related prosocial behaviors. Such understanding can only benefit individuals and the human interactions in which they engage. The world's populations need more compassion and empathy for one another. The study of MDMA provides one small but potentially important step toward reaching that goal.[43]

MAPS has also compiled and published a comprehensive Investigator's Brochure, which is a summary and analysis of the world's relevant, peer-reviewed literature about MDMA. MAPS published the Eighth Edition of the IB in March 2016.[44] The Investigator's Brochure includes a number of notable findings, a short excerpt of which is quoted below:

> The combined neurobiological effects of MDMA can increase compassion for self and others, reduce defenses and fear of emotional injury, and make unpleasant memories less disturbing while enhancing communication and capacity for introspection. These factors taken together can provide the opportunity for a corrective emotional experience in the context of psychotherapy. Many of the therapeutic effects of MDMA-assisted psychotherapy are evident within a short period of treatment, often after the initial session.
>
> Increased feelings of interpersonal closeness, changes in social perception and reduced anxiety may make MDMA a suitable pharmacological adjunct to enhance psychotherapy for anxiety disorders, such as PTSD and social anxiety in autistic adults. MDMA may provide a much needed option in the treatment of PTSD and anxiety associated with other conditions. Published results from MAPS study (MP-1) showed clinically and statistically significant improvements in PTSD severity in 20 per protocol subjects. Findings from the long-term follow-up of MP-1 suggest that therapeutic benefits were sustained for an average of 41 months post-treatment. The sponsor's second Phase 2 pilot study conducted in Switzerland (MP-2) demonstrated clinically significant improvements in PTSD symptoms, with results in the 125 mg MDMA dose group numerically but not statistically superior to the

[43] Heifets, Boris, M.D., Ph.D., and Malenka, Robert, M.D., Ph.D., *MDMA as a Probe and Treatment for Social Behaviors*, Cell (July 14, 2016) ("Heifets"). Found at: http://www.cell.com/cell/fulltext/S0092-8674(16)30853-4.
[44] IB (*supra* note 3).

> 25 mg MDMA dose group. Long-term follow-up data 12 months later suggest that therapeutic benefits continued to increase in this subject population. There were no drug-related Serious Adverse Events (SAEs) or safety concerns in either study.
>
> Data from MAPS studies and published literature show that MDMA produces sympathomimetic effects that...are likely to be well tolerated by healthy individuals. Most people do not experience elevations that exceed those seen after moderate exercise….Common reactions reported in the literature and clinical trials from MDMA are transient and diminish as drug effects wane during the session and over the next one to 7 days…. Due to [the limited duration of listed effects,] these sub-acute reactions are not likely to have clinical significance.
>
> As of 01 October 2015, with 1180 individuals exposed to MDMA in controlled research settings (which includes 122 in MAPS-sponsored studies), there have been no unexpected drug-related SAEs to date, and expected SAEs have been rare and non-life threatening.[45]

In sum, there is evidence that MDMA can result in increased compassion, decreased anxiety, and a change in perception that combines effectively with psychotherapy to produce fertile grounds for personal healing and development. Results from MAPS-sponsored research with MDMA-assisted psychotherapy for PTSD is particularly encouraging. At this time, MAPS has completed Phase 2 investigations of MDMA-assisted psychotherapy for PTSD, we are now preparing to begin Phase 3.

c. MAPS has sponsored and published FDA-approved studies demonstrating the healing capacity of MDMA-assisted psychotherapy in clinical settings.

Since 2001, MAPS has sponsored nine FDA-approved drug development studies evaluating the efficacy of MDMA-assisted psychotherapy for psychiatric disorders including PTSD, anxiety associated with a life threatening illness, and social anxiety in autistic adults, at research sites across the United States and around the world. MAPS' FDA-approved clinical trials have demonstrated that MDMA, in conjunction with psychotherapy, has promising therapeutic capabilities. In November 2016, the Food and Drug Administration approved a large-scale, Phase 3 trial of MDMA-assisted psychotherapy for chronic PTSD, the final phase of research required for full FDA-approval for MDMA-assisted psychotherapy. If Phase 3 follows Phase 2's success, the trial would trigger MDMA's rescheduling, as MDMA would no longer qualify for Schedule I with "no accepted medical use."

[45] IB (*supra* note 3) at 9.

FDA's green light for Phase 3 MDMA/PTSD studies was based on the results of a meta-analysis from Phase 2 MDMA/PTSD pilot studies in 107 subjects: in all participants' evaluated so far for the 12-month follow up after experiencing MDMA-assisted psychotherapy for PTSD (N=86), 67% of participants no longer met PTSD diagnostic criteria. For comparison: the only medications currently FDA-approved to treat PTSD, Zoloft and Paxil, are approximately 50% effective at reducing symptoms of PTSD, but not eliminating them. In one small MDMA-assisted psychotherapy pilot study in Charleston, South Carolina, 83% of participants no longer qualified for PTSD,[45] and three-quarters of participants sustained their PTSD-free results three and a half years later.[46]

A MAPS pilot study evaluating MDMA-assisted psychotherapy for the treatment of social anxiety in autistic adults has produced promising results that support a large effect size in treating social anxiety symptoms, with data being prepared for a scientific paper to be submitted for publication. Results are not available for our study of MDMA-assisted psychotherapy for anxiety associated with life-threatening diagnoses, but the study is ongoing and a review of the safety data has revealed that MDMA is well-tolerated in this population.

MDMA-assisted psychotherapy works by allowing the participant to address the root cause of his or her trauma in a safe and supportive environment, and re-process that trauma without the debilitating associations of fear and anxiety. MDMA reduces fear activation in the amygdala, which allows participants to revisit past trauma, and develop compassion for themselves.

One study participant, a military veteran named CJ Hardin, explained to the New York Times in November 2016: "[MDMA] changed my life...It allowed me to see my trauma without fear or hesitation and finally process things and move forward…[Before] I just felt hopeless and in the dark...But the MDMA sessions showed me a light I could move toward. Now I'm out of the darkness and the world is all around me."[46]

Another study participant named Julie Nelson, who survived sexual assault, recounts to Elle magazine in March 2017: "[MDMA] was like stepping off a burning tightrope...I always felt shredded internally, and this was the first time I felt whole and soft, and that the world wasn't trying to eat me."[47]

d. Highlights of Non-MAPS MDMA Research

As more MDMA research is published, more institutions continue to show interest in pursuing this promising line of research. MAPS is collaborating with a number of VA therapists across the country and is funding several research pilot projects combining MDMA with existing psychotherapeutic approaches to PTSD including Cognitive Behavioral Conjoint Therapy and Prolonged Exposure. In the U.K. a MAPS-trained psychiatrist is starting a study evaluating MDMA-assisted psychotherapy in the treatment of alcohol use disorder. Yale University's Department of Psychiatry will be starting a study increasing exploration of MDMA's mechanism

[46] Philipps, David. *F.D.A. Agrees to New Trials for Ecstasy as Relief for PTSD Patients*, New York Times (November 29th, 2016). Found at: https://www.nytimes.com/2016/11/29/us/ptsd-mdma-ecstasy.html?_r=0.
[47] Kamp, Louisa, *Could a Club Drug Be The Secret to Curing PTSD?* Elle Magazine (March 1, 2017). Found at: http://www.elle.com/culture/a43266/mdma-ecstasy-molly-ptsd-treatment/.

of action, with a focus on fMRI neuroimaging research in people with PTSD after they have taken MDMA. NIDA has provided grants to the University of Chicago Psychiatry and Behavioral Neurosciences Department to conduct studies of MDMA and emotional processing. Two such studies, which draw conclusions about MDMA's prosocial capacities, are summarized here:

One study, entitled "MDMA decreases the effects of simulated social rejection," concluded:

> Our finding that MDMA decreases perceptions of rejection in simulated social situations extends previous results indicating that MDMA reduces perception of social threat in faces. Together these findings suggest a cognitive mechanism by which MDMA might produce pro-social behavior and feelings and how the drug might function as an adjunct to psychotherapy. These phenomena merit further study in non-simulated social environments.[48]

A second study entitled "MDMA alters emotional processing and facilitates social interaction" concluded:

> MDMA alters basic emotional processes by slowing identification of negative emotions and increasing responses to positive emotions in others. Further, it positively affects behavior and perceptions during actual social interaction. These effects may contribute to the efficacy of MDMA in psychotherapy, but appear less closely related to its abuse potential.[49]

e. Non-clinical MDMA use can produce self-healing.

While non-clinical use of Ecstasy can be problematic for some people, and in rare instances even fatal when consumed in certain temperature-elevated settings without harm reduction services , there are also thousands of people who have experienced healing benefits from MDMA even when taken outside of clinical settings. There are numerous anecdotal accounts of self-medication and self-healing posted on the internet. Multiple short documentaries have been produced detailing the experiences of veterans who cured their own PTSD with MDMA.[50] MAPS has heard hundreds of anecdotes of personal accounts from people who have used MDMA to heal from a number of other mental and physical health disorders, ranging from eating disorders to alcoholism; dozens of these accounts have been published on the MAPS website.[51] One such anecdote, written by a woman who used MDMA with her husband to heal from her sexual trauma,

[48] Frye, C.G., M.C. Wardle, G.J. Norman, H. de Wit (2014) MDMA decreases the effects of simulated social rejection. *Pharmacology, Biochemistry and Behavior*, 117, 1-6. PMC3910346
[49] Wardle, M.C., H. de Wit (2014) MDMA alters emotional processing and facilitates social interaction. *Psychopharmacology*. PMC4194242
[50] *See* Ecstatic States, found at: https://vimeo.com/94074343. *See also* Psychedelic Soldiers, found at: https://www.youtube.com/watch?v=hGVaiC0SwsQ.
[51] *Accounts of MDMA's Healing Effects,* MAPS. Found at: http://www.maps.org/research/mdma/104-research/mdma/other-mdma-resources/5401-accounts-of-mdma%E2%80%99s-healing-effects.

is excerpted here:

> My first experience [with MDMA] was marriage-saving and life-changing, allowing me to acquire an emotional bond with my husband through empathy, compassion, and understanding that I had never before experienced, and a "discovery of body", which (after years of sexual dysfunction in our marriage, i.e. painful intercourse only endured with tears streaming out of my eyes and following through out of duty alone, never knowing if I had ever experienced an orgasm,) was beyond words as I experienced sex "how it was meant to be" for the first time ever. I achieved a different perspective on life and a sense of harmony with the universe and that I was wanted and somehow needed on the planet, just enough to give me back the will to live. Little did I know that this was the first step that had to take place in the uncovering of the layers that were built up around at least one sexual trauma in my past; walls so thick that I convinced even myself that the trauma never existed.
>
> […]
>
> This MDMA substance was able to provide the necessary detachment from the physical pain that I needed in order to get in touch with what physically happened, it opened me up to the compassion that I needed to feel towards myself and gave me the courage to accept my own responsibility and why it happened, it provided the confidence I needed to be able to have faith in my own ability to honestly communicate this event to my husband after having lied to him about it for all those years, it gave me faith in his ability to understand and have compassion towards me while at the same time it gave me compassion and understanding towards him for the hurt that he felt from the lies and misrepresentation, and it drove me with a resolve I needed to pursue getting better and to seek out the proper help that I needed to deal more effectively with these issues. This MDMA substance gave me a passion for and a drive toward seeking out the truth about myself and about this event, whereas other prescription anti-depressant and anti-anxiety type drugs that I had taken in the past had killed the memories and "made me happy" in a denial-type, temporary fashion.[52]

[52] Anonymous. *MDMA for PTSD for Violent Sexual Abuse*. Found at: http://www.maps.org/research-archive/mdma/june022704.html. (Note that this was anonymously reported for fear of incrimination).

IV. Conclusion

In sum, the totality of evidence we have available, which is significantly more than there was when the USSC came to its first conclusion - that one gram of MDMA should carry with it the same penalties as 500 grams of cannabis – strongly indicates that the sentencing guidelines are extremely disproportionate and in fact unrelated to MDMA's actual risks. The MDMA Sentencing Guideline should reflect MDMA's actual risk profile, rather than the exaggerated and inaccurate risk profile that it has been presented with in the past.

V. Appendices

APPENDIX A: MDMA Investigator's Brochure, 8th Ed. (30 March 2016) ("IB")

APPENDIX B: *US v. Phan* (W.D. WA 2011), Supplemental Sentencing Memorandum ("*Phan* memo")

APPENDIX C: *US v. McCarthy* (S.D. NY 2011), Memorandum and Order ("*McCarthy* order")

APPENDIX D: MAPS/ACLU Sentencing Press Release

APPENDIX E: Media Highlights

APPENDICES:

A. MDMA Investigator's Brochure, 8th Ed. (30 March 2016) ("IB") 2

B. *US v. Phan* (W.D. WA 2011), Supplemental Sentencing Memorandum ("*Phan* memo") 146

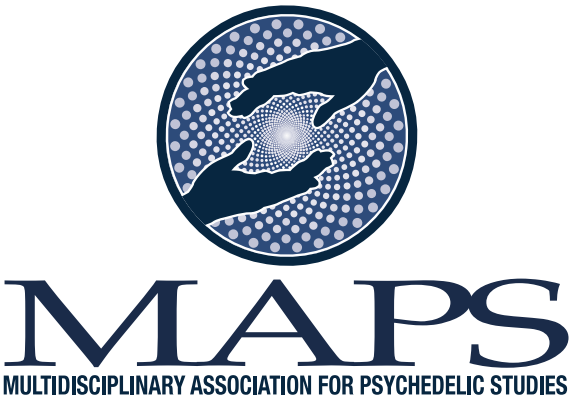
C. *US v. McCarthy* (S.D. NY 2011), Memorandum & Order ("*McCarthy* order") 183

D. MAPS/ACLU Sentencing Press Release 193

E. Media Highlights 196

APPENDIX A

MDMA Investigator's Brochure, 8th Ed. (30 March 2016) ("IB")



Investigator's Brochure

SPONSOR	Multidisciplinary Association for Psychedelic Studies (MAPS)
PRODUCT	3,4-methylenedioxymethamphetamine (MDMA)
IND #	063384
DATA CUT-OFF DATE	01 October 2015
EFFECTIVE DATE	30 March 2016
EDITION	8th Edition
REPLACES	7th Edition (dated 01 August 2013)

Table of Contents

List of Figures and Tables **4**
List of Abbreviations **6**
1.0 Summary **8**
2.0 Introduction **10**
3.0 Physical, Chemical, and Pharmaceutical Properties and Formulation **12**
4.0 Nonclinical Studies **13**
4.1 Nonclinical Pharmacology **14**
4.2 Pharmacology in Animals **14**
4.2.1 Pharmacokinetics in Animals 14
4.2.2 Pharmacodynamics in Animals 15
4.2.2.1 Stable Effects on Gene Expression in Animals 17
4.2.2.2 Immunological Effects in Animals 18
4.2.2.3 Thermoregulatory Effects in Animals 18
4.2.2.4 Cardiovascular Effects in Animals 19
4.2.2.5 Osmoregulatory Effects in Animals 19
4.2.2.6 Neurobiological Effects in Animals 20
4.2.2.7 Neuropsychological Effects in Animals 20
4.3 Physiological Effects in Epidemiological Settings **21**
4.3.1 Immunological Effects 22
4.3.2 Thermoregulatory Effects 22
4.3.3 Cardiovascular Effects 23
4.3.4 Osmoregulatory Effects 23
4.3.5 Neurobiological Effects 23
4.3.6 Neuropsychological Effects 25
4.4 Toxicology in Animals and Epidemiological Settings **26**
4.4.1 Single Dose Studies in Animals 26
4.4.2 Repeated Dose Studies in Animals 27
4.4.3 Genotoxicity 27
4.4.4 Carcinogenicity 27
4.4.5 Reproductive and Developmental Toxicity 27
4.4.6 Hyperthermia 30
4.4.7 Cardiovascular Toxicity 30
4.4.8 Hyponatremia 31
4.4.9 Hepatotoxicity 31
4.4.10 Neurotoxicity 32
4.5 Serious Reports, Mortality, and Morbidity in Animals and Epidemiological Settings **34**
4.6 Abuse Potential in Nonclinical Studies **38**
5.0 Effects in Humans in Clinical Settings **39**
5.1 History of Use in Clinical Settings **39**
5.2 Pharmacology in Humans **41**
5.2.1 Pharmacokinetics 41
5.2.2 Pharmacodynamics 44
5.3 Safety of MDMA in Humans **46**
5.3.1 Reproductive and Developmental 47
5.3.2 Immunological Effects 48
5.3.3 Thermoregulatory Effects 48
5.3.4 Cardiovascular Effects 50
5.3.5 Osmoregulatory Effects 56

5.3.6 Hepatic Effects 56
5.3.7 Neurobiological Effects 57
5.3.8 Neuropsychological Effects 58
5.3.8.1 Cognitive Function 59
5.3.8.2 Perceptual Effects 61
5.3.8.3 Social Effects 62
5.3.8.4 Emotional Effects 63
5.3.8.5 Suicidal Ideation, Behavior, and Depression 64
5.3.9 Adverse Events 73
5.3.9.1 Commonly Reported Adverse Events 73
5.3.9.2 Adverse Events 79
5.3.9.3 Serious Adverse Events 87
5.3.10 Abuse Potential 88
5.4 Efficacy of MDMA Across Populations 89
5.4.1 PTSD 89
5.4.2 Social Anxiety in Autistic Adults 91
5.4.3 Anxiety Associated with Life-Threatening Illness 91
6.0 Summary of Data and Guidance for the Investigator 92
6.1 Pharmacology 92
6.2 Toxicology 93
6.3 Physiological Effects 95
6.3.1 Immunological Effects 96
6.3.2 Hepatic Effects 96
6.4 Suicidal Ideation, Behavior, and Depression 97
6.5 Adverse Events 97
6.6 Risk Mitigation in MDMA-Assisted Clinical Trials 98
6.7 Abuse Potential 100
7.0 Conclusion 101
8.0 References 102
9.0 Appendix 134

List of Figures and Tables

Table 1: Pharmacokinetic Constants for Plasma MDMA After Various Routes of Administration to Humans or Animals 15
Table 2: Summary of Published Morbidity and Mortality Reports 35
Figure 1: Metabolism of MDMA in Humans 43
Table 3: Pre-Drug, Peak, and Final Body Temperature During Experimental Sessions with Placebo or any MDMA Dose in MAPS-Sponsored Studies Across Populations 50
Table 4: Pre-drug, Peak, and Final Systolic Blood Pressure During Experimental Sessions with Placebo or any MDMA Dose in MAPS-Sponsored Studies Across Populations 52
Table 5: Pre-drug, Peak, and Final Systolic Blood Pressure During Experimental Sessions in Controlled Hypertension Subjects in MAPS-Sponsored PTSD Study MP-8 53
Table 6: Pre-drug, Peak, and Final Diastolic Blood Pressure During Experimental Sessions with Placebo or any MDMA Dose in MAPS-Sponsored Studies Across Populations 54
Table 7: Pre-drug, Peak, and Final Diastolic Blood Pressure During Experimental Sessions in Controlled Hypertension Subjects in MAPS-Sponsored PTSD Study MP-8 54
Table 8: Pre-drug, Peak, and Final Heart Rate During Experimental Sessions with Placebo or any MDMA Dose in MAPS-Sponsored Studies Across Populations 55
Table 9: List of All Clinically Significant Changes in Laboratory Values in Two Subjects from MP-2 56
Table 10: Average ALT Values at Baseline and 2-Month Follow-up After Two Experimental Sessions in Subjects from MP-1 57
Table 11: Neurocognitive Function - RBANS Mean Total Scores at Baseline, Primary Endpoint, End of Stage 1, and End of Stage 2 for MP-1, MP-4, and MP-12 as of 01 October 2015 60
Table 12: Neurocognitive Function - PASAT Trial 1 and Trial 2 Mean Raw Total Scores at Baseline, Primary Endpoint, End of Stage 1, and End of Stage 2 for MP-1, MP-4, and MP-12 as of 01 October 2015 61
Table 13: Summary of Baseline Positive and Serious Responses on C-SSRS for Studies MP-4, MP-8, MP-9, MP-12, MAA-1, and MDA-1 as of 01 October 2015 65
Table 14: C-SSRS Positive and Serious Responses During Experimental Sessions and 1-Day Post-Drug for Studies MP-4, MP-8, MP-9, and MP-12 as of 01 October 2015 66
Table 15: C-SSRS Positive and Serious Responses During Experimental Sessions and 1-Day Post-Drug for Studies MAA-1 and MDA-1 as of 01 October 2015 68
Table 16: C-SSRS Positive Responses During Telephone Contact Following Experimental Sessions for Studies MP-4, MP-8, MP-9, MP-12, MAA-1, and MDA-1 as of 01 October 2015 69
Table 17: C-SSRS Positive Responses at Endpoints After Treatment for Studies MP-4, MP-8, MP-9, MP-12, MAA-1, and MDA-1 as of 01 October 2015 70
Table 18: Mean BDI-II Scores at Baseline, Primary Endpoint, and End of Stage 1 by Dose for Studies MP-4, MP-8, MP-9, and MP-12 as of 01 October 2015 71
Table 19: Mean BDI-II Scores at Secondary Endpoint, End of Stage 2, and 12-month Follow-up for Studies MP-4, MP-8, MP-9, and MP-12 as of 01 October 2015 72
Table 20: Mean BDI-II Scores After MDMA or Placebo in MAA-1 as of 01 October 2015 72
Table 21: Mean Percentage of Subjects Reporting Commonly Reported Reactions During MDMA or Placebo Treatment Collected from 12 Phase 1 Studies Conducted Outside of Sponsor Support 74
Table 22: Percentage of Observations of Most Commonly Reported Spontaneously Reported Reactions During Experimental Sessions in Studies MP-1, MP-2, MP-4, MP-8, MP-9, MP-12, MDA-1, MAA-1, and MP1-E2 as of 01 October 2015 75
Table 23: Percentage of Observations of Most Commonly Reported Spontaneously Reported Reactions During Telephone Contact on Day 1-7 After Experimental Sessions in

Studies MP-1, MP-2, MP-4, MP-8, MP-9, MP-12, MDA-1, MAA-1, and MP1-E2 as of 01 October 2015 77
Table 24: Overview of All Adverse Events Post-Drug by Severity and Relationship in MAPS-Sponsored Studies Across Populations as of 01 October 2015 79
Table 25: Body Systems of All Adverse Events Post-Drug Reported by 2% or More of Subjects in MAPS-Sponsored Studies Across Populations 81
Table 26: Related Adverse Events in Sponsor Supported Studies of MDMA-Assisted Psychotherapy Across Populations Organized by Body System as of 01 October 2015 84
Table 27: Severe Related Adverse Events in Sponsor Supported Studies of MDMA-Assisted Psychotherapy Across Populations as of 01 October 2015 87
Table 28: Serious Adverse Events in Sponsor-Supported Studies of MDMA-Assisted Psychotherapy Across Populations as of 01 October 2015 88
Table 29: Mean Global CAPS Scores in Stage 1 of Sponsor-Supported Studies of MDMA-Assisted Psychotherapy for PTSD as of 01 October 2015 90
Table 30: Mean Global CAPS Scores in Stage 2 and Long-term Follow-up of Sponsor-Supported Studies of MDMA-Assisted Psychotherapy for PTSD as of 01 October 2015 91
Table 31: Percentage of Observations of Spontaneously Reported Reactions During Experimental Sessions in Studies MP-1, MP-2, MP-4, MP-8, MP-9, MP-12, MDA-1, MAA-1, and MP1-E2 as of 01 October 2015 134
Table 32: Spontaneously Reported Reactions on Day 1-7 After All Experimental Sessions in Studies MP-1, MP-2, MP-4, MP-8, MP-9, MP-12, MDA-1, MAA-1, and MP1-E2 as of 01 October 2015 139

List of Abbreviations

Ach	Acetylcholine
AE(s)	Adverse Event(s)
ALT	Alanine Aminotransferase
API	Active Pharmaceutical Ingredient
ARF	Acute Renal Failure
AVP	Arginine Vasopressin
BDI	Beck Depression Inventory
BDI-II	Beck Depression Inventory II
BDNF	Brain Derived Neurotrophic Factor
BOLD	Blood Oxygen Level Dependent
C	Celsius
CAPS	Clinician Administered PTSD Scale
CBF	Cerebral Blood Flow
cGMP	Current Good Manufacturing Practice
CNS	Central Nervous System
COMT	Catechol-O-methyltransferase
CPK	Creatine Phosphokinase
CRA	Clinical Research Associate
C-SSRS	Columbia Suicide Severity Rating Scale
CTproAVP	Stimulating Secretion of Copeptin
DAT	Dopamine Transporters
DEA	Drug Enforcement Administration
DBP	Diastolic Blood Pressure
DIC	Disseminated Intravascular Coagulation
DMF	Drug Master File
DNA	Deoxyribonucleic Acid
DSM-IV	Diagnostic and Statistical Manual of Mental Disorders IV
E	Embryonic Days
EEG	Electroencephalography
EKG	Electrocardiogram
ESR	Erythrocyte Sedimentation Rate
FDA	Food and Drug Administration
fMRI	Functional Magnetic Resonance Imaging
G-CSF	Granulocyte-colony Stimulating Factor
GD	Gestational Days
HHMA	3,4-Dihydroxymethamphetamine
HMA	4-Hydroxy-3-methoxy-amphetamine
HMMA	4-Hydroxy-3-methoxy-methamphetamine
HPA	Hypothalamus-pituitary-adrenal
HR	Heart Rate
IB	Investigator's Brochure
IL	Interleukin
IND	Investigational New Drug
LD50	Lethal Dose in 50% of Cases
LSD	d-Lysergic Acid Diethylamide
MAA-1	Phase 2 clinical trial of MDMA-assisted therapy for social anxiety in people on the autism spectrum
MAO	Monoamine Oxidase
MAO-A	Monoamine Oxidase A
MAOI	Monoamine Oxidase Inhibitor

MAPS	Multidisciplinary Association for Psychedelic Studies
MDA	3,4-Methylenedioxyamphetamine
MDA-1	Phase 2 clinical trial of MDMA-assisted psychotherapy for anxiety in relation to a life-threatening illness
MDE	Methylenedioxyethylamphetamine
MDMA	3,4-Methylenedioxymethamphetamine
MP-1	Phase 2 clinical trial of MDMA-assisted psychotherapy for PTSD in Charleston, South Carolina
MP1-E2	Relapse study Phase 2 clinical trial of MDMA-assisted psychotherapy for PTSD in Charleston, South Carolina
MP-2	Phase 2 clinical trial of MDMA-assisted psychotherapy for PTSD in Switzerland
MP-3	Phase 2 clinical trial of MDMA-assisted psychotherapy for PTSD in Israel
MP-4	Phase 2 clinical trial of MDMA-assisted psychotherapy for PTSD in Canada
MP-8	Phase 2 clinical trial of MDMA-assisted psychotherapy for PTSD in Canada
MP-9	Phase 2 clinical trial of MDMA-assisted psychotherapy for PTSD in Canada
MP-12	Phase 2 clinical trial of MDMA-assisted psychotherapy for PTSD in Canada
MRI	Magnetic Resonance Imaging
mRNA	Messenger Ribonucleic Acid
MT-1	Phase 1 clinical trial of MDMA-assisted psychotherapy for PTSD in healthy volunteers in Charleston, South Carolina
NET	Norepinephrine Transporter
NK	Natural Killer
NLP	Natural Language Processing
PASAT	Paced Auditory Serial Addition Task
PET	Positron Emission Tomography
PFC	Prefrontal Cortex
PMA	Paramethoxyamphetamine
PMMA	Paramethoxymethamphetamine
PND	Postnatal Day
PTSD	Posttraumatic Stress Disorder
RBANS	Repeatable Battery for the Assessment of Neuropsychological Status
*r*CBF	Regional Cerebral Blood Flow
SAE(s)	Serious Adverse Event(s)
SBP	Systolic Blood Pressure
SERT	Serotonin Transporter
SIADH	Syndrome of Inappropriate Antidiuretic-hormone Secretion
SNRI	Selective Serotonin and Norepinephrine Uptake Inhibitor
SPECT	Single Photon Emission Tomography
SSRI	Selective Serotonin Reuptake Inhibitor
SUD	Subjective Units of Distress
TNF-α	Tumor Necrosis Factor-alpha
VHD	Valvular Heart Disease
VMAT2	Vesicular Monoamine Transporter 2
WBC	White Blood Cell Count
8-OH-DPAT	8-Hydroxy-2-(di-n-propylamino)tetralin

1.0 Summary

The Multidisciplinary Association for Psychedelic Studies (MAPS) is a U.S.-based non-profit research and educational organization supporting research of the therapeutic potential of 3,4-methylenedioxymethamphetamine (MDMA). MAPS is sponsoring clinical trials of MDMA-assisted psychotherapy for patients with chronic disorders such as Posttraumatic Stress Disorder (PTSD), social anxiety associated with autism, and anxiety related to terminal illnesses. MDMA-assisted psychotherapy is an experimental treatment that combines psychotherapeutic techniques with administration of MDMA, a pharmacological adjunct that enhances aspects of psychotherapy. Prior to placement on the Drug Enforcement Administration's (DEA) list of Schedule I substances, MDMA was administered to thousands of people in psychotherapeutic practice outside of clinical trials. According to the 2011 United Nations World Drug Report, 11 to 28 million people aged 15 to 64 used Ecstasy, material represented as containing MDMA, around the world in various non-medical settings [1-5, 631]. The information presented in this Investigator's Brochure (IB) is summarized from published research studies of MDMA conducted by groups outside of the sponsor, sponsor collected data and published studies of Ecstasy use. For the purposes of this document MDMA will be used to refer to drug of known purity used in a controlled setting and Ecstasy will be used to describe drug-related information gathered from epidemiological settings.

MDMA is a ring-substituted phenethylamine also known as methylenedioxymethamphetamine. MDMA is structurally similar, but functionally distinct, from amphetamines. MDMA is a chiral molecule, the sponsor uses racemic MDMA in the form of white crystalline powder compounded with inert material into capsules. The hydrochloride salt of MDMA is readily water soluble and once ionized is lipophilic. A substantial amount of data, both clinical and nonclinical, has been collected for over half a century of research on the physiological and psychological effects of MDMA in humans and animals. Estimates from animal data suggest a median lethal dose (LD50) in humans between 10 to 20 mg/kg [632]. Due to a wide range of responses to identical milligram per kilogram (mg/kg) dosing [7], the sponsor's human trials use fixed doses equivalent to between 1 and 4 mg/kg (active doses in studies range from 75 mg to 225 mg). Onset of MDMA effects occurs 30 to 60 minutes after oral administration [7, 8, 9], peak effects appear 75 to 120 minutes post-drug [10, 11, 12], and duration of effects lasts from 3 to 6 hours [10, 12, 13], with most effects returning to baseline or near-baseline levels 6 hours after drug administration. The elimination half-life of active doses is 8 to 9 hours [14].

The pharmacokinetics of MDMA in humans has been characterized using oral doses of up to 150 mg MDMA. MDMA disposition in the body follows nonlinear pharmacokinetics. As described in Figure 1 (see Section 5.2.1 Pharmacokinetics), metabolism of MDMA results in *N*-demethylation to 3,4-methylenedioxyamphetamine (MDA). The parent compound and MDA are further *O*-demethylenated to 3,4-dihydroxymethamphetamine (HHMA) and 3,4-dihydroxyamphetamine (HHA), respectively. Both HHMA and HHA are subsequently *O*-methylated mainly to 4-hydroxy-3-methoxy-methamphetamine (HMMA) and 4-hydroxy-3-methoxy-amphetamine (HMA). These four metabolites, particularly HMMA and HMA, are known to be excreted in the urine as conjugated glucuronide or sulfate metabolites [14].

MDMA is a triple monoamine reuptake inhibitor, and similar drugs in this class have been found to exert potent anti-depressant activity with a favorable safety profile in clinical trials [15, 16]. MDMA concomitantly promotes release, inhibits reuptake, and extends duration of serotonin, norepinephrine, and dopamine in the synaptic cleft to increase serotonergic, noradrenergic, and dopaminergic neurotransmission. MDMA has self-limiting subjective and physiological effects due to inhibitory activity on tryptophan hydroxylase [17-19], which prevents additional serotonin from being produced and released. This inhibition is reversible [20]. MDMA produces anxiolytic

and prosocial effects through release of the monoaminergic neurotransmitters, with the greatest effect on serotonin, followed by norepinephrine and dopamine [21-25]. MDMA has been shown to acutely decrease activity in the left amygdala and increase blood flow to the prefrontal cortex (PFC) in the brain [26-28]. MDMA has also been found to increase serum levels of the neurohormones oxytocin and arginine vasopressin (AVP) in humans [19, 29-33]. Some studies in healthy volunteers suggest that MDMA increases trust and attenuates reactivity to threatening cues, which are at least partially associated with oxytocin release [29, 34, 35]. The combined neurobiological effects of MDMA can increase compassion for self and others, reduce defenses and fear of emotional injury, and make unpleasant memories less disturbing while enhancing communication and capacity for introspection [36-39]. These factors taken together can provide the opportunity for a corrective emotional experience in the context of psychotherapy. Many of the therapeutic effects of MDMA-assisted psychotherapy are evident within a short period of treatment, often after the initial session.

Increased feelings of interpersonal closeness, changes in social perception and reduced anxiety may make MDMA a suitable pharmacological adjunct to enhance psychotherapy for anxiety disorders, such as PTSD and social anxiety in autistic adults [40]. MDMA may provide a much-needed option in the treatment of PTSD and anxiety associated with other conditions. Published results from MAPS study (MP-1) showed clinically and statistically significant improvements in PTSD severity in 20 per protocol subjects [41]. Findings from the long-term follow-up of MP-1 suggest that therapeutic benefits were sustained for an average of 41 months post-treatment [42]. The sponsor's second Phase 2 pilot study conducted in Switzerland (MP-2) demonstrated clinically significant improvements in PTSD symptoms, with results in the 125 mg MDMA dose group numerically but not statistically superior to the 25 mg MDMA dose group [43]. Long-term follow-up data 12 months later suggest that therapeutic benefits continued to increase in this subject population. There were no drug-related Serious Adverse Events (SAEs) or safety concerns in either study.

Data from MAPS studies and published literature show that MDMA produces sympathomimetic effects that include significant transient, self-limiting increases in heart rate (HR) and blood pressure that are likely to be well tolerated by healthy individuals [7, 9, 10, 12, 26, 44-46]. Most people do not experience elevations that exceed those seen after moderate exercise. These results were reproduced in MAPS Phase 1 safety study [47]. Risks posed by elevated blood pressure are addressed by excluding candidates with a history of cardiovascular, cerebrovascular disease, or with pre-existing uncontrolled hypertension and by regularly monitoring blood pressure and pulse throughout experimental sessions. Common reactions reported in the literature and clinical trials from MDMA are transient and diminish as drug effects wane during the session and over the next one to 7 days. The effects include lack of appetite, insomnia, dizziness, tight jaw or bruxism, difficulty concentrating, headache, impaired gait or balance, muscle tension, ruminations, feeling cold, and thirst (see Section 5.3.9 Adverse Events). MDMA is also a mild immunosuppressant [48]. Due to their limited duration, these sub-acute reactions are not likely to have clinical significance.

As of 01 October 2015, with 1180 individuals exposed to MDMA in controlled research settings (which includes 122 in MAPS-sponsored studies), there have been no unexpected drug-related SAEs to date, and expected SAEs have been rare and non-life threatening. As of the data cut-off, a single expected related SAE (increased ventricular extrasystoles), and 10 unrelated SAEs after drug administration have been reported in MAPS-sponsored clinical trials.

There have been a number of SAEs reported in individuals who use Ecstasy (material represented as containing MDMA, as defined above) around the world in various non-medical settings [1-5]. These include fatalities reported after Ecstasy and poly-drug use in unsupervised and uncontrolled

settings. These events are relatively rare given the prevalence of Ecstasy use, estimated to be in the millions worldwide [49, 50]. The most common adverse effects in Ecstasy and poly-drug use include hyperthermia, psychiatric problems, hepatotoxicity, and hyponatremia [51-55] (see Section 4.4 Toxicology in Animals and Epidemiological Settings and 4.5 Serious Reports, Mortality, and Morbidity in Animals and Epidemiological Settings).

2.0 Introduction

MDMA is not a novel compound. The history of its use in humans predates controlled studies in healthy volunteers and clinical trials. MDMA was first synthesized and patented by Merck in 1912 [56] and is currently not covered by a patent. MAPS holds the Drug Master File (DMF) and an Investigational New Drug (IND) for MDMA with the U.S. Food and Drug Administration (FDA). After MDMA was rediscovered by the chemist Alexander Shulgin in 1976 [57], he and his colleagues provided initial reports of its pharmacology, with 80 mg to 160 mg MDMA required to produce desired subjective effects in humans [58, 59]. MDMA was found to robustly influence human emotional status in a unique way [59] without adversely effecting physiological functions or perception, such as visual perception or cognition [8, 11, 13].

MDMA possesses a complex pharmacological profile that is dominated by its effects as a monoamine releaser and reuptake inhibitor, with additional effects on limiting neurotransmitter production and degradation. Its prominent effects on serotonin differentiate it from amphetamine and methamphetamine, which primarily act to increase catecholamines such as norepinephrine and dopamine [21, 60]. In the Merck Index, MDMA resides in the Entactogen class [61]. Entactogens contain a ring-substituted amphetamine core, belong to the phenethylamine class of psychoactive drugs, and are described as promoting acceptance and compassion for self and others, changing recognition and response to emotions, and increased interpersonal closeness [19, 37, 62, 63]. In comparison to anxiolytics, antidepressants and atypical antipsychotics, MDMA does not require steady state levels in the blood to function as a catalyst to psychotherapy. Two to six administrations of MDMA, spaced approximately 1 month apart at active doses of 75 mg to 125 mg, may be an alternative to other medications that require daily dosing. This infrequent dosing regimen mitigates adverse event (AE) frequency and improves the risk/benefit ratio of MDMA, which may provide a significant advantage over daily dose medications.

Shulgin and Nichols were the first to report the effects of MDMA in humans [59]. MDMA-assisted psychotherapy first occurred during the mid-to-late 1970s after Shulgin introduced MDMA to a psychotherapist, Leo Zeff. Reported effects of MDMA include enhanced feelings of closeness to others, wellbeing, and insightfulness [64-66]. Prior to placement in Schedule I, MDMA was used in psychotherapy for individuals, couples, and groups to treat diverse psychological disorders, including moderate depression and anxiety [65, 67-69]. It was also found to be useful in reducing physical pain secondary to certain kinds of cancer [68]. No formal controlled clinical trials of safety and efficacy were conducted at the time [65, 70].

During the early 1980s, increasing numbers of people began using MDMA, sold as "Ecstasy" outside of therapeutic contexts [1]. The first wave of non-medical use occurred not only in dance clubs, but also in groups of people who used the drug in a self-exploratory or spiritual context. Non-medical use continues today in the same contexts [4, 71]. In the U.S., an estimated 800,000 people reported initiating Ecstasy use in the past year [72], and approximately 2.1 million Europeans between the ages of 15 and 64, or approximately 0.6% of the population, reported using Ecstasy in 2013 [73].

MDMA was added to the list of Schedule I controlled substances in the U.S. in 1985, defining it as a drug with a high potential for abuse and no accepted medical use [74, 75]. Classification as a Schedule I controlled substance, combined with the early research in animals and recreational users, hampered clinical research into the medical uses of MDMA until the 1990s. Shortly after it was scheduled, animal studies described long-term decreases in markers of serotonergic functioning after high or repeated doses of MDMA administration [76], however these were not relevant to doses in clinical trials [77, 78]. A recently published meta-analysis took careful steps to overcome methodological limitations in previous work, and found only modest indicators of long-term impairment in cognitive function in humans [53]. A systematic review of brain imaging studies in moderate ecstasy users found no convincing evidence for structural or functional changes [79]. Reports of AEs, such as hyperthermia, following Ecstasy use [80-82] and studies in Ecstasy users reporting changes in serotonin transporter (SERT) density, impaired memory and executive function raised concerns regarding the safety of MDMA administration [83-87]. However uncontrolled studies of Ecstasy use and preclinical animal studies that use inappropriately high doses of MDMA produce findings that are open to several interpretations [78, 88]. The vast majority of publications of Ecstasy users are retrospective reports in polydrug-users [53, 89].

While the initial studies in the 1990s conducted in humans examined the physiological effects of MDMA strictly from a safety perspective, current investigations have examined the effects on attention, prosocial effects, memory and brain activity, and human drug discrimination. Findings from an initial sponsor-funded study indicated that MDMA-assisted psychotherapy could be conducted safely in people with chronic PTSD who had failed first line treatments [90, 527]. This was repeated in a chronic, treatment-resistant PTSD sample in a sponsor-supported study (MP-1) [42] which demonstrated durable improvement in PTSD severity, with no difference in cognitive function between placebo and MDMA groups after an active dose of MDMA was given on two occasions, 1 month apart. In addition, placebo-controlled Phase 1 clinical trials confirmed that MDMA produces an easily controlled intoxication characterized by euphoria, increased well-being, sociability, self-confidence, extroversion, transient increases in anxiety, and minor alterations in perception [8, 10-12, 29, 30, 35, 91, 92].

MAPS is completing Phase 2 investigations of MDMA-assisted psychotherapy. Significant durable improvement in PTSD symptoms lasted for at least 12 months after MDMA-assisted psychotherapy in two completed studies (MP-1, MP-2) [42, 43]. There are four Phase 2 studies for treatment of PTSD that have completed treatments and are in follow-up: two studies in the U.S. (MP-8, MP-12), one in Canada (MP-4), and one in Israel (MP-9). Data from Phase 2 studies will be submitted to FDA for an End-of-Phase 2 meeting to support an application for Phase 3 multi-site MDMA/PTSD research studies. Based on the current state of scientific knowledge and the risk/benefit profile of active doses of MDMA, it appears favorable to continue the research of MDMA as an adjunct to psychotherapy.

Based on clinical experience with PTSD, MAPS is exploring new indications for this treatment. Studies for additional indications include one Phase 2 study (MAA-1) of MDMA-assisted therapy for social anxiety in people on the autism spectrum and one study of MDMA-assisted psychotherapy to address anxiety associated with a life-threatening illness (MDA-1). In addition, there is one ongoing Phase 1 study of MDMA-assisted psychotherapy to assess psychological effects in healthy volunteers (MT-1). When completed, this will be the first Phase 1 investigation to assess acute effects in a therapeutic setting that is comparable to MDMA-assisted psychotherapy studies for PTSD.

This IB will present preclinical and clinical studies of MDMA, as well as epidemiological studies in Ecstasy users.

3.0 Physical, Chemical, and Pharmaceutical Properties and Formulation

MDMA is structurally similar, but functionally distinct, from amphetamines and mescaline. MDMA, also known as 3,4-methylenedioxy-N-methylamphetamine and N-methyl-3,4-methylenedioxyamphetamine, has the chemical formula of $C_{11}H_{15}NO_2$. It was first synthesized as a precursor of a haemostatic drug called methylhydrastinine as a phenylisopropylamine derivative of safrole, an aromatic oil found in sassafras, nutmeg, and other plants [56].

MDMA is a chiral molecule, possessing two enantiomers, S(+)-MDMA and R(-)-MDMA, with S(+)-MDMA being more potent than R(-)-MDMA [6, 58]. Research in humans to date and the majority of nonclinical studies have used racemic MDMA, or an admixture containing equal amounts of both enantiomers. Studies of drug discrimination in rodents [94, 95] and studies of self-administered and experimenter-administered MDMA enantiomers in primates [23, 96-99] suggest that MDMA enantiomers may produce different physiological and rewarding effects, and there may be some synergy between the two when administered as a racemate. It seems that R(-)-MDMA may have hallucinogen-like effects, compared to S(+)-MDMA, which exhibits psychomotor stimulant-like effects. Findings comparing the effects of the enantiomers of the related compound methylenedioxyethylamphetamine (MDE) suggest that these different effects of MDMA enantiomers may occur in humans [100]. According to an *in vivo* microdialysis study in rodents, S(+)-MDMA may be associated with greater dopamine release in specific brain areas [101]. A study conducted in 2014 in monkeys found that S(+)-MDMA, but not R(-)-MDMA, significantly increased extracellular dopamine levels in the dorsal striatum, whereas S(+)-MDMA significantly increased serotonin levels [23]. In vitro studies reported greater binding at a specific alpha nicotinic acetylcholine (Ach) receptor by R-MDMA compared with S-MDMA [102]. MDMA available for humans in clinical trials is racemic, containing roughly equal amounts of both enantiomers. Any differential effects of the enantiomers remain untested in humans. The sponsor will use racemic MDMA in all current and planned studies. Unless otherwise stated, MDMA is used throughout this document to refer to the racemic mixture.

For clinical trials, the sponsor used racemic hydrochloride salt of MDMA from two sources. Since this is the formulation used in all prior investigations in humans, the sponsor will continue to use the hydrochloride salt of MDMA. The hydrochloride salt of MDMA is readily water soluble with a pK_a of 9.9 [103], which influences whether it is ionized in plasma and slightly reduces its ability to cross into oral fluid. MDMA is also more lipophilic, which drives it into oral fluid, and may influence its ability to pass the blood brain barrier and influence signaling in the central nervous system (CNS) [104].

Sponsor-supported studies in the U.S. use MDMA manufactured in 1985 by David Nichols, Ph.D., at the Department of Medicinal Chemistry and Pharmacology, Purdue University, West Lafayette, IN. The MDMA was manufactured as a single lot for use in federally approved clinical research. A stability analysis conducted in 2006 indicates that the compound remains highly stable and pure after 21 years of storage [105]. Studies conducted outside of the U.S. use MDMA from a single batch manufactured in 1998 by Lipomed AG in Arlesheim, Switzerland. The most recent analysis of drug stability and purity conducted on February 2, 2010 confirmed that this MDMA is 99.9% pure with no detectable decomposition. For sponsor-supported studies, MDMA in the form of white crystalline powder is compounded with inert material into capsules. Capsules are administered orally with a glass of water.

The sponsor has contracted with Shasun, a manufacturer in the United Kingdom, to manufacture active pharmaceutical ingredients (APIs) to produce 1 kg of MDMA following current Good

Manufacturing Practices (cGMP). The material is planned for use in all Phase 3 studies. Details of manufacturing are available from the manufacturer upon request.

MDMA doses in sponsor-supported studies are fixed within a therapeutic dose range, rather than based on body weight, based on epidemiological information and lack of linear dose response with behavioral effects in Phase 1 and sponsor-supported studies [7]. A typical active dose is 125 mg, which is equivalent to 2 mg/kg for the initial dose. The optional supplemental dose of 62.5 mg is equivalent to 1 mg/kg, for a cumulative dose of 3 mg/kg. Various comparator and active doses of MDMA are also being tested in the clinical trials.

MDMA does not require special conditions for storage. The capsules are stored in sealable containers placed within a dark safe at ambient temperature. MDMA is a Schedule I compound and is stored and handled in compliance with relevant federal and state regulations. In accordance with the requirements of the U.S. DEA and international drug regulatory authorities, license holders will be responsible for storing and dispensing the MDMA, and ensuring it is stored under appropriate protections, often in a floor-mounted safe.

Lactose is used as inactive placebo and as an inactive filler intended to maintain blinding by creating capsules of equal weight. Lactose has been in use as an inactive material of similar appearance and was selected because it can be safely consumed by most people and is inactive. Whenever conducting blinded studies, the sponsor will continue to employ lactose or inactive materials that exist as white powders without significant odor that can be safely administered in humans. The purpose of this excipient is solely to permit placebo or active placebo administration under blinded conditions.

4.0 Nonclinical Studies

Findings from nonclinical animal research, retrospective studies of Ecstasy use and case reports of Ecstasy use in humans are presented. Research into the pharmacological, physiological, or psychological effects of MDMA began in the 1950s, when the U.S. Army administered MDMA to guinea pigs, monkeys, mice, rats, and dogs as part of a military research program, possibly intending to develop chemical incapacitants or means of enhancing interrogation [106]. Investigations of the pharmacology, functional effects, and toxicity of MDMA in animals have generally included injections of large and often repeated doses of MDMA that are not human-equivalent doses. Studies of MDMA have been conducted in primates and rodents. Primate species studied include baboon, macaque, rhesus monkey, and squirrel monkey, and rodents include mice and rats. Studies of circadian rhythm have occurred in hamsters. Beginning in the mid-2000s onwards, reports re-examining these effects have questioned the applicability of interspecies scaling models for MDMA, and have supported nonlinear pharmacology [78, 107, 108]. In general, doses in the range of 1 to 5 mg/kg in animals are relevant to human research and are described in more detail in Section 4.2.2 Pharmacodynamics in Animals. Findings in doses above this that show a toxic effect are described when relevant in Section 4.4 Toxicology in Animals and Epidemiological Settings.

Evidence exists for intentional human use of MDMA, known as Ecstasy among other names, as early as the late 1960s [57], and there are records of a police seizure of MDMA in the early 1970s [109]. MDMA was administered to thousands of people prior to scheduling and many continue to use Ecstasy around the world in various non-medical settings [1-5]. In this IB, "Ecstasy" (or other common names) refers to material assumed to be MDMA used in naturalistic settings (see epidemiology sections), however when used in these uncontrolled settings the drug may not contain only or any MDMA. One of the problems in assessing the effects of Ecstasy in users is determining the purity and identity of the substance. It may contain other substances along with

or instead of MDMA, and when present, the amount of MDMA can vary widely [110-112]. The majority of studies rely on self-reported use and do not attempt to confirm that material used is MDMA. Synthesis of MDMA is relatively simple, and is often produced illegally in laboratories with no quality control, these synthesized tablets also may be cut or mixed with other psychoactive substances. Substances found mixed with MDMA have included amphetamine methamphetamine, dextromethorphan, paramethoxymethamphetamine (PMMA), paramethoxyamphetamine (PMA), cathinones, ketamine, caffeine, and ephedrine. Retrospective studies in Ecstasy users are described in Section 4.3 Physiological Effects in Epidemiological Settings and case reports of morbidity and mortality in Ecstasy users are included in Section 4.5 Serious Reports, Mortality, and Morbidity in Animals and Epidemiological Settings to provide the context of potential safety information of a related compound to MDMA which has extensive use outside of a research setting.

4.1 Nonclinical Pharmacology

MDMA possesses a complex pharmacological profile that is dominated by its effects as a monoamine releaser and reuptake inhibitor. Its prominent effects on serotonin differentiate it from amphetamine and methamphetamine, which primarily act on dopamine and norepinephrine [21, 60]. In the following sections, the pharmacology of MDMA is presented based on nonclinical animal studies and epidemiological studies.

4.2 Pharmacology in Animals

4.2.1 Pharmacokinetics in Animals

MDMA is metabolized via two hepatic pathways. In the major pathway in rats, MDMA is *O*-demethylenated by cytochrome P450 CYP2D1 and 3A2 to form HHMA, which is *O*-methylated to generate HMMA by catechol-O-methyltransferase (COMT). In the minor pathway in rats, MDMA is *N*-demethylated by CYP1A2 and 2D1 to form MDA, which is an active metabolite. MDA is *O*-demethylenated by the same enzymes as MDMA, with subsequent metabolism by COMT. Metabolites of MDMA are excreted in urine as glucuronide and sulfate conjugates. MDMA and metabolites have shorter half-lives in rats than humans at comparable doses based on plasma C_{max} values. Rats tend to form more MDA and glucuronide-conjugated metabolites than humans [113]. As MDMA dose increases above 2.5 mg/kg s.c. or i.p. in rats, a larger percentage of the administered dose is shunted to the *N*-demethylation pathway, resulting in greatly enhanced formation of MDA [114]. Comparison of metabolic pathways between rats and mice given 10 mg/kg intraperitoneal (i.p.) MDMA indicate that 49.1% of MDMA is metabolized through the HMMA pathway in mice versus 72% in rats, and 18.3% of MDMA is metabolized through the MDA pathway in mice versus 28% in rats based on AUC ratios to MDMA. MDMA at 10 mg/kg was also found to be eliminated more rapidly in mice (0.4 hours, i.p.) than rats at (1.1 hours, subcutaneous (s.c.)) [78, 115].

To address questions of the applicability of interspecies scaling models and nonlinear pharmacology of MDMA, a study examining MDMA and metabolites in rats given 2.5, 5, and 10 mg/kg s.c. found that MDMA metabolism is nonlinear in rats, with 2.5 mg/kg producing plasma C_{max} levels approximating those seen in humans receiving between 75 and 100 mg [14, 114, 116]. Injections of 2 mg/kg s.c. or i.p. in rats were found to be similar to oral administration of 100 mg MDMA in humans based on plasma MDMA and metabolite concentrations [78]. Based on plasma values, a dose of 3 mg/kg i.p. MDMA administered in mice was comparable to a single oral dose of 100 mg in humans [94]. Studies in rats and mice provide compelling evidence of nonlinear pharmacokinetics, likely due to saturation of metabolic enzymes, determined by greater

than expected AUC values for MDMA and MDA after subsequent MDMA doses, while AUCs for HHMA and HMMA remained lower than expected [114, 115].

Single dose pharmacokinetics of oral 7.4 mg/kg MDMA in squirrel monkeys shows two to three-fold higher plasma MDMA concentrations than humans receiving an oral dose of 100 mg, although allometric interspecies scaling predicts an equivalent dose [107]. A study directly comparing MDMA pharmacokinetics in humans and monkeys found that the two species metabolized MDMA in a similar but not identical manner - MDMA half-life in monkeys was less than half the duration seen in humans (1.1 hours at a dose of 2.8 mg/kg in squirrel monkeys versus 8.4 hours after 1.5 mg/kg in humans). Both monkeys and humans exhibit nonlinear pharmacokinetics [14, 118, 119], and it appears they exhibit similar plasma MDMA levels after receiving the same dose of MDMA [119, 120]. These pharmacokinetic findings suggest that nearly all toxicological and behavioral preclinical studies of MDMA use overestimated doses that exceed human-equivalent doses by 2.7 to 10.7 times, depending on route of administration, due to both simple dose conversion and allometric scaling. As a consequence, it is difficult to interpret the relevance of findings in preclinical studies employing these dosing regimes.

Table 1: Pharmacokinetic Constants for Plasma MDMA After Various Routes of Administration to Humans or Animals

	C_{max} (ng/ml)	AUC (h•ng/ml)	T_{max} (h)	$t_{1/2}$ (h)	References
Rat [A]					
2 mg/kg i.p.	210±108	163±56	0.14±0.08	0.80±0.16	[78]
2 mg/kg s.c.	196±50	304±65	0.75±0.29	0.79±0.14	[78]
2 mg/kg p.o.	46±15	61±42	0.56±0.31	0.77±0.11	[78]
2.5 mg/kg s.c.	164.1±47.1	272.1±71.6	0.6±0.2	1.1±0.9	[114]
5 mg/kg s.c.	370.8±41	879.1±133.2	0.9±0.6	0.9±0.1	[114]
10 mg/kg s.c.	893.9±90.7	2879.9±491.5	1.1±0.4	2±0.6	[114]
Mouse [B]					
3 mg/kg i.p.[C]	369.8	---	0.17	0.6	[94]
10 mg/kg i.p.	1109±87	1233±53	≤0.3	0.4	[115]
20 mg/kg i.p.	2152±82	2611±86	≤0.3	0.6	[115]
Squirrel Monkey					
1.4 mg/kg p.o.	100.2±51.5	340.3±248.4	1±0.4	1.8±0.9	[121]
2.8 mg/kg p.o.	312.7±92.8	1314.2±581.5	1.1±0.4	2.1±0.8	[121]
5.7 mg/kg p.o.	723.6±228	3866.2±891	1.3±0.9	2.6±0.7	[121]
10 mg/kg p.o.	1594.5±295.6	12,839.2±2144.6	1.3±0.9	4.2±1.5	[121]
7.4 mg/kg s.c.	1227±167	5006±528	---	3.5±0.9	[107]
7.4 mg/kg p.o.	773±157	3408±821	---	3.1±0.5	[107]
Human					
1.0 mg/kg p.o.	147±10	1389±119	2.3±0.2	7.2±0.6	[122]
1.6 mg/kg p.o.	292±76	3485±760	2.4±0.6	8.1±2.1	[116]
1.6 mg/kg p.o.	254.7±60.4	3070.6±673.4	2.4±0.6	8.4±1.6	[119]
2.0 mg/kg p.o.	442-487	5133-5232	1.5-2.0	6.9-7.2	[14]

[A] Male Sprague-Dawley rats
[B] Male FVB mice
[C] Fantegrossi et al. reported mean pharmacokinetic parameters of R(-)-MDMA and S(+)-MDMA after administering racemic MDMA. In this table, plasma racemic C_{max} values estimated by taking sum of R(-) and S(+), while T_{max} and $t_{1/2}$ presented as an average of the enantiomers' values.

4.2.2 Pharmacodynamics in Animals

Most effects of MDMA likely arise directly from monoamine reuptake inhibition and release, and indirectly from activation of downstream monoamine receptors and subsequent secretion of

neuromodulators oxytocin and AVP. MDMA binds primarily to membrane-bound monoamine transporters, which remove monoaminergic neurotransmitters from the space between neurons, known as the synaptic cleft. MDMA appears to alter the conformation of the transporters, enabling monoamines to diffuse out of the neuron rather than being actively transported into the presynaptic neuron [60, 123, 124]. MDMA prevents the reuptake of serotonin, and to a lesser extent, norepinephrine and dopamine, and facilitates release of these neurotransmitters [60, 125-127]. The selectivity of MDMA for specific monoaminergic neurotransmitters is species-dependent, and cannot solely be attributed to differences in binding affinity for specific reuptake transporters observed *in vitro,* as described below. In *in vitro* studies, MDMA was also found to compete with monoamines for sites on the vesicular monoamine transporter-2 (VMAT2), suggesting MDMA also promotes active release of monoamines from vesicular stores, in addition to inhibiting reuptake [128-130].

MDMA can inhibit monoamine oxidase A (MAO-A) *in vitro* at high concentrations, which preferentially degrades serotonin, and leads to accumulation of extracellular serotonin in the synaptic cleft [131, 132]. Inhibition of MAO-A may have played a role in fatalities and medical emergencies seen after combining Ecstasy with MAO inhibitors in epidemiological settings [133, 134]. Spurred on by prior reports hypothesizing that apparent greater serotonergic toxicity of MDMA in primates, as compared to rodents, could be attributed to greater SERT affinity [135], researchers specifically examined affinity in cells transfected to express human monoamine transporters [127, 136]. These studies found that even though binding affinity of MDMA for the human norepinephrine transporter (NET) exceeded the affinity for SERT and dopamine transporters (DAT), serotonin was preferentially released over norepinephrine and dopamine [127], which may account for primarily serotonergic effects of MDMA. On the other hand, in rodents MDMA affinities for transporters are ordered as SERT>NET>DAT [137]. MDMA does not have as strong an affinity for the DAT as methamphetamine [21].

The ability of MDMA to stimulate release of pre-synaptic serotonin, norepinephrine, and dopamine in multiple brain regions and inhibit reuptake has been well documented [138]. *In vivo* microdialysis and voltammetry results show significant enhancement of serotonin, and to a lesser extent dopamine following MDMA administration, a response attenuated by various transporter inhibitors. MDMA-stimulated serotonin and dopamine release has been measured in the striatum, nucleus accumbens, PFC, and the hippocampus of freely moving rats [139-142]. In addition, enhancement of Ach release has been demonstrated in the PFC, striatum, and hippocampus by both a dopaminergic and serotonergic dependent mechanism [143, 144]. The subjective and physiological effects of MDMA are produced by the dynamic interaction of these transmitter systems on numerous brain networks that modulate learning and memory, emotion, reward, attention, sympathetic/parasympathetic activity, and neuroplasticity.

In addition to carrier-mediated monoamine release, MDMA has affinity *in vitro* for specific serotonin, norepinephrine, Ach, and histamine receptors, although the concentrations tested may not translate to standard human MDMA doses [24, 145-147]. An *in vitro* binding study comparing MDMA with a number of drugs that include cathinone derivatives suggests that contrary to an earlier report of low affinity for $5HT_{2A}$ serotonin receptors, MDMA may have significant effects at the receptor [25]. MDMA likely modulates $5HT_{1A}$ serotonin receptors indirectly through serotonin release, though it is possible that MDMA may also act as a partial $5HT_{1A}$ agonist in some brain areas [148]. Findings from other studies suggest that MDMA shares qualities with $5HT_{1A}$ agonists. Early studies in rats suggest that pharmacological activation of $5HT_{1A}$ receptors reduce anxiety and aggression [149, 150], and some drug discrimination studies suggest that the $5HT_{1A}$ agonist 8-hydroxy-2-(di-n-propylamino)tetralin (8-OH-DPAT) partially or fully substitutes for MDMA [151-153]. In addition to its primary effects, both enantiomers of MDMA enhance Ach release in the PFC [144, 154] and promote changes in GABA-ergic systems

that correlate with sociability [155]. At least some direct or indirect effects of MDMA on serotonin receptors may alter GABA uptake in the ventral tegmental area of rats [156]. An *in vitro* study found that S-MDMA showed signs of competitive interaction with the alpha-4 beta-2 nicotinic receptor which are implicated in learning [157], while R-MDMA did not produce this effect [102].

Infusion of serotonin in the rat brain stimulates secretion of oxytocin into peripheral blood via activation of $5HT_{1A}$, $5HT_{2C}$, and $5HT_4$ receptor subtypes, as well as AVP secretion via activation of $5HT_{2C}$, $5HT_4$, and $5HT_7$ receptor subtypes [158]. MDMA was shown to increase oxytocin and AVP secretion in rats [159] through a $5HT_{1A}$ mechanism [160]. Administering a $5HT_{1A}$ antagonist attenuates the prosocial behavior of rats, measured by preference to lie adjacent to each other, possibly because it prevents elevation in oxytocin [160, 161]. MDMA also promotes norepinephrine release through reuptake inhibition, which is an additional pathway that can contribute to oxytocin secretion and may control emotion regulation. Both oxytocin and AVP are implicated in the widespread regulation of behavioral aspects of mood and also act on different target organs to modulate physiological functions in the periphery [162]. Taken together, MDMA has been shown to have a diverse array of pharmacodynamic effects in animals, with findings of interest presented below by topic.

4.2.2.1 Stable Effects on Gene Expression in Animals

Epigenetic modifications, including deoxyribonucleic acid (DNA) methylation, demethylation, and histone acetylation, are thought to be involved in dynamic regulation of memory reconsolidation in the adult nervous system and play a role in memory formation [163]. Early childhood adversity and trauma is associated with transcriptional silencing of the brain-derived neurotrophic factor (BDNF) gene through DNA methylation, which can either be a risk factor in development of PTSD or a result of having PTSD in adulthood [164]. In a 2015 report, MDMA showed DNA hypermethylation and hypomethylation activity in cardiac tissue by microarray analysis in mice [165], and this activity may extend the CNS. Epigenetic effects on BDNF and other gene expression is a hypothesized mechanism by which MDMA in combination with training in animal studies modeling anxiety disorders, or psychotherapy in humans, exerts its therapeutic effects.

A number of research teams have studied the effects of MDMA on gene expression in rodents [166-169]. However, many of these reports used 10 to 20 mg/kg MDMA, a dose range that is 5 to 10.7 times greater than the 1.5 to 2 mg/kg doses employed in human trials, making it less likely that these changes can be generalized to humans given lower doses. However, even at these doses toxicity was not observed, and a self-administration study at clinically relevant doses reproduced findings of elevation of genes such as serum/glucocorticoid kinase 1 and 3 (*Sgk1, Sgk3*), which regulate glutamatergic signaling and are associated with neuroplasticity and learning, as well as processes involved in memory consolidation in serotonergic neurons [170]. These studies also report an increase in expression of genes that regulate the GABA transporter [166], which is expressed in GABA-ergic neurons indirectly regulated by glutamatergic afferent neurons. Serotonin-transporter knockout mice did not display some of these changes in gene transcription, suggesting that serotonin release is required for this activity [166]. In the acute period 24 to 48 hours after MDMA exposure, a study in rats found 33 to 70% upregulation of BDNF messenger ribonucleic acid (mRNA) transcripts in the frontal cortex, with a time-dependent decrease, up to 73%, of BDNF transcripts in the hippocampus [171]. The frontal cortex and hippocampus are both regions known to play a causal role in memory retrieval and reconsolidation in animals and humans [172], mediated in part through GABA-ergic signaling [173], suggesting that these transcriptional changes may be functionally related.

Examining rat brains after repeated MDMA administration for 2 weeks detected a sharp drop in SERT expression [174], suggesting a compensatory downregulation in response to repeated high doses of MDMA. A study in rats found repeated administration of MDMA at 1 or 5 mg/kg weekly for 4 weeks increased transcripts for $5HT_{1B}$ receptors in various brain regions and $5HT_{2C}$ receptors in the cortex and hypothalamus, likely due to serotonin depletion and subsequent need to increase serotonin receptor availability [175]. Increased levels of gene transcripts regulating extracellular signaling in mice were also reported after MDMA [176]. Serotonin may play a more significant role than dopamine in transcription changes mediated by MDMA [175]. Mouse brains examined 8 hours after 8 days of self-administration or non-contingent administration detected increased transcription of genes related to inflammation and immune modulation in both groups and transcription of genes related to neuroadaptation in mice self-administering MDMA [170]. Transcripts in these studies were assessed 8 to 10 hours after the last of repeated MDMA administrations and it is unclear whether these changes reflect residual acute effects of the MDMA or changes related to repeated MDMA administration. In addition, changes in transcription do not always correlate with functional consequences in proteins levels. BDNF has been shown to have multiple functionally distinct splice variants which have tight temporal and spatial control in an activity-dependent, stimulus-specific manner [177]. However, MDMA produces a durable enhancement of fear extinction in mice, an effect mediated by an MDMA-associated increase in BDNF expression specifically in the context of fear extinction training, suggesting that gene expression changes after MDMA are functionally relevant [178].

4.2.2.2 Immunological Effects in Animals

MDMA acts as a mild immunosuppressant in rodents. MDMA administration at 5 mg/kg in rats is associated with impaired macrophage activity as evidenced by inhibition of Tumor Necrosis Factor-alpha (TNF-α) secretion for 12 hours post-drug [179]. In mice injected with 10 mg/kg MDMA for 5 days, increases in in epithelial tissue of cytokines interleukin 1-alpha (IL-1α), granulocyte-colony stimulating factor (G-CSF), and interleukin 3 (IL-3) were found, while decreased serum levels of many cytokines were reported [180]. MDMA decreased neutrophil oxidative bursts and phagocytosis, and increased the number of circulating neutrophils while decreasing the number of lymphocytes. MDMA also increased hypothalamus-pituitary-adrenal (HPA) axis activity through a noradrenergic pathway in the hypothalamus [181]. MDMA also suppresses interferon-γ secretion and signaling in mice [182]. Interestingly, MDMA was shown to reduce inflammation and airway reactivity in a mouse model of allergic asthma, suggesting that MDMA could have beneficial immunomodulatory effects in cases of heightened inflammation [183]. This constellation of findings was in the 10 mg/kg dose range, which calls to question the applicability to moderate dosing regimens. However, a microarray study found that mice self-administering MDMA at moderate doses had transcriptional changes in many genes related to immune and inflammatory responses as well as neuroplasticity and learning [170], suggesting that immunosuppressant effects of MDMA at clinically relevant doses could be beneficial in the treatment of psychoneuroimmunological disorders such as PTSD [184].

4.2.2.3 Thermoregulatory Effects in Animals

Rodents have generally been used to study the hyperthermic effects of MDMA. Rodents have a much smaller body mass and do not perspire, but use their tail to regulate body temperature which has a large surface to volume ratio, and is perfused with many blood vessels for thermoregulation. Since thermoregulation is different in rodents and humans [185], findings may have limited applicability to humans. MDMA doses that are moderate to high elevate body temperature and disrupt thermoregulation in mice [124], and doses of MDMA in the 1 to 2 mg/kg range only cause a slight increase in body temperature [186]. Rats given doses of 10 mg/kg MDMA (s.c. and i.p.), but not 2 mg/kg, experienced increases in body temperature correlated

with levels of the active metabolite MDA [78, 114]. A study of rats receiving subcutaneous injections of 1 and 3 mg/kg MDMA demonstrated minimal effect on brain hyperthermia using thermal couplers installed in the nucleus accumbens, however ambient temperatures of 29°C and social interaction had a potentiating effect on body temperature and malignant hyperthermia at higher doses [187], described in Section 4.4 Toxicology in Animals and Epidemiological Settings. MDMA effects on body temperature are susceptible to changes in ambient temperature in rodents, with high ambient temperature significantly increasing body temperature in mice and rats, and low ambient temperatures reducing it [188-190]. The MDMA-induced impairment in thermoregulation is caused, at least in part, by peripheral vasoconstriction in the tail, an effect mediated by brain neurotransmitter activity [191, 192].

High doses of MDMA also produce significant elevations in body temperature in primates [107, 193, 194]. At doses closer to those humans ingest [195], monkeys exhibit only slight to moderate elevation in body temperature [196, 197]. In contrast to findings in rodents, primates are not susceptible to changes in ambient temperature when given MDMA, exhibiting slight to moderate increases in body temperature regardless of the temperature of the environment [195-197], though at least one study found that the ambient temperature influenced the effects of 1.5 mg/kg i.v. MDMA on body temperature in monkeys, with lower body temperatures seen after MDMA administered in cool temperatures and higher body temperatures in another group given MDMA at warm temperatures [198]. Findings in rodents do not extrapolate well to primates in this area. Given that the thermoregulatory effects in rodents are highly dose-dependent, the majority of physiological effects seen after low to moderate MDMA administration suggest that a controlled environment and moderate doses would be sufficient to mediate physiological complications associated with hyperthermia, including cardiovascular, osmoregulatory, neurological, and immunological effects.

4.2.2.4 Cardiovascular Effects in Animals

In vivo assessments of cardiovascular effects of MDMA in animals detected increased sympathomimetic activity, as seen in humans [124, 199]. An injection of 2 mg/kg MDMA elevated heart rate in rabbits [633]. Ten mg/kg MDMA produced a relatively larger increase in heart rate in rats than blood pressure, an effect possibly controlled by beta adrenergic receptors [199]. The researchers found that MDMA has both pressor and depressor effects, acting through adrenergic receptors [201-203]. Another study in rodents also suggests that norepinephrine may play a role in cardiovascular effects [204], findings that have been more intensively investigated in humans [205-208]. Given the affinity of MDMA for the NET, it is possible that the cardiovascular effects of MDMA could be attributed to norepinephrine signaling in the peripheral nervous system.

4.2.2.5 Osmoregulatory Effects in Animals

AVP is a key regulator of water balance in the body, and has antidiuretic actions when acting at its V2 receptor subtype in the kidneys [209, 210]. MDMA can influence water regulation by activation of the AVP system, as shown in several animal studies. A study of isolated *in vitro* rat hypothalamus initially reported AVP and oxytocin release after MDMA and its metabolite HMMA [33]. *In vivo* drug-discrimination studies in rats suggest that AVP receptors are involved in producing interoceptive effects of MDMA [162]. When 10 mg/kg i.p. MDMA was administered at 30°C ambient temperature to male Wistar rats, MDMA induced expression of Fos, a marker of neural activation, in the supraoptic nucleus, a brain region important for osmoregulation and a key mediator of oxytocin and AVP release [211]. This finding suggests that MDMA can have osmoregulatory effects in rats at high doses administered at warm ambient temperatures.

4.2.2.6 Neurobiological Effects in Animals

It appears that single doses of MDMA (2.5 mg/kg i.p. in monkeys, 7.5 mg/kg i.p. in rats), approximately four times a human equivalent dose, reduces brain serotonin production for 2 weeks or more [107] but does not increase validated markers of neurotoxicity associated with neurodegeneration [108]. Monkeys allowed to self-administer MDMA for an 18-month period had no reductions in brain dopamine, slight reductions in brain serotonin, and no chemical markers of neuronal injury [509]. One report detected a reduction in N-acetylaspartate to creatine ratio, which the authors considered a sign of neuronal injury, although no decreases in brain serotonin were detected after administration of two human-equivalent doses of MDMA to marmoset monkeys for 2 days [213]. A study examining the rat hippocampus reported indications of apoptosis after 5 or 10 mg/kg given daily for 1 week but not after 2.5 mg/kg [214]. Doses of 10 mg/kg administered s.c. and i.p., but not 2 mg/kg, produced signs of serotonin syndrome in rats, but neither dose reduced total serotonin levels in the brain 2 weeks after drug administration. Serotonin syndrome is defined as an excess of serotonin in the CNS causing a suite of specific signs and symptoms that can require intervention [215-217]. Serotonin syndrome severity correlates with MDMA plasma concentrations [78]. Taken together, MDMA doses up to 2.5 mg/kg appear to alter regulation of serotonergic signaling in the rat brain without producing damage to serotonin axons, based on transient reductions in brain serotonin and SERT levels, in the absence of indicators of neuronal injury or decreased expression of the SERT gene [88].
In rats, large doses of MDMA (10 or 20 mg/kg) elevated serum corticosterone (a rodent cortisol analog) and prolactin [218-220], with elevation lasting up to 4 hours after dosing, and with hormone levels attenuated by a $5HT_{2A}$ serotonin receptor antagonist. Given the dosage used was five to 10.7 times larger than an active dose in humans, it is unclear if this response is analogous to elevated cortisol in humans or whether it reflects a different process. Administering 1 to 3 mg/kg doses found that R(-)-MDMA, but not S(+)-MDMA, significantly increased prolactin levels in rhesus monkey plasma, suggesting that at least the R(-) enantiomer of MDMA can influence endocrine signaling at doses relevant for studies in humans [23]. Fluoxetine attenuated prolactin release after administration of racemic MDMA, and fluoxetine and a $5HT_{2A}$ antagonist attenuated prolactin release after R(-)-MDMA, indicating that prolactin release is associated with serotonin release and indirect action on $5HT_{2A}$ receptors by R(-) -MDMA [99].

Serotonergic deficits are associated with disruption of sleep patterns and architecture. In drug-naïve rats, a single dose of 15 mg/kg MDMA i.p. contributed to marked increases in motor activity, deep slow wave sleep, and wakefulness for 5 to 6 hours. Circadian patterns of motor activity and sleep/vigilance parameters were altered for up to 5 days post-treatment, after which most parameters returned to normal. In a single exposure to MDMA 3 weeks prior to the same procedure, rats experienced the same acute effects, but with shorter duration, suggesting that MDMA has the ability to influence sleep architecture and patterns acutely after this dose in drug-naïve rats, but these effects are mediated by experience with MDMA and do not persist beyond 1 week [221].

4.2.2.7 Neuropsychological Effects in Animals

In rodents, doses of MDMA equivalent to human doses produce few behavioral effects. However, several dose-dependent differences on behavioral tests in rats have been reported, including increased locomotor activity and anxiety-related behaviors thought to be associated with serotonin syndrome [161, 222], and decreased social anxiety at 5 mg/kg i.p. [161]. Rats given 7.5 mg/kg MDMA, equivalent to four times the dose tested in humans, exhibited increased anxiety in the elevated plus maze [223], while rats given 15 mg/kg MDMA, equivalent to eight times the

dose tested in humans, exhibited reduced anxiety on the maze. A study of the sub-acute effects of four different doses of MDMA given daily for 1 week, found reduced anxiety with 1.25 and 2.5 mg/kg and increased anxiety with 5 and 10 mg/kg [214]. Lower doses used in these studies are comparable to dose used in human research and nonmedical settings. However, sample sizes used in the study were small. Rats given higher doses also reduced aggressive behavior as well as social investigation. MDMA produces some repetitive behavior in rodents, but not to the same degree as psychostimulants. Rats on MDMA walk around a cage perimeter, interpreted as an indicator of thigmotaxis, which is a sign of anxiety [124]. However, it is notable that a 2007 publication failed to find thigmotaxis in rats given 5 mg/kg MDMA [224]. In contrast, rhesus monkeys do not exhibit increased locomotor activity after receiving up to 2.4 mg/kg MDMA [197]. Some researchers have proposed that behavioral tests of anxiety may instead be measuring risk-taking behavior, or impulsivity [225]. It is also notable that the majority of rat studies with deleterious behavioral findings were conducted specifically in inbred male Wistar rats, suggesting that individual and gender-based differences could influence these findings [226, 227]. Preclinical data in animals suggests that the profile of neurotransmitter release observed after MDMA administration may increase the risk of mania in some individuals [228], although mania has not been a reported as a side effect of MDMA or Ecstasy in humans. Conflicting findings on anxiogenic and anxiolytic dose-dependent effects of MDMA are likely to have limited applicability to humans, with transient anxiety being a possible side effect.

To date, no empirical investigations have been conducted on the effects of MDMA on primate social interactions, which limits the generalizability of rodent studies to the more complex and relevant social behavior of primates and humans. Morley and colleagues observed rat behavior after receiving 5 mg/kg MDMA, noting that this dose correlated with prosocial behavior, such as lying next to each other [161]. Subsequent studies suggest that MDMA increases prosocial behavior in rats by elevating oxytocin in the paraventricular nucleus through $5HT_{1A}$ receptor agonism, with the oxytocin increase arising from the indirect effects of MDMA on $5HT_{1A}$ receptors via serotonin release [160, 229, 230]. There have been no human pharmacological challenge studies combining MDMA with $5HT_{1A}$ agonists, while $5HT_{1A}$ antagonists have negligible effects on subjective or physiological effects of MDMA in humans [92, 231-233]. As a result, it is unclear whether the rat behavior is analogous to human reports of increased feelings of empathy or interpersonal closeness while under the influence of MDMA [2, 13, 234, 235].

MDMA given before training persistently enhances fear extinction learning in mice through a BDNF-dependent mechanism [178], which could be a possible mechanism of action for MDMA in combination with psychotherapy as a treatment for anxiety disorders. The dose of 5.6 mg/kg was approximately two times a human equivalent dose based on plasma values, but the findings are the first biological evidence of a lasting effect of MDMA on disruption of anxiety-related behavior in mice.

4.3 Physiological Effects in Epidemiological Settings

The vast majority of non-clinical epidemiological studies are retrospective comparisons of people who have previously self-administered Ecstasy, a study design that is unable to eliminate the possibility that one or more predisposing factors may lead to repeated Ecstasy use and the variables compared [5, 89, 236]. Samples are often selected on the basis of moderate to heavy self-reported Ecstasy use, with very few studies conducted in samples reporting the levels of moderate exposure seen in clinical trials. Many investigations have compared people reporting use of Ecstasy with non-Ecstasy using controls, mostly as a means of detecting long-term effects of Ecstasy use. Many of the studies do not appropriately match samples for substance use behavior, there is often concurrent use other illicit substances and the Ecstasy used is of unknown purity, dosage, and composition.

The acute effects of MDMA have an initial onset of approximately 30 minutes after oral intake and are characterized by anxiety, tachycardia, and elevated blood pressures [237]. Typical effects include diaphoresis, bruxism, jaw clenching, paresthesias, dry mouth, increased psychomotor activity, and blurred vision. Within an hour, these sympathomimetic effects are replaced by feelings of relaxation, euphoria, increased empathy, and communication. Taking a smaller supplemental dose may prolong these effects and this is being tested in the context of clinical trials. However, when too much additional MDMA is consumed in an uncontrolled setting, individuals report unpleasant symptoms of autonomic hyperarousal associated with feelings of restlessness, paranoia, and anxiety. With increased dosage sympathomimetic effects predominate, placing the patient at risk for cardiovascular instability, arrhythmias, and hyperthermia (see Section 4.4 Toxicology in Animals and Epidemiological Settings).
Retrospective surveys of Ecstasy use offer similar accounts of subjective effects to those reported in controlled studies of MDMA. Study respondents report experiencing stimulant-like effects, such as greater energy or talkativeness, and hallucinogen-like effects, including perceptual changes, visual distortions, or poor concentration, as well as feelings of closeness, compassion, or empathy toward the self or others [2, 234, 235, 238, 239]. The disparity in detection of entactogenic effects in retrospective versus controlled studies is largely due to failure to measure these effects, but might also relate to aspects of setting in controlled studies that do not permit enough unstructured interpersonal contact to produce or facilitate feelings of interpersonal closeness. Starting in the 2010s, more researchers are seeking to assess the prosocial effects of MDMA [35, 37, 38, 240].

The findings discussed in this section are of effects in low to moderate users of Ecstasy. Serious and life threatening events and effects in heavy users are discussed in Section 4.4 Toxicology in Animals and in Epidemiological Settings. Because of these many confounds and issues, findings discussed from retrospective comparisons and case reports of Ecstasy using samples and controls are considered cautiously with respect to their degree of relevance for safety in clinical trials.

4.3.1 Immunological Effects

As supported by mild immunosuppressant effects found in rodents, a longitudinal study of regular Ecstasy and cannabis users found a sustained reduction in IL-2, increased levels of Transforming Growth Factor-Beta (TGF-ß), and reduced CD4 cells, and regular Ecstasy and cannabis users reported experiencing a greater number of mild infections than occasional Ecstasy and cannabis users on a structured questionnaire [241]. Immunological effects of MDMA in humans are likely to involve serotonergic pathways and are discussed in more detail in Section 5.3.2 Immunological Effects.

4.3.2 Thermoregulatory Effects

Thermoregulatory effects of Ecstasy taken in epidemiological settings are highly dependent on dose [242] and permissive factors, including high ambient temperature [243, 244], crowded conditions involving overwhelming social interaction, physical exertion, reduced fluid intake [243], and thyroid dysregulation [245, 246]. In the absence of these permissive factors from use in epidemiological settings, hyperthermia is rarely reported. For a detailed discussion on thermoregulatory effects when Ecstasy is combined with permissive factors, see Section 4.4.6 Hyperthermia.

4.3.3 Cardiovascular Effects

Studies in Ecstasy users indicate that only people reporting average lifetime exposure of 900 tablets had cardiac abnormalities [247]. No abnormalities were found in people reporting lifetime exposure of approximately 200 tablets in the same study. Previous to this, echocardiographic readings in eight Ecstasy users also failed to find any cardiac abnormalities [45]. Valvular heart disease (VHD) only occurred after extremely heavy Ecstasy use, it is unlikely to be a risk within the research or therapeutic context where subjects are screened for relevant pre-existing conditions. For more information on toxicological effects, see Section 4.4.7 Cardiovascular Toxicity.

4.3.4 Osmoregulatory Effects

Ecstasy use has been associated in the literature with acute symptomatic hyponatremia with the syndrome of inappropriate antidiuretic-hormone secretion (SIADH) involving raised antidiuretic-hormone, also known as AVP [248]. SIADH refers to disorders related to water and sodium balance characterized by the impairment of urinary dilution and hypotonic hyponatremia in the absence of renal disease or other identifiable non-osmotic stimuli known to activate the release of AVP [249]. MDMA is known to cause central release of both oxytocin and vasopressin through indirect effects of serotonergic signaling as previously described, and this activity indicates that it is not accurate to attribute the osmoregulatory effects of Ecstasy to SIADH, but rather this should be characterized as a pharmacological effect on AVP secretion.

AVP plays a key role in osmoregulation, and is released upon a change in plasma osmolality [250]. AVP is also involved in the response and adaptation to stress, through its effects on the HPA axis [250]. The rise in AVP does not seem to be part of a generalized stress response, but results from a pharmacological effect compounded by excessive fluid ingestion [251]. In Ecstasy users with confirmed urinary MDMA, a significant association was found between plasma osmolality, plasma sodium, and CYP2D6 extensive metabolizer/ intermediate metabolizer genotypes and COMT low-activity genotypes [252]. Effects of Ecstasy, combined with increased consumption of water and permissive factors, such as strenuous exercise in warm ambient temperatures, can be further exacerbated in the context of poor metabolism. Gauging appropriate water intake may be difficult for users to estimate because MDMA reduces perception of thirst and impairs judgment [253]. For more information on the risk of hyponatremia, see Section 4.4.8 Hyponatremia.

4.3.5 Neurobiological Effects

Spurred on by animal studies that found repeated or high doses of MDMA damaged the axons of serotonin neurons, researchers began studying the effects of repeated non-medical or recreational use of Ecstasy in humans [83-85, 254]. Early investigations had a number of methodological flaws, including retrospective design and poor matching of Ecstasy users with appropriate controls [89, 255]. Later studies sought to remedy some of these problems by using carefully matched polydrug user or cannabis user controls, or by relying on a sample with relatively low exposure to psychoactive substances, including alcohol [256-259]. Some of these investigators also conducted longitudinal studies, comparing Ecstasy users, sometimes alongside controls, at two separate time points [260-262].

Researchers using slightly different methods have reported differing results. These include finding no differences between Ecstasy user and polydrug user controls in SERT binding sites [263], modest reductions in estimated SERT sites in Ecstasy users versus non-drug using or cannabis-using controls [264], and an association between decreased SERT sites and lifetime

Ecstasy use [265]. This study also reported finding slightly fewer $5HT_{2A}$ receptor binding sites in both "Ecstasy preferring" and "hallucinogen preferring" groups. Studies in low to moderate Ecstasy users did not report an increase in this marker [266], and only one of three studies in heavy users detected a change in $5HT_{2A}$ receptor density. [267-269]. A prospective study in moderate Ecstasy users also failed to find any chemical markers of neuronal injury, and only found decreased cerebral blood volume in the dorsolateral frontal cortex [266, 270]. A re-examination of brain imaging using the less specific SERT marker Beta-CIT indicate an inverse relationship between age of first use of Ecstasy and mid-number of midbrain serotonin sites without detecting any relationship between age of first use and frontal SERT sites [271]. A retrospective imaging study using a radioligand that maps serotonin synthesis found lower ligand presence ("trapping") in prefrontal, orbitofrontal and parietal areas and higher presence in brainstem, frontal and temporal areas in Ecstasy users versus polydrug user controls, with a greater difference seen in men [272]. The researchers reported relationships between differences in trapping and cumulative use, duration and temporal proximity of use. The samples were not well-matched for drug use.

Studies comparing brain activity in Ecstasy users and non-Ecstasy using controls reported some but not many differences in brain activity. These included greater brain activation in the occipital cortex, with concomitant methamphetamine use contributing to increased activation to a visual stimulus [273]. The same group of researchers detected less within-region coherence in the thalamus in Ecstasy users who averaged 29 episodes of use when compared with non-Ecstasy-using controls [274]. In a retrospective study, Ecstasy users exhibited lower brain activity in bilateral dorsolateral prefrontal cortex compared with controls reporting no illicit drug use, with neither group exhibiting impaired task performance [275]. Ecstasy users exhibited a single difference in brain activity compared to polydrug using controls. A prospective study comparing brain activity before and after use of Ecstasy failed to detect differences in working memory, attention or brain activity [276], suggesting a relationship between repeated, regular use of Ecstasy and other drugs and changes in brain activation. Investigations of the interaction between genotype and regular Ecstasy use have supported differential effects upon reward-based attention or visual or verbal memory [277-279], with some findings supporting differences due to genotype and some failing to do so. A systematic examination of imaging studies comparing ecstasy users reporting consumption of 100 or fewer tablets with controls reported finding no evidence for an association between moderate Ecstasy and signs of structural or functional changes in the brain [79]. Given the small samples and uneven numbers with different genotypes, any conclusions await further support.

Sleep disturbances are thought to be associated with deficiencies in serotonergic signaling [280]. Examining sleep architecture in Ecstasy users, investigators found less total sleep time and less stage 3 and 4 sleep on the adaptation night, but no overall differences in sleep architecture [281]. Another study comparing heavy Ecstasy users with non-drug using controls found no differences in baseline sleep using electroencephalography (EEG) [282]. Early studies in mostly heavy Ecstasy users reported significant decreases in total sleep as well as stage 2 sleep [283], while studies conducted in the 2000s found Ecstasy users were able to fall asleep more easily upon depletion of catecholamine neurotransmitters suggesting an underlying difference in serotonergic control of sleep architecture [284, 285]. Findings of sleep disruption in Ecstasy users are not likely to be applicable to the exposures seen in research or therapeutic settings.

A study of breathing during sleep in 71 Ecstasy users and 62 polydrug users did not find overall differences in disrupted breathing, assessed via nasal cannula, but found that all moderate and severe breathing disruptions occurred in the Ecstasy using sample [286]. McCann and colleagues reported a relationship between cumulative (lifetime) Ecstasy exposures and instances of disrupted breathing during non-REM sleep and suggested Ecstasy users could be vulnerable to

potentially fatal sleep apnea. In contrast, other researchers failed to find greater night-time awakenings indicative of sleep apnea in Ecstasy users [281, 282], and the high rate of disrupted breathing McCann and colleagues detected even in the controls suggest that this measure may not provide clinically significant assessments. Taken together, it appears that MDMA acutely produces lighter sleep with fewer REM periods.

4.3.6 Neuropsychological Effects

Previous reports have found an association between Ecstasy use and symptoms of depression or anxiety [287, 288]. A meta-analysis of self-reported depressive symptoms detected an association between Ecstasy use and scores on the Beck Depression Inventory (BDI), a popular self-report measure of depression symptoms [289]. However, the association was strongest in studies with small samples, and drug use variables were often incompletely reported and not verified through any methods save self-report in the studies analyzed. Many studies found that increases in self-reported anxiety or depression were more strongly related to polydrug use rather than to use of any one substance [290-293]. Two studies found an equal or stronger association between regular use of cannabis, and not Ecstasy, with anxiety, depression or other psychological problems [294, 295]. Anxiety regarding loss of control under the influence of Ecstasy could develop to a degree where it could lead to panic attacks. Case reports have been published describing panic attacks in individuals under the acute influence of Ecstasy [296]. Enduring panic attacks have been reported in individuals after repeated Ecstasy use [297, 298] and in one case, even after a single dose [299].

Neuroendocrine response to oral citalopram did not differ between Ecstasy users, cannabis users and controls [300]. People reporting regular drug use and Ecstasy use had higher levels of salivary cortisol in the evening, and higher salivary cortisol on the day of a multitasking activity [301], and higher salivary cortisol on waking that was unrelated to prefrontal SERT binding or self-reported depression symptoms [302]. A 4-year longitudinal study reported that factors other than Ecstasy use, including female gender and presence of financial and relationship difficulties, were more closely related to self-reported symptoms of depression [303]. Comparison of self-reported psychological symptoms in samples of people grouped by self-reported drug use found current Ecstasy users had lower global symptom severity scores than polydrug users [304]. In conclusion, it appears that the relationship between Ecstasy use on self-reported mood or psychiatric problems is not strong, with equal or stronger involvement of other factors.

In a prospective study comparing cognitive function in people before and up to 18 months after reported initiation of Ecstasy use, Schilt and colleagues found an association between Ecstasy use and performance on measures of verbal memory, but not attention or working memory [305]. All scores were within normal range; people who did not use Ecstasy showed greater improvement in performance at the second time of assessment than people reporting some use. A second prospective study examined working memory in people reporting Ecstasy use similar to subjects in Schilt's study with controls, and failed to find any significant differences in working memory and selective attention [276]. An analysis of findings from largely retrospective studies of Ecstasy users reported a small deficit in verbal or working memory [53]. Retrospective studies of polydrug users who use Ecstasy and controls reported impaired global motion processing without changes to local processing [306].

Not all studies report that Ecstasy users fare worse on measures of cognitive function than controls. A number of reports detected little or no significant differences between Ecstasy users and polydrug user controls in performance on tasks of cognitive function [236, 275, 276, 307-311], though other studies continue to find consistent differences, particularly in verbal memory [285, 312-315]. Regular use of many substances, including alcohol, may affect cognitive

function, with Ecstasy being only one of those substances [316]. Several reports have found relationships between cognitive function and use of other drugs as well as or instead of Ecstasy [278, 307, 309, 312, 317, 318].

The only study attempting to address effects of Ecstasy use on cognitive function in middle aged versus younger users did not find a greater degree of impairment. Schilt and colleagues reported impaired verbal memory in people who began using Ecstasy in their 30s compared with age-matched drug-naïve and polydrug using controls reporting some lifetime Ecstasy use, but did not find a greater effect size for Ecstasy use in this sample than in samples of younger Ecstasy users, leading them to conclude that Ecstasy use does not have a greater impact on cognitive function in older users [319].

The relationship between Ecstasy use and impulsivity has also been extensively examined, with some researchers reporting greater impulsivity in Ecstasy users and others failing to find any differences [84, 320]. Recent studies using both behavioral and self-report measures of impulsivity reached contradictory conclusions [311, 321, 322]. Two recent studies using the same measure of behavioral impulsivity in samples of heavy Ecstasy users obtained different findings [311, 321]. It is notable that Quednow and colleagues compared Ecstasy users with abstinent cannabis users and drug-naïve controls while Roiser and colleagues compared Ecstasy users with former Ecstasy users, polydrug users and drug-naïve controls, raising the possibility that results might have differed in part due to control group selection. It is possible that people who self-administer Ecstasy may already possess above-average levels of sensation-seeking and impulsiveness. To date, all such studies have used retrospective study designs and cannot rule out this possibility, and studies published in the last 2 years suggest that polydrug use may be equally or more strongly related to impulsivity in Ecstasy users [323-325]. The relationship between drug use, including Ecstasy use, and impulsivity, is complex.

4.4 Toxicology in Animals and Epidemiological Settings

In the sections below, nonclinical toxicological findings are presented for animals and epidemiological studies or case reports of morbidity and mortality in Ecstasy users. Data from epidemiological studies are provided, subject to the limitations in interpretation that result from unknown purity, dose, and quantity of MDMA existing in Ecstasy use in naturalistic settings.

4.4.1 Single Dose Studies in Animals

Single doses between 5 and 60 mg/kg have been administered in rodents. Since rodents are similar to primates in mg/kg dosing, the doses of 5 mg/kg and above, administered by any route of administration in rodents, are inappropriately high for comparison to human studies utilizing doses less than or equal to 125 mg, so findings are only useful as models of toxicology or abusive use in humans. A study of the long-term effects of a single dose of 5.7 mg/kg MDMA on estimated SERT sites in the brains of squirrel monkeys reported reduced sites in some frontal, temporal and parietal areas [326]. The plasma C_{max} of 725 µg/L in squirrel monkeys was three times greater than what is observed in humans after a single dose of 100 mg MDMA (C_{max} of 202.92 to 222.5 µg/L) [113, 327, 328], even after administration of a supplemental dose twice that of the initial dose 2 hours later, which increased C_{max} to 311.16 µg/L [328]. A handful of studies in rats have examined the effects of single toxic doses in comparison to low doses and determined that single doses have transient effects on serotonin depletion [78, 114, 108], likely due to reversible inhibition of tryptophan hydroxylase [17, 18, 20], which prevents additional serotonin from being produced and released.

4.4.2 Repeated Dose Studies in Animals

The majority of toxicological studies employed multiple dosing regimens to account for the shorter drug half-life in animals compared to humans, with doses ranging from 5 mg/kg to 20 mg/kg, via s.c., i.p., oral, or gavage administration. Frequently, doses are administered at regular intervals of two to four times per day. Other regimens employ these doses once daily for 5 or 7 days. Nearly all preclinical toxicology data is derived from repeated dose studies. Preclinical research selected doses through use of simple dose conversions or allometric scaling, a method of modeling human equivalent doses in other species [329]. Comparison of pharmacokinetic data ($C_{max,}$ AUC, T_{max}) for plasma MDMA concentrations between humans and rodents, in light of the impact of route of administration, it is difficult to translate the relevance of high dose multi-day dosing findings in preclinical toxicity studies to intermittent dosing regimens in humans.

In order to establish the DMF and IND for MDMA, the sponsor supported randomized 28-day general toxicity studies in both genders of the rat (0, 10, 50, 100 mg/kg oral) and the dog (0, 3, 9, 15 mg/kg oral)[330]. Both sexes of dogs on 9 and 15 mg/kg MDMA and rats on 50 and 100 mg/kg MDMA gained less weight than those on control and 3 mg/kg, with significant differences in food consumption observed as early as the first week which were no longer significantly different by the fourth week. Gross observations at necropsy in the dog possibly related to MDMA included reduced testicular size on 9 and 15 mg/kg in the dog and prostatic enlargement in two dogs on 15 mg/kg. No gross lesions were seen in the rats at necropsy. Blood chemistry and urinalysis values were unremarkable in the dog. Clinical pathology findings showing a trend to decrease with dose in the rat were urinary pH, blood urea nitrogen, glucose, creatinine (females), lactate dehydrogenase (females), and chloride, in contrast total white blood cell count (WBC) and phosphorus showed a trend to increase with dose. No MDMA-related lesions were seen in the brains of either species.

4.4.3 Genotoxicity

An Ames test of Ecstasy tablets with 0 to 57.5% MDMA, quantified by GC-MS, found no evidence of genotoxicity [331]. Micronuclear and chromosomal aberrance tests were performed in Chinese hamster ovary cells with MDMA purified from seized Ecstasy tablets and with N-nitroso-MDMA (N-MDMA), a putative metabolite of MDMA [332]. MDMA did not produce increases in either *in vitro* genotoxicity test.

4.4.4 Carcinogenicity

There are no preclinical findings directly addressing the carcinogenicity of MDMA. No tumors were reported after 28 days of daily MDMA administration in rats (0, 10, 50, 100 mg/kg) and dogs (0, 3, 9, 15 mg/kg) in a sponsor-supported preclinical study [330]. In the absence of positive results in genotoxicity tests, carcinogenic potential from intermittent dosing of limited number of exposures to MDMA in controlled settings is not of concern.

4.4.5 Reproductive and Developmental Toxicity

MDMA (15 mg/kg, s.c.) administered to pregnant rats was detected in amniotic fluid [333] indicating the potential for neonatal exposure. Preliminary teratological studies in rats (N=12 per dose) given 0, 2.5, or 10 mg/kg MDMA by gavage on alternate gestational days (GD) 6 to 18 found no abnormalities in gestational duration, litter size, neonatal birth weights, or birth defects (N=10 litters per dose), despite statistically significant reduction in maternal weight gain at 10 mg/kg [334]. These results are in contrast to physiological abnormalities resulting from prenatal methamphetamine and d-amphetamine exposure in mice and rabbits [335].

In a single-generation fertility and developmental toxicity study, C57BL/6 mice (N=25 per dose per gender) received a daily dose of 0, 1.25, 5, or 20 mg/kg MDMA via gavage [336]. Dosing for females spanned 2 weeks before mating through GD15 of pregnancy. Dosing for males spanned 4 weeks through the first day of pregnancy. There were no cases of MDMA-related mortality in females at all treatment levels. Gross necropsy of organs of MDMA-treated groups of male and female mice were unremarkable. No changes in copulation or fertility indices arose in MDMA-treated animals, but fewer pregnancies arose in all three MDMA-treated groups. When the fetuses were examined, no external, visceral, or skeletal malformations were detected in control or 1.25 mg/kg groups, but at 5 mg/kg (2 of 129) and 20 mg/kg (5 of 138) fetuses exhibited a cleft palate, anophthalmia, or skeletal malformations (short tail). Taken together, these studies suggest that MDMA has weak reproductive or developmental toxicity at high doses when MDMA exposure starts 2 weeks prior to mating and continues through GD15, which temporally covers ovulation through organogenesis and closure of the hard palate, in the females and spermatogenesis in the males.

In a separate perinatal/postnatal toxicity study done by the same researchers, C57BL/6 female mice (N=25) received a daily dose of 0, 1.25, 5, or 20 mg/kg MDMA via gavage daily from GD6 slightly after implantation through postnatal day (PND) 21 end of lactation [336]. Pup viability was assessed daily and gross external examination of pups occurred on PND 0, 4, 7, 14, 21, and 28. Behavioral and physical indices of development were observed in the F1 animals, such as pinnae detachment and righting reflex. Testes descent in males occurred on PND20 and vaginal opening occurred in selected females on PND30. Delivery and post-partum (nesting) behavior did not differ across treatment groups, and no MDMA-related differences in pup viability were detected, including pup survival rate and sex ratios per litter. No significant abnormalities were observed at necropsy of mice either found dead at lactation nor killed at PND20. In contrast to the first study described above where MDMA was given 2 weeks before mating through GD15, when MDMA was given to only the females from GD6 to the end of lactation (both studies covered the period of organogenesis and closure of hard palate), there were no signs of impaired development and no significant differences in sexual development or reproductive capacity of F1 and F2 mice. This suggests that either dual exposure of male and female breeding pairs exacerbated reproductive toxicity, or possible evidence of a critical period for MDMA reproductive toxicity prior to organogenesis.

Male fertility after prenatal exposure was studied in male pups born to female Sprague-Dawley rats (N=6 per group) that received 0, 0.5, 5, or 10 mg/kg s.c. daily for three consecutive days per week for 10 weeks, including gestation and 3 weeks of lactation [337]. These females were mated with untreated males. The 5 mg/kg s.c. dose is two-fold greater than a human-equivalent dose based on plasma levels in other studies [78, 114, 119] and s.c dosing leads to higher plasma levels then dosing by gavage which was used in the studies above. There were no signs of toxicity in the 0.5 and 5 mg/kg groups, but dams in the 10 mg/kg group showed signs of sickness the week before delivery, and four of the six receiving 10 mg/kg and one of the five receiving 5 mg/kg were found dead at or prior to GD16. Mortality at 10 mg/kg s.c. indicates that this dose is too high for use in reproductive toxicity studies; the authors subsequently discontinued the 10 mg/kg dose after week 10. Vestibular and motor function were assessed on PND21, with no differences between groups. Balano-preputial separation happened later than controls after 5 mg/kg in male pups on PND37-54. There were no differences in mating or fertility rate in F1 males. Hormone levels were similar across groups at PD81 and sperm morphology was unaffected. However, MDMA administration resulted in a significant higher incidence of DNA damage in Comet Test of sperm DNA at 5 mg/kg in relation to the control group. Minor dose-dependent alterations were seen in testicles, spleen and kidneys. There were no pathologies of the epididymis. Testicles showed a slight decrease in numbers of germ cells in 5 mg/kg treated rats.

A second study investigated male fertility after 0.5, 5 and 10 mg/kg administered s.c. once daily three times per week in rats (N=20 per group) for 12 weeks, covering puberty to onset of sexual maturity [338]. Ten rats per dose were mated with untreated females, with mating behavior alone serving as measure of reproductive function without reporting signs of conception. The other 10 rats per group were examined for testicular and sperm parameters, including sperm count and motility and morphology. There was a dose-dependent increase in tubular degeneration in testes in MDMA-treated rats, but sperm motility and morphology was unaffected. In a sponsor-supported preclinical study, microscopic evidence of possible testicular atrophy and prostatic enlargement was also found in one of three dogs after 28 days of 9 mg/kg oral MDMA and in two of three dogs after 15 mg/kg oral MDMA [330]. Taken together, these studies suggest minimal male fertility toxicity at human-equivalent doses, with signs of increased toxicity at higher doses.

In an initial developmental toxicity study, pregnant rats were administered twice-daily injections of high doses of MDMA (15 mg/kg) or saline from embryonic days (E) 14 to 20. Rat pups that had received MDMA showed reductions in the dopamine metabolite homovanillic acid, along with reductions in the serotonin metabolite 5-HIAA. Prenatally exposed MDMA animals also had reduced dopamine and serotonin turnover in the nucleus accumbens [339]. The same team reported postnatal exposure to MDMA correlated with reductions in serotonin and its metabolite, as well as significant increases in dopamine turnover and the prevalence of a dopamine metabolite in multiple forebrain structures and the brainstem. BDNF was significantly increased (19% to 38%) in all forebrain structures and in the brainstem in MDMA-exposed neonates [340]. The researchers proposed that the increase in BDNF was compensating to minimize MDMA effects. However, later studies found that neonatal MDMA exposure did not affect hippocampal concentrations of serotonin or dopamine [341] and that enhanced BDNF detected in the occipital lobe did not mediate the abnormal serotonergic signaling observed following neonatal MDMA exposure [342]. PND 11 and 20 were proposed to be equivalent to the third trimester of gestation in humans [340], so it is possible that exposure to high doses of MDMA *in utero* could have developmental effects, but these do not appear to be related to BDNF levels. The doses used in the rat studies are approximately eight to 10 times greater than a human equivalent dose.

Prenatal MDMA exposure at high doses significantly increased locomotor activity of rat pups in a 20-minute novel cage environment test [339]. Rodents treated with MDMA during development were not significantly different than rodents who received MDMA as adults. The results of several behavioral tests indicate that developmental MDMA exposure combined with adult exposure may interfere with some aspects of learning, including visual-spatial memory and time spent with a novel object [341]. Neonatal MDMA administration did not alter working memory in the object-recognition test in young adulthood (PD 68 to 73) and there were no differences in binding of the radiolabeled selective serotonin reuptake inhibitors (SSRI) citalopram to the SERT at this age. However, the pretreated animals showed increased thermal dysregulation and serotonin syndrome responses following MDMA challenge, especially with respect to head-weaving stereotypy [343]. Another team also found that neonatal rat MDMA exposure exacerbated hyperthermic response to a subsequent dose to MDMA [344]. A study in neonatal rats suggests two distinct critical periods wherein repeated doses affected learning versus acoustic startle [345]. Serotonergic factors may be involved in the developmental effects of MDMA, with the SSRI citalopram producing similar learning impairments in neonatally exposed rats [346]. Given differences between human and rodent development and thermoregulation, it is not clear whether such findings can be generalized to humans (see Section 4.2.2.3 Thermoregulatory Effects in Animals).

Previous research supported a possible link between Ecstasy use and birth defects [347], while an epidemiological study of a large cohort of pregnant women in England conducted in 2004 failed

to support this link, at least in respect to a specific cardiac defect [348]. However, the authors also stated that exposure to MDMA in their sample was too low to establish risk. An earlier survey of a drug-using population suggests that most women cease using Ecstasy when they learn they are pregnant [349]. A 2012 survey of 96 women in the UK interviewed about their drug use during pregnancy found a link between self-reported extent of prenatal MDMA exposure and delays in infant development at 12 months, with heavily exposed infants delayed in mental and motor development, but not language or emotional development [350]. These results were repeated in a 2016 survey of 96 mothers who reported heavier MDMA use (1.3±1.4 tablets per week) during pregnancy. Infants had motor delays from 4 months to 2 years of age that were not attributable to other drug or lifestyle factors [351]. Since there may be a critical period during which exposure to MDMA could alter development, and as a result of the relative lack of information concerning its developmental toxicity, women who are pregnant or who are not using an effective means of birth control should not receive MDMA in clinical trials. None of the sponsor's studies enroll pregnant or lactating subjects.

4.4.6 Hyperthermia

At least one case series of individuals seen on the same night and near or in the same nightclub suggest a relationship between Ecstasy dose and likelihood of hyperthermia [352]. A case report and some findings in rodents suggest that hyperthyroidism or thyroid dysregulation may play a role in MDMA-related hyperthermia in humans [245, 246]. When assessing acute effects of Ecstasy, hyperthermia is one of the more frequently reported acute harms of Ecstasy [53, 242].

A study of rats receiving subcutaneous injections of 9 mg/kg MDMA, just under half the LD50 of 20 mg/kg in rats housed together, reliably produced malignant hyperthermia in the context of warm ambient temperatures of 29°C and during social interaction [187]. At this dose, MDMA monotonically increased intracerebral heat production and muscle temperature while causing strong and sustained peripheral vasoconstriction, which inhibits heat dissipation. Social interaction on its own also induced metabolic brain activation and transient vasoconstriction in rats, which compounds the hyperthermic effects of MDMA observed at toxic doses and warm ambient temperatures. These effects are likely to be mediated through dopaminergic pathways [353, 354], which have been shown to be play a minor role in producing the effects of MDMA in humans [34].

4.4.7 Cardiovascular Toxicity

Injections of 20 mg/kg MDMA in conscious rats assessed by radiotelemetry (10.7 times the equivalent dose in humans), found that MDMA caused a prolonged increase in blood pressure [202]. In the same study, MDMA was found to produce mild isotonic contractions of aorta and vas deferens vascular tissue in anesthetized rats, but could also inhibit prejunctional contractions evoked by stimulation [202].

The elevation of blood pressure and increased heart rate produced by MDMA, similar to that produced by other sympathomimetic drugs, can lead to additional risks and complications [355-357], such as stroke, cardiac events, or other cerebrovascular events, including cerebral venous sinus thrombosis [358] and cerebral or subarachnoid hemorrhage [80, 359-363]. In two such cases, a previously existing underlying arteriovenous malformation appeared to play a role in the event [359, 361]. Intra-cardiac pressures, intra-arterial pressures, angiotensin II, pain, and adrenergic (α_2) central nervous stimuli can also influence AVP secretion [364]. Increased AVP concentration is described in several studies as a strong predictor of mortality in patients with chronic heart failure and acute heart failure, and contributes to increases in blood pressure [365]. As with any amphetamine, increased heart rate (tachycardia) and elevated blood pressure can also

lead to cardiac events, such as arrhythmias or myocardial infarction [366, 367]. Fatal dysrhythmias have been reported following heavy MDMA use, resulting in ventricular fibrillation and asystole. Individuals with underlying cardiac and/or pulmonary disease and preexisting conditions such as Wolff-Parkinson-White syndrome are especially at risk for heart failure and fatal arrhythmias. Although the presence of MDMA was rarely confirmed in reported cases, these types of events are all well-established complications of hypertension and can occur after use of amphetamines. There have been no such events to date in any clinical trial of MDMA.
Some researchers have expressed concern that MDMA activity at $5HT_{2B}$ receptors might be indicative of increasing risk of VHD with repeated use [24]. Studies in Ecstasy users indicated that only people reporting average lifetime exposure of 900 tablets had cardiac abnormalities indicative of potential VHD [247], and a case of VHD has occurred in a man reporting approximately 16 years of heavy Ecstasy use, from age 17 to 33 years old. [368]. No abnormalities were found in people reporting lifetime exposure of approximately 200 tablets in the same study. Echocardiographic readings in eight Ecstasy users also failed to find any cardiac abnormalities [45]. Since VHD-associated changes and VHD only occurred after extremely heavy Ecstasy use, they are unlikely to be a risk within the research or therapeutic context.

4.4.8 Hyponatremia

A number of case reports describe hyponatremia after uncontrolled, non-medical Ecstasy use [54, 369-371]. A recent meta-analysis showed that a moderate reduction of serum sodium concentration is associated with an increased risk of death in different pathologic conditions [372]. Relationships have been found between reduced plasma sodium, a measure of hyponatremia, and variations in COMT and CYP2D6 genotypes, possibly related to increased AVP and oxytocin release associated with MDMA [252]. Active doses of MDMA likely inhibit CYP2D6 in most individuals, as described in Section 5.2.1 Pharmacokinetics. Behavioral factors, including vigorous exercise and excessive consumption of water without an attempt to replace electrolytes, and an increase in the anti-diuretic hormones AVP and oxytocin, likely all contribute to this very rare but SAEs in Ecstasy users [32]. Women are generally more likely to exhibit hyponatremia than men [373, 374], including Ecstasy or MDMA related hyponatremia [54]. Heart failure is commonly associated with hyponatremia, and is also characterized by increased concentrations of AVP [375-377]. Hyponatremia has not occurred during a controlled clinical trial with MDMA.

4.4.9 Hepatotoxicity

In vitro studies and studies employing high, repeated doses of MDMA, estimated as being at least five times greater than expected in a clinical trial [378], report damage to liver cells [379-381]. Though many of these studies employed MDMA concentrations much higher than would occur after human ingestion, there are reports of liver disease in Ecstasy users. Studies in rats suggest a role of body temperature in promoting liver toxicity. A review of the literature highlights a number of potential factors, including body temperature and metabolism in preclinical studies and polydrug use, including alcohol, and environmental factors in humans [382]. Due to disparities in dosing and method, it is hard to establish whether these findings are relevant for liver toxicity in human Ecstasy users.

Hepatotoxicity (liver disease or damage) was reported in approximately 16% of 199 case reports from Ecstasy users in non-medical, uncontrolled settings, collected from the mid-1990s to 2001, making it the third most common serious adverse report in the literature. There appears to be more than one pattern of Ecstasy-related hepatotoxicity, and a number of factors, including polydrug use and setting of use may be involved [382]. Acute liver failure or hepatitis has

occurred after reported ingestion of a single Ecstasy tablet [383-386]. In other cases, hepatotoxicity has occurred after months of regular Ecstasy use [387]. Standard toxicity studies failed to find liver damage after MDMA in rats or dogs after 28 days of exposure [330], nor have any cases of liver disease arisen during controlled studies. Examinations of case reports and a number of *in vitro* studies suggest an association between hyperthermia and hepatotoxicity. However, liver disease also occurred in some individuals without the occurrence of hyperthermia, appearing after continued use and resolving after abstinence. These reports suggest a potential immunological mechanism. Since hepatotoxicity has been noted in Ecstasy users, *in vitro* and *in vivo* studies have examined the hepatotoxicity of MDMA. These studies show that high repeated doses of MDMA can impair liver cell viability *in vivo* [379], and can increase profibrogenic activity in cultured stellate cells [381] while reducing cell viability without producing lipid peroxidation *in vitro* [379, 388]. At higher ambient temperatures, a toxic dosing regimen was capable of increasing lipid peroxidation and activating apoptosis due to oxidative stress [389]. A single intraperitoneal dose of 20 mg/kg in rats was still capable of disrupting glutathione homeostasis, decreasing antioxidant enzyme activity, and lipoperoxidation activating apoptosis in one study [390]. However, peak liver exposure to MDMA in sponsor-supported studies should be approximately one-eleventh the concentration shown to impair cell viability in these studies. No cases of liver disease or hepatotoxicity have occurred in controlled clinical trials with MDMA. See Section 5.3.6 Hepatic Effects for discussion of liver panel results in sponsor-supported clinical trials.

4.4.10 Neurotoxicity

Repeated very high doses of MDMA in animals reduce total serotonin levels in the brain, impair transport of serotonin, and cause psychobehavioral changes such as increased anxiety [124, 226, 391-393]. In combination with other drugs or in high dose binge administration studies, MDMA may provoke serotonin syndrome. For example, rodents respond to high doses of MDMA by exhibiting flat body posture, forepaw treading and an erect tail ("Straub tail") [393]. These behaviors are considered indicators of serotonin syndrome. Doses used in most preclinical studies of neurotoxicity are at least five times the amount used in clinical trials or nonmedical settings, and can be as high as 20 times that amount. Studies in rodents and primates suggest that repeated high doses of MDMA could reduce regional serotonin, damage serotonin axons and cause neurotoxicity [124, 135, 394-397] and promote apoptosis in the hippocampus after 5 or 10 mg/kg MDMA given daily for 1 week [214]. However, the majority of these studies employed large doses of MDMA that overestimated human-equivalent doses, with findings now clearly indicating that doses used in nearly all rat and most primate studies are inappropriately high for comparison to use in clinical settings and are more pertinent toxicological effects of MDMA [78, 114, 119].

Most studies suggested that heavy but not moderate Ecstasy users had impaired verbal memory and lower numbers of estimated SERT sites, assessed via imaging with radioactively labeled ligands in positron emission tomography (PET) or single photon emission tomography (SPECT), with heavy use often defined as 50 or more times or tablets. Taken together, findings from these studies suggest there is some risk of long-term effects in heavy Ecstasy users with respect to number of estimated SERT sites in specific brain areas and performance on measures of memory. However, interpreting findings of changes in serotonin receptors or cognitive function after repeated Ecstasy use are complicated by the possible impact of polydrug use and other potential pre-existing factors in retrospective reports, and the findings are not readily transferrable to use of MDMA in a therapeutic or research context.

Many investigations have examined cognitive function in Ecstasy users with the goal of demonstrating long-term effects of purported neurotoxicity of Ecstasy. Rogers and colleagues

performed a meta-analysis on a large number of retrospective studies of Ecstasy users and various cognitive functions. Given methodological flaws in this type of analysis, the investigators cautiously concluded that there might be a significant effect of Ecstasy use on verbal memory, and a lesser effect on visual memory [53]. Retrospective designs and inappropriately matched samples continue to appear in the literature [398-400], even when using multiple control groups. Two meta-analyses of memory in Ecstasy users arrived at somewhat contradictory conclusions [401, 402]. Both detected an association between Ecstasy use and impaired performance on at least some measures of memory. However, one reported that this association had a medium to large effect size with no effect of Ecstasy dose [401], while the other reported that the association had a small to medium effect size with an Ecstasy dose effect, and that polydrug use itself contributed to impaired cognitive function [402]. A meta-analysis comparing current Ecstasy users and drug-using controls on visuospatial skills reported that current users performed less well on measures of visual recall, recognition and item production than controls [403], but found no significant relationship between lifetime Ecstasy use and visuospatial task performance. A longitudinal study comparing people who continued to use Ecstasy with those who did not do so detected lower performance on immediate and delayed visual memory [404]. In a second follow-up in the same sample reported lower scores in visual memory, at marginal significance and no further impairment [405]. An examination of the relationship between elements of Ecstasy use history and verbal memory reported that use in the past year, especially in men, was associated with impaired verbal memory [406]. The authors suggest that gender differences in polydrug use may be involved. A study comparing performance on a test of verbal memory in 65 ecstasy users enrolled in clinical trials of MDMA and an equal number of age and gender matched non-drug using controls from other trials failed to detect significant differences between the two groups [407]. This study employed a pre-determined measure of clinical significance, 1.5 times the average standard deviation of the healthy controls, and used a Bayesian statistical test suited for assessing a null hypothesis. It is notable that none of the subjects were enrolled in studies designed to compare cognitive function in ecstasy users, which may have reduced anxiety and potential risk of "stereotype threat" that may be faced by substance users completing assessments of cognitive function, which was done to reduce expectancy in the study [408].

The nature and strength of the association between regular Ecstasy use and any impairments in executive function remains inconclusive, with studies reporting conflicting results [5, 258, 259, 409, 410]. Findings from a study published in 2014 did not find differences in multitasking [301]. A meta-analysis comparing executive function in Ecstasy users and non-Ecstasy using controls found a significant effect of Ecstasy use on one component of executive function (updating), no effect on another (shifting) and mixed results when looking at other components (response inhibition and access to long-term memory) [411]. Polydrug use likely contributes to findings of impaired executive function seen in Ecstasy users [292, 412]. Current research has not settled the question.

Psychiatric problems after uncontrolled, non-medical Ecstasy use were reported in 22.1% of 199 case reports from the early 1990s to 2001, and are the most common reason for appearance at an emergency department [52, 55]. Psychiatric symptoms included affective responses, such as dysphoria, anxiety, panic, and psychotic response, as well as cases with mixed psychotic and affective features. The most common problem reported included panic, restlessness and psychotic response, as seen a systematic review and several epidemiological case series [53, 413]. The mechanisms behind Ecstasy-associated psychiatric problems remain unclear, but are likely the result of an interaction between pharmacology and individual susceptibility. The difficulty of assessing the frequency of these events is increased given that pre-existing psychiatric problems occur in people who choose to use Ecstasy [414] and findings of an association between use of Ecstasy and other drugs and self-reported symptoms of anxiety and depression. As described earlier, most cases of psychological distress after Ecstasy use resolved after supportive care [52, 55].

Anxiety responses associated with MDMA administration reported in controlled trials have resolved over time, usually either during the period of acute drug effect or with the waning of drug effects.

4.5 Serious Reports, Mortality, and Morbidity in Animals and Epidemiological Settings

Intravenous MDMA doses that cause lethality in 50% of the cases, known as the LD50, are 97 mg/kg in mice, 49 mg/kg in rats, 14 to 18 mg/kg in dogs, and 22 mg/kg in monkeys [106]. LD50 may vary across strains, sexes, and housing conditions [415-417]. For example, LD50 in mice housed together is 20 mg/kg, which is considerably lower than in isolated animals [189, 418]. Reducing ambient temperature and administering the $5HT_{2A}$ antagonist ketanserin reduced lethality, suggesting that amplified elevation in body temperature and activity at serotonin receptors may promote lethality in group-housed mice given MDMA [189]. Considerable variation across studies in environmental factors, that are often underspecified in published reports, contribute to challenges in extrapolating findings in animal studies that may be relevant in epidemiological settings.

A number of SAEs, including fatalities, have been reported in humans after Ecstasy use in unsupervised and uncontrolled settings. These events are relatively rare given the prevalence of Ecstasy use [49, 50]. These include hyperthermia (potentially arising from "serotonin syndrome"), psychiatric problems, hepatotoxicity (secondary to hyperthermia), cardiac disorders and hyponatremia [49, 52-54, 419]. Set and setting likely play a role in the development of some Ecstasy-related AEs, such as vigorous exercise, lack of attention to somatic cues, and too little or too much hydration combined with pharmacological action on AVP resulting in hyperthermia or hyponatremia [51, 371]. Even if ambient temperature does less to moderate the effects of MDMA on body temperature than originally believed based on animal studies, other environmental and behavioral factors, as those related to vigorous exercise, may be involved. It is important to note that not all reports of AEs in Ecstasy users provide information on whether MDMA was detected in plasma or other fluids, with some relying on self-report or the reports of friends as to identity of substances consumed. Reports indicating detectable MDMA will thus be the best indicators of an actual association. Unexpected drug-related SAEs have not occurred in any of the human MDMA research studies thus far.

While case reports do not provide an appropriate basis for estimating the relative frequency of these events, they can provide information on the possibility of an event occurring. Most Ecstasy-related emergency department admissions are the result of people experiencing anxiety or panic reactions after use and involve supportive care only [52, 55, 420]. An extensive systematic review reached similar conclusions concerning the frequency and nature of emergency department admissions, though also noting that owing to complexities of nonmedical and recreational use, the researchers found it hard to establish a lethal dose [53]. However, a pair of case series drawn from two different events suggests a general relationship between estimated dose and number of emergency department admissions after exhibiting seizures, unresponsiveness or hyperthermia, with both series reporting high doses of MDMA (230 and 270 mg) in sample tablets or capsules [421, 422]. As is the case with fatalities associated with reports of Ecstasy use, medical emergencies after Ecstasy use are more likely to occur in men [52]. Individuals consuming Ecstasy with pre-existing conditions are at increased risk when consuming drugs of unknown purity, identity, and dose in uncontrolled settings.

Table 2: Summary of Published Morbidity and Mortality Reports

Body System	Reports	Morbidity Reports	Mortality Reports	Total Reports
Thermoregulatory Disorders	Hyperthermia, Hyperprexia, Rhabdomyolysis, Hypoglycemia	135 [80, 421, 423-438]	43 [80, 217, 421, 423, 435, 439, 440]	178
Cardiac Disorders	Cardiac valve disease, Ventricular fibrillation, Cardiac arrest, Arrythmia, Myocardial infarction, Generalized tonic-clonic seizure, Acute coronary syndrome, Myocardial necrosis, Cardio-respiratory arrest, Cardiomyopathy	15 [367, 368, 441-447]	12 [366, 423, 448-452]	27
Osmoregulatory Disorders	Cerebral oedema, SIADH, Urinary retention, Hyponatremia, Acute renal failure	18 [453-465]	6 [367, 466-470]	24
Hepatobiliary Disorders	Acute fulminant hepatitis, Liver disease, Disseminated intravascular coagulation	4 [386, 447, 471, 472]	5 [473-477]	9
Blood and Lymphatic System Disorders	Aplastic anemia	3 [478, 479]	1 [480]	4
Injuries, Poisonings, and Procedural Complications	Anaphylactic shock, Facial rash eruption	1 [481]	1 [482]	2
Nervous System Disorders	Hemorrhage, Infarct, Hippocampal sclerosis (suspected), Encephalopathy, Amnestic syndrome	13 [355, 356, 483-490]	0	13
Dental Disorders	Xerostoma, Bruxism, Dental erosion	15 [491-493]	0	15

Body System	Reports	Morbidity Reports	Mortality Reports	Total Reports
Psychiatric Disorders	Psychotic episode, Depressive episode, Obsessive-compulsive disorder, Autoenucleation	4 [494-496]	0	4
Respiratory, Thoracic, and Mediastinal Disorders	Subcutaneous Pneumomediastinum Epidural pneumatosis, Diffuse alveolar hemorrhage, Asthma	9 [366, 497-504]	0	9
Opthalmic Disorders	Lagophthalmos, Keratopathy, Bilateral sixth nerve palsy	4 [505, 506]	0	4
Injuries, Poisonings, and Procedural Complications	Unknown cause of death	0	204 [366, 507]	204

Four hundred ninety-three case reports, with 272 of these resulting in death, associated with Ecstasy use from 1986 through 2016 are summarized in Table 2. Of these 272, 32 were described in a cumulative 2002 literature review with incomplete citations of sources, and are reported in addition to individual case reports of morbidities in the literature [423]. Detectable levels of MDMA in blood or urine are reported in less than half of these case reports, and range from 50 ng/mL (reported as less than 0.05 mg/L) in the case of anaphylactic shock [482] to 1500 ng/mL (reported as 1.5 mg/L) in a fatal case of hyperthermia and rhabdomyolisis [440]. It is more difficult to associate events with MDMA when the compound is not detected or when detection is for amphetamines in general. Some events, such as VHD, acute hepatitis with gallbladder inflammation, liver disease, or urinary retention occurred in individuals who self-reported daily use for months to years prior to the event. In the majority of the 202 poisoning cases with unknown cause of death, Ecstasy was used in combination with opiates by drug addicts who died in the UK and Wales between 1996 and 2002 [507], and polysubstance use is common in the majority of serious reports presented.

Thermoregulatory disorders play a part in the development of a constellation of disorders across body systems described below. Primary symptoms are hyperthermia resulting rhabdomyolysis described in 135 reports of morbidity and 43 reports of mortality, constituting the most common acute adverse effect associated with Ecstasy. Sympathomimetic effects of MDMA, at unknown doses and purity, in combination with permissive factors in uncontrolled settings, can lead to serious reports of acute and persisting adverse effects on multiple organs. In research settings, the risk of hyperthermia is limited by controlling ambient temperature, conducting treatment sessions in relaxed, private environments, and generally limiting permissive factors.

Cardiac disorders associated with Ecstasy in the context of hyperthermia resulted in 15 reports of morbidity and 12 reports of mortality. Several fatal cases of cardiac arrest were reported. In addition, a non-fatal cardiac arrest occurred in the context of a genetic arrhythmia disorder, catecholaminergic polymorphic ventricular tachycardia [442]. Apparent use of Ecstasy, with concurrent use of other amphetamines during pregnancy, was associated with seizures and myocardial infarction [445, 446]. As evidenced by these reports, individuals consuming Ecstasy

with pre-existing conditions that can influence cardiovascular and cardiac function are at increased risk when consuming drugs of unknown purity, identity, and dose in uncontrolled settings.

Osmoregulatory disorders associated with Ecstasy in the context of hyperthermia resulted in 18 reports of morbidity and six reports of mortality, with acute renal failure (ARF) as the most common cause of death. As described in Section 4.4.8 Hyponatremia, increased AVP secretion caused by MDMA in combination with permissive factors in uncontrolled settings can lead to serious reports of acute and persisting adverse effects on multiple organs, including the liver. Individuals consuming Ecstasy with pre-existing conditions that can influence renal function are at increased risk. In response to this risk, many users tend to overcompensate with excessive consumption of water, leading to dilutional hyponatremia. Prevention of hyponatremia with limited consumption of electrolyte containing fluids and controlled ambient temperatures are required to preserve the body's homeostatic maintenance of fluid balance.

Hepatobiliary disorders associated with Ecstasy use resulted in four reports of morbidity and four reports of mortality. One of the mortality reports happened 1 week after Ecstasy use and was consistent with acute fulminant hepatitis in the absence of viral infection. This patient died despite liver transplantation efforts [473]. Typically, mortality results from disseminated intravascular coagulation (DIC) caused by platelet dysfunction associated with liver failure. Non-fatal morbidity reports range from acute hepatitis associated with daily usage of five to eight tablets of Ecstasy for 3 months in combination with alcohol [471] to liver damage in combination with congestive cardiomyopathy [447]. Given that polysubstance use and prior insult to liver function cannot be ruled out, the frequency of isolated serious hepatotoxicity cases in the absence of hyperthermia are rare among serious reports associated with Ecstasy use. Hepatotoxicity is more common among serious reports in combination with hyperthermia and acute renal failure.

Blood and lymphatic system disorders associated with Ecstasy use resulted in three morbidity reports and one mortality report of aplastic anemia. The death after aplastic anemia occurred from complications of immunosuppressant therapy followed by an allogenic stem cell transplant, 17 months after the first admission [480]. The patient had initially presented with progressive weakness and epistaxis, resulting from daily Ecstasy use for 7 months, combined with heavy alcohol intake. Further examination revealed the replacement of bone marrow tissue with fatty deposits, likely due to alcohol consumption and exacerbated by chronic Ecstasy use. Three reports of morbidity ranged in prior Ecstasy use levels from once to four times in the prior year, with two cases spontaneously resolving within 2 months and the treated case failing immunosuppressive therapy and recovering 4 months after subsequent bone marrow transplant [480].

The report of possible anaphylactic shock and subsequent death occurred in a 13-year old girl who had at least one previous exposure to Ecstasy [482]. Her friends reported that she experienced swelling lips after her first exposure. After approximately 1.5 tablets, the girl experienced nausea and vomited, and later had difficulty breathing. On admission she was hypothermic and hypotensive. A low level of MDMA (<0.5 mg/dL) was detected in blood. None of the other individuals consuming tablets from the same batch underwent similar experiences. Autopsy found a massive brain edema as well as laryngeal oedema and lung congestion. Chemical analyses ruled out hyponatremia. The reaction may have been to MDMA or to an adulterant in the tablet. The authors of the report do not report whether tablets were assessed for contents.

Memory difficulties arising immediately after Ecstasy use have been reported in a sporadic user [487]. The memory difficulties arose in a man reporting use of Ecstasy five or six times, with

confusion and cognitive impairment reportedly occurring after taking a single tablet at a party. Cognitive function was assessed 7 years later. Imaging showed signs of hippocampal sclerosis. It is not clear from the report whether the individual used Ecstasy prior to or after this event. The individual had hypertension, raising questions concerning possibility of a cerebrovascular event. In a neurological serious report with 0.83 ng/mL MDMA detected in the hair of a girl who developed encephalopathy [486] during chronic low or moderate Ecstasy use, cognitive function and memory problems associated with neurological damage was reported. Upon cessation of use 16 months later, extensive hippocampal remodeling was reported assessed through PET scans. This finding is consistent with hippocampal dendritic spine remodeling observed in rats receiving 20 mg/kg MDMA for four days intended to simulate chronic usage in humans [508], however the clinical presentation was also similar to CNS herpes infection, so it is difficult to attribute this isolated case report to only Ecstasy use. Two reports have identified bilateral lesions in the globus pallidus of ecstasy users during magnetic resonance imaging (MRI) or autopsy, with a third report finding hippocampal changes in imaging associated with amnestic syndrome [488-490]. Due to the retrospective and infrequent nature of these reports, it is difficult to determine causality.

Overall, the risks of serious reports appear to be minimal in controlled settings with adequate screening with eligibility criteria defined in study protocols. None of these events have occurred within the context of human clinical studies with MDMA.

4.6 Abuse Potential in Nonclinical Studies

Studies in Ecstasy users and animals suggest MDMA possesses some abuse potential, but not nearly that of amphetamine. Mice, rats, and monkeys self-administer MDMA, indicating that MDMA has rewarding properties in animals [509-511]; however, the rate and response-acquisition of self-administration is much lower than other drugs of abuse, such as cocaine or heroin. In rodents, acquisition of MDMA self-administration requires a lengthy training period with consecutive sessions [510, 512, 513]. Physical dependence and drug withdrawal was investigated by treating mice with 10 mg/kg i.p. MDMA twice daily for 5 days. Results showed that mice did not exhibit aversive/dysphoric or anxiogenic behaviors after treatment, indicating that high doses of MDMA do not induce classical symptoms of physical dependence [514]. Monkeys choose to self-administer MDMA in doses equivalent to or only slightly higher than doses used by humans [509], but typically reduce their MDMA intake over time. While monkeys work hard to obtain MDMA, they work harder to obtain other psychostimulants, such as cocaine or methamphetamine [512, 513]. Taken together, results in animals suggest that the abuse liability of MDMA is moderate.

Drug discrimination studies investigating the discriminative stimulus effects of MDMA as either hallucinogenic or stimulant have reported inconsistent findings. Some drug discrimination studies have shown MDMA to completely substitute for S-(+)-amphetamine in rats [634], monkeys [635], and pigeons [636]; where as other reports did not [637]. In a two-lever procedure, MDMA did not substitute for the hallucinogens (+)-lysergic acid diethylamide (LSD) or (+)-2,5-dimethoxy-4-methylamphetamine (DOM) [66, 638-639]. A three-lever procedure found that LSD produced dose-dependent increased substitution for MDMA while neither cocaine nor 2,5-dimethoxy-4-bromoamphetamine (DOB) substituted for it [640]. Serotonin and dopamine may be involved in producing stimulus characteristics in rats [641]. On the other hand, MDMA has been shown to substitute for mescaline [638]. Given MDMA's unique pharmacological profile and it's ability to produce stimulant-like, mild hallucinogen-like, and empathogenic effects, in 1986 Nichols coined a novel pharmacological class, the 'entactogens' [66].

Research of Ecstasy dependence comes from a combination of published case studies and assessment of symptoms based on the Composite International Diagnostic Interview,

the Diagnostic and Statistical Manual of Mental Disorders Version IV (DSM-IV), and/or the Severity of Dependence Scale [521]. Of the small number of individuals assessed in a representative sample of Munich residents aged 14 to 24, only 1% were diagnosed with Ecstasy abuse and 0.6% with dependence [520], though other reports of large (N=173) but non-representative samples, including subjects recruited from substance abuse programs, reported 30% (N=52) had used Ecstasy and of these, 43% met DSM-IV criteria for dependence [519]. In a large Australian sample (N=329), approximately 25% of polydrug users wanted to reduce their Ecstasy use and 20% had received treatment for an Ecstasy-related problem, although this sample likely had an over-representation of chaotic intravenuous polydrug users [522]. In a study of self-reported cravings in Ecstasy users, exposure to Ecstasy-related cues induced greater subject ratings of craving. Although over 50% of subjects agreed on some level with two or more statements regarding Ecstasy-related craving, the average score for craving was negative [523]. It also appears that MDMA has fewer or less intensely rewarding effects than stimulants, and even heavy Ecstasy users fail to report the intensive patterns of use seen with other stimulants [2, 4, 515]. Based on two structural analyses, Ecstasy dependence is bifactorial [517]. Although Ecstasy dependence does have a compulsive use factor as well as an escalating use factor, withdrawal symptoms do not include significant physical symptoms such as alcohol, cocaine, methamphetamine, opioids, and tobacco [516, 518]. In a prospective longitudinal study (N=2446), German polydrug users reported low prevalence of initial Ecstasy abuse or dependence, as well as substantial decline in use factors at 12-month follow-up, suggesting that Ecstasy use is a self-limiting transient phenomenon in many cases [520]. Features of Ecstasy abuse and dependence in humans are consistent with preclinical findings in self-administration studies of moderate abuse liability that is greater than that for serotonergic hallucinogens, but less than that for stimulants [510, 524].

5.0 Effects in Humans in Clinical Settings

5.1 History of Use in Clinical Settings

Shulgin and Nichols were the first to report on the effects of MDMA in humans [59]. In the 1970s, psychotherapists used MDMA-assisted psychotherapy to treat psychological disorders, including anxiety [65]. Legal therapeutic use continued until its placement on the U.S. list of Schedule I drugs in 1985 [64, 68, 525]. An estimated 500,000 doses of MDMA were administered during psychotherapy sessions in North America prior to its scheduling [57, 525]. A few uncontrolled human studies of MDMA occurred in the 1980s [44, 62], including Greer and Tolbert's study of MDMA in a psychotherapeutic context.

Controlled human studies of MDMA commenced in the mid-1990s with a MAPS funded investigator-initiated Phase 1 dose-response safety study [47, 526]. MAPS also funded a Phase 2 investigator-initiated dose-response safety and efficacy pilot study in Spain that was terminated early due to political concerns. This study enrolled six subjects, with four receiving a single session of MDMA-assisted psychotherapy without any safety concerns and experiencing some PTSD symptom reduction [527].

Based on past reports of MDMA use, preclinical studies and the results from these investigator-initiated trials with MDMA, the sponsor launched a Phase 2 Clinical Development Program in 2001 to develop MDMA-assisted psychotherapy for the treatment of chronic PTSD under U.S. IND. Eight sponsor-supported Phase 2 studies of MDMA-assisted psychotherapy for PTSD have been conducted. Two have been published, one main study with an extension in three subjects who relapsed in the U.S. (MP-1, MP1-E2) [41, 42], and one in Switzerland (MP-2)[43]. Four additional studies have completed treatments (MP-4, MP-8, MP-12) and are in follow-up, one

study in Israel was terminated early (MP-3) and re-initiated with a new study team (MP-9) and has completed enrollment.

MP-1, the first Phase 2 proof of principle study, explored the effect of MDMA-assisted psychotherapy for PTSD with a 125 mg initial dose and 62.5 mg supplemental dose of MDMA, as compared with inactive placebo in a chronic PTSD population (N=23). MP-1 enrolled eighteen women and five men, all European-American, average age 41.3±7.1 years. Subjects had no history of major medical conditions, psychotic disorders, dissociative identity disorder, or borderline personality disorder. Safety data obtained included: cognitive function before and after study participation, vital signs, liver panels, psychological distress during experimental sessions, concomitant medications, and AEs. Two subjects experienced unrelated SAEs, including a fractured clavicle from a motor vehicle accident and vasovagal syncope nearly 2 months after the second and final MDMA administration. Three MP-1 subjects relapsed after treatment, two of the them during the 3.8-year follow-up period and one after the follow-up. These three subjects were enrolled in an extension study, MP1-E2, to understand if a single MDMA-assisted psychotherapy session would improve PTSD symptoms after a relapse. The study has been completed. One subject experienced an unrelated SAE, a major depressive episode with suicidal ideation. MP-1 and MP1-E2 are now complete.

MP-2, the second Phase 2 proof of principle study, was conducted in Switzerland (N=14). This study explored reproducibility of MDMA-assisted psychotherapy for PTSD with a 125 mg initial dose and 62.5 mg supplemental dose of MDMA, as compared with 25 mg active placebo initial dose and 12.5 mg supplemental dose of MDMA (N=14). MP-2 enrolled 11 women and three men, average age 41.8±10.9 years. Most were of European ethnicity, one woman was South African and one man was Middle Eastern. Subjects enrolled had no psychotic disorders, dissociative identity disorder, or borderline personality disorder. One subject had a previous history of breast cancer, but had been in remission for over 10 years and was not symptomatic at screening. Safety data obtained from this study included: vital signs and psychological distress during experimental sessions, liver panels before and after treatment, concomitant medications, and AEs. One subject was diagnosed with a metastatic brain tumor during follow-up that resulted in death, which was an unrelated SAE. A second subject was hospitalized prior to dosing for psychiatric crisis, also reported as an unrelated SAE. MP-2 is now complete.

MP-3, the third Phase 2 study, was conducted in Israel with two Israeli therapist teams. This study was designed to explore reproducibility of MDMA-assisted psychotherapy for endemic PTSD with a 125 mg initial dose and 62.5 mg supplemental dose of MDMA, as compared with 25 mg active placebo initial dose and 12.5 mg supplemental dose of MDMA (N=5). MP-3 enrolled five male subjects, average age 39.4±15.9 years, with PTSD symptoms that failed to respond to at least one course of psychotherapy or at least one course of pharmacotherapy. Two subjects were Middle Eastern and three were European. This study was terminated early due to personnel turnover at the clinical site and difficulty of ensuring consistent training of site staff. These subjects are included in demographics data, and excluded from all other data due to inconsistencies in data collection. No SAEs or severe AEs were reported in this study.

There are three Phase 2 studies currently in follow-up (MP-8, MP-12, MP-4) and one that is completing treatments (MP-9). These studies explore the reproducibility of treatment outcomes of MDMA-assisted psychotherapy in people with chronic PTSD that failed to respond to at least one course of psychotherapy or at least one course of pharmacotherapy. Two of the randomized, blinded studies are taking place in the U.S. MP-8 (N=26) compares 30 mg versus 75 mg versus 125 mg initial dose of MDMA, with an optional supplemental dose equivalent to half the initial dose, in military veterans, firefighters and police officers ("first responders") with service-related PTSD, with an average age of 37.2±10.3 years. MP-12 (N=28) compares 40 mg versus 100 mg

versus 125 mg initial dose of MDMA, with an optional supplemental dose equivalent to half the initial dose, in subjects with PTSD from any cause, with an average age of 42.0±12.9 years. The Canadian study MP-4 (N=6) compares placebo to 125 mg initial dose of MDMA, with an optional supplemental dose equivalent to half the initial dose, in subjects with an average age of 47.7±6.0 years, and MP-9 (N=10) in Israel compares an initial dose of 25 mg to 125 mg MDMA, with an optional supplemental dose equivalent to half the initial dose, in subjects with an average age of 36.7±8.0 years.

The sponsor is also supporting two additional Phase 2 studies of MDMA-assisted therapies in parallel indications: one for treatment of social anxiety in autistic adults (MAA-1, N=12), and another for anxiety associated with a life-threatening illness (MDA-1, N=18). Subjective effects, mood, and reactions are also being assessed in the ongoing Phase 1 placebo-controlled study of MDMA-assisted psychotherapy, in healthy volunteers who have completed training in manualized MDMA-assisted psychotherapy (MT-1).

In sponsor-supported studies, MDMA or placebo/comparator is administered after preparatory psychotherapy during two or three 8-hour experimental sessions scheduled 2 to 5 weeks apart, each followed by at least three sessions of integrative psychotherapy. This treatment model is based on historical experience with MDMA use as an adjunct to psychotherapy.

Most data reported is from the Phase 2 studies of MDMA-assisted psychotherapy for PTSD. The studies have employed a range of comparator and active doses, from an initial dose of 25 mg to 150 mg MDMA. The highest dose (150 mg) was offered to a limited number of subjects in MP-2 as part of "Stage 3," an open-label arm for non-responders in Stage 1 and/or Stage 2. All studies have employed 125 mg usually followed 1.5 to 2 hours later by a supplemental dose of 62.5 mg MDMA as the primary active treatment.

The effects in humans presented in the sections below will include findings from both sponsor-supported clinical trials in patient populations as well as studies conducted in controlled laboratory settings in healthy volunteers without sponsor support. Findings from extensive human research being conducted on the pharmacology and mechanism of action will be presented in addition to the information required by FDA in order to support the safety profile of MDMA.

5.2 Pharmacology in Humans

As of 2015, the sponsor has not conducted studies on the pharmacodynamics or pharmacokinetics of MDMA, but relies on published literature. Beginning in the early to mid-1990s, several research teams conducted studies of the pharmacodynamics and pharmacokinetics of MDMA [10, 14, 22, 29, 116, 327, 528-530] without receiving sponsor support. Findings from these teams are described below, with specifics of metabolism detailed in Section 5.2.1 Pharmacokinetics.

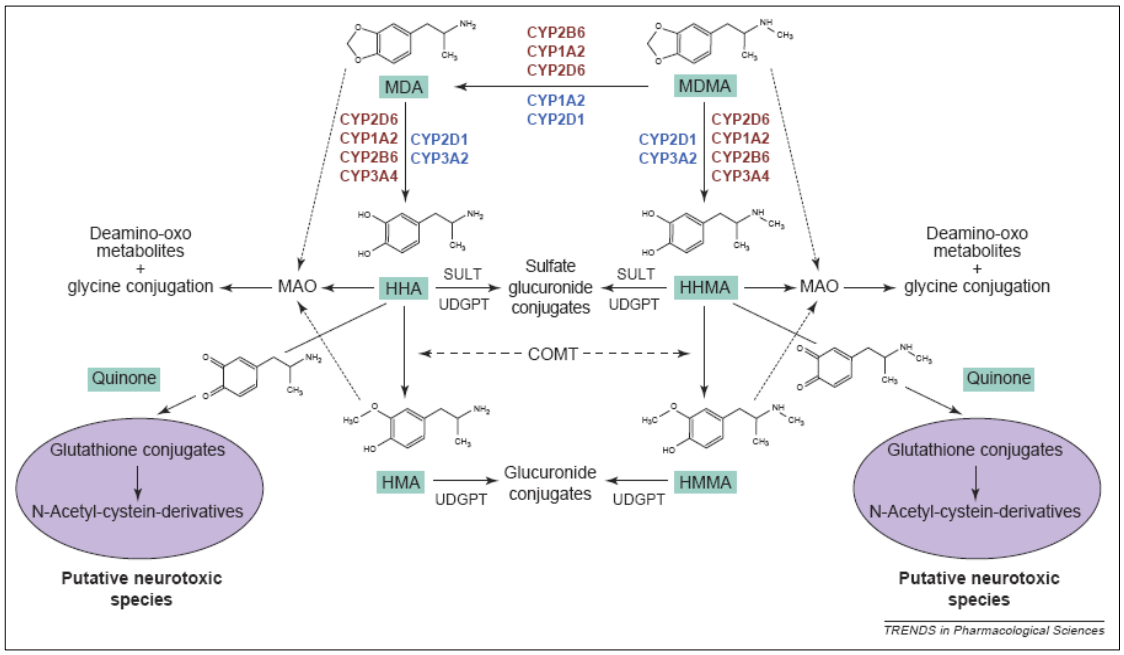
5.2.1 Pharmacokinetics

Onset of MDMA effects occurs 30 to 60 minutes after administration [8, 9], peak effects appear 75 to 120 minutes post-drug [7, 10-12], and duration of effects lasts from 3 to 6 hours [10, 12, 13], with most effects returning to baseline or near-baseline levels 6 hours after final drug administration. Self-reported duration of effects may increase as the dose of MDMA increases [7]. Administering a second dose of MDMA 2 hours after the initial dose, twice that of the initial dose, does not significantly extend the duration of measureable physiological or subjective effects [328]. Orally administered MDMA has a half-life of 7 to 8 hours in humans, with one report listing a half-life of 11 hours [531], and half-life is marginally extended if an additional dose is administered 2 hours after an initial dose [328]. Metabolites of MDMA are summarized in Figure

1 [532-537]. Metabolites are primarily excreted as glucuronide and sulfate conjugates [534]. Studies examining metabolism of 100 mg MDMA reported excretion values similar to those reported by de la Torre and associates [118, 531, 538-540]. MDMA and its metabolite MDA appear in oral fluid samples at much higher concentrations than plasma, for 24 to 48 hours for the former and 12 to 47 hours for the latter after oral administration of 1 to 1.6 mg/kg MDMA [541]. Urinary excretion of the MDMA metabolite HHMA after 100 mg MDMA in four men was 91.8±23.8 mol and 17.7% recovery [540]. By contrast, urinary recovery of the major metabolite HMMA after 100 mg was 40% [542]. As was the case for maximal plasma values, urinary recoveries for MDMA and MDA were higher when a second dose of 100 mg MDMA was administered 24 hours after an initial dose of 100 mg MDMA when compared with a single dose [118]. In one study, urinary excretion of the metabolite HMMA exceeded that of MDMA by 33 hours after a dose of 1.6 mg/kg MDMA [543], suggesting that secondary metabolism of MDMA continues during this period. Findings support the enantioselective nonlinear metabolism of MDMA and its metabolites measured in blood and urine [544, 545].

A study comparing the effects of a single 100 mg dose with an initial administration of 50 mg followed 2 hours later by 100 mg reported higher peak plasma MDMA than might be expected, and lower levels of the MDMA metabolites HMMA and HMA [328], findings further supported by examining plasma MDMA after two doses of 100 mg given 4 hours apart [546], likely due to metabolic autoinhibition. Comparison of pharmacokinetic-pharmacodynamic relationships for MDMA reveals acute pharmacodynamic tolerance. Despite 8 hours of plasma half-life of MDMA, and persistent high drug levels in the blood, most pharmacodynamic effects of the initial dose rapidly return to baseline within 4 to 6 hours [530]. These findings suggest that intensity of most subjective and physiological effects of MDMA would not be significantly impacted by the supplemental doses in sponsor-supported studies due to acute tolerance to its prototypical effects [546]. This acute tolerance could be caused by functional depletion of stores of serotonin so that no more can be released despite MDMA still being present [530], or suggests that MDMA transport into intracellular spaces is saturable due to limited transport capacity [127]. Additionally, reversible inhibition of tryptophan hydroxylase as observed in rodents [20], or internalization of serotonin reuptake transporters from the plasma membrane leading to less serotonin release [78], would support self-limiting effects of MDMA. On the other hand, although SERT can be internalized, evidence suggests that accumulation of extracellular serotonin stimulated by MDMA affects SERT trafficking by perpetuating cell-surface SERT expression, but in contrast promotes internalization of DAT and NET [127, 547].

Figure 1: Metabolism of MDMA in Humans



Metabolism of MDMA in humans (in red) compared to metabolism in rats (in blue). Reproduced with permission of R. de la Torre [113].

MDMA is metabolized in the liver by several cytochrome P450 CYP enzymes, including CYP1A2, CYP3A4, and CYP2D6. It is likely that active doses of MDMA inhibit CYP2D6 function, as measured by examining the effects of MDMA on dextromethorphan metabolism. Inhibition of CYP2D6 by MDMA was demonstrated first in a physiological model derived from data collected after oral administration in humans [548]. O'Mathuna and colleagues present evidence that CYP2D6 activity may not fully recover until 10 days after MDMA [549, 550]. After reviewing their data and the literature on MDMA pharmacokinetics, de la Torre and colleagues concluded variation in CYP2D6 genotype is not clinically significant, due in part to the fact that the enzyme is inhibited in most people after administration of an active dose [327]. In contrast, MDMA may produce increased activity of the enzyme CYP1A2, as evidenced by comparing caffeine metabolism before and after MDMA [551]. The enzyme COMT and monoamine oxidase may also be involved in the metabolism of MDMA [542]. At least one variation in COMT genotype may affect MDMA elimination rate (K_e) and systolic blood pressure (SBP) after MDMA [552]. As a monoamine reuptake inhibitor that leads to monoamine release and inhibits monoamine oxidase-A [132] combining MDMA with a monoamine oxidase inhibitor (MAOI) medication presents a risk for provoking serotonin syndrome and increases in sympathetic activity. Fatalities have occurred apparently as a result of combining MAOI medications with MDMA [133, 134]. For this reason, MAOI medications are tapered for at least five half lives of the medication and active metabolites, plus 1 week for symptom stabilization in sponsor-supported studies.

Researchers have attempted to compare MDMA pharmacokinetics in humans and other species, including other primates, as discussed in Section 4.2.1 Pharmacokinetics in Animals and Section 5.2.1 Pharmacokinetics. These investigations sought to establish human-equivalent doses given nonlinear pharmacokinetics. Doses that researchers assumed to be human-equivalent produced greater plasma concentrations. However, duration of exposure expressed in half-life was often shorter. For example, a dose of 1.6 mg/kg MDMA produced a half-life of 8.4 hours in a small sample of humans while a dose of 2.8 mg/kg had a half-life of 2.1 hours [119]. A dose of 7.4

mg/kg in squirrel monkeys, four times a human-equivalent dose and never administered in a human trial, had a half-life of 3.4 hours [107]. Researchers have detected nonlinear pharmacokinetics of MDMA in all species studied to date, leading Mueller and colleagues to conclude that a preclinical study cannot accurately and simultaneously model human-equivalent plasma levels and equivalent duration of exposure [119].

5.2.2 Pharmacodynamics

Estimates from animal data suggest the LD50 in humans is probably between 10 to 20 mg/kg [6]. Typically, human trials have used doses between 1 and 2 mg/kg, with therapeutic studies using fixed dosing rather than adjusting dosing on a mg/kg basis, in order to achieve a more consistent subjective response between subjects. The pharmacokinetics of MDMA in humans have been characterized in blood and urine samples using oral doses of up to 150 mg MDMA [14]. MDMA is a triple monoamine reuptake inhibitor, and similar drugs in this class have been found to exert potent anti-depressant activity with a potentially favorable safety profile [15, 16]. MDMA concomitantly promotes release, inhibits reuptake, and extends duration of serotonin, norepinephrine, and dopamine in the synaptic cleft to increase serotonergic, noradrenergic, and dopaminergic neurotransmission. MDMA has self-limiting subjective and physiological effects as previously described.

Many researchers categorize MDMA as belonging to a unique class of drugs referred to as the Entactogens [13, 66], defined as substances that produce changes in mood and social interaction, as well as feelings of interpersonal closeness and changes in perception. MDMA shares some of the pharmacological effects of stimulants and serotonergic hallucinogens [8, 10, 11, 553], as well as a small number of pharmacologically related compounds, such as MDE [553]. Initially, narrative reports and surveys supported the social cognitive effects of MDMA or Ecstasy [2, 234, 235, 554]. Controlled trials detected self-reported empathy or closeness to others in healthy volunteers [7, 12, 91], and starting in the late 2000s to 2010s, controlled studies measured effects of MDMA on social cognition or emotion [29, 30, 35]. Although researchers have offered several models and explanations for the effects of Entactogens, it appears that serotonin and norepinephrine release play a significant role in producing at least some of these effects. Indirect action on $5HT_{1A}$ or $5HT_{2A}$ receptors and neuroendocrine responses such as increases in the hormones oxytocin, AVP, prolactin, and cortisol may also play a role in producing the unique effects of MDMA.

In addition to neuroendocrine and norepinephrine-mediated effects, MDMA may target similar binding sites on the SERT, as do already approved PTSD medications Paxil and Zoloft, which are both SSRIs. Similar to the SSRI Prozac, MDMA also inhibits MAO-A to extend presence of serotonin in the synaptic cleft [132]. Pre-treatment or co-administration studies of SSRIs with MDMA appear to attenuate or eliminate most subjective, physiological and immunological effects of MDMA due to competition for binding sites on the SERT which may prevent transporter-mediated serotonin release [91, 555-558]. Pre-treatment or co-administration with SSRIs attenuates serotonergic effects of MDMA on mood and perception, without influencing specific effects, such as nervousness or excitability [555]. Some researchers report that SSRIs attenuate MDMA-induced increases in heart rate and blood pressure [91, 556], while others report that SSRIs only attenuate elevated heart rate [558]. Additional effects of each SSRI beyond reuptake inhibition on production, release, and degradation of serotonin are likely responsible for variations between SSRI co-administration findings. All three studies of SSRI pre-treatment suggest that co-administration of SSRIs with MDMA is safe, but the combination prevents or significantly reduces the subjective effects of MDMA. The role of serotonin release on the potentially therapeutic effects of MDMA-assisted psychotherapy has yet to be investigated, however reduced feelings of sociability and closeness to others after paroxetine pre-

administration suggests that serotonin release is at least partially involved in prosocial effects that are thought to be therapeutically relevant [91]. These subjective effects are predominately mediated by direct or indirect action on $5HT_{2A}$ receptors [92, 233, 559], with at least one study concluding that the effects of MDMA upon positive mood are at least due in part to $5HT_{2A}$ receptor activation [92]. In contrast, the $5HT_{1A}$ receptor appears to be partially involved in producing the subjective effects of MDMA [92, 231-233]. Co-administration of the beta-blocker and $5HT_{1A}$ antagonist, pindolol, along with 1.6 mg/kg MDMA to 15 men attenuated self-reported "dreaminess" and pleasantly experienced derealization after MDMA without attenuating MDMA-related reduction in performance on a task requiring visual attention, and co-administration of pindolol failed to alter the acute effects of 75 mg MDMA on self-reported mood [92, 231].

Human MDMA studies suggest that norepinephrine release also contributes to the pharmacodynamic, physiological and psychological effects of MDMA [205, 208, 560, 561]. Tricyclic antidepressants, as well as many of the current antidepressant medications, are known to promote norepinephrine signaling, as does MDMA. Studies with the norepinephrine uptake inhibitor reboxetine, and the α_1-adrenergic receptor antagonist doxazosin, suggest that norepinephrine plays a role in the effects of MDMA on blood pressure and subjective effects of positive mood and excitement [206, 560], but not in "entactogenic" or "empathogenic" effects. Most of the psychostimulant-like and psychological effects of MDMA are blocked after administration of the dual selective Serotonin and norepinephrine uptake inhibitor (SNRI) duloxetine [208, 561]. There is evidence that norepinephrine and serotonin may play a role in the elevation in the neuroendocrine hormone copeptin, the C-terminal precursor of pre-pro-AVP, detected in women acutely after MDMA administration [561]. Some *in vitro* findings with human monoamine transporters expressed in cells indicate that MDMA displays a higher affinity for the NET than the serotonin or dopamine transporter, while still producing greater detectable release of serotonin versus norepinephrine, suggesting a role for both transmitter systems [127]. As the NET unexpectedly has a greater affinity than the DAT for dopamine, it preferentially clears dopamine in brain areas where there is a greater concentration of NET, such as the frontal cortex [562]. The relative affinities of MDMA for various monoamine reuptake transporters, and the affinity of the respective transporters for each neurotransmitter, can thus influence the selectivity of signaling pathways MDMA activates in a region-specific manner depending on transporter density and availability.

Some MDMA effects on human mood and anxiety may be attributed to dopamine release based on the finding that pretreatment with haloperidol, a dopamine receptor antagonist with partial selectivity for the D_2 receptor subtype, diminished MDMA-induced positive mood and increased anxiety [563]. However, the control group receiving haloperidol alone also experienced dysphoric mood, suggesting that this finding may overestimate the dopaminergic effects of MDMA. Studies comparing MDMA with the dopaminergic and adrenergic drug methylphenidate (Ritalin) suggest that dopamine release and inhibition of uptake play a minor role, if any, in producing the effects of MDMA [34]. Co-administration of MDMA with the potent dopamine reuptake inhibitor methylphenidate neither enhanced nor attenuated the effects of MDMA [530]. MDMA, but not methylphenidate, increased trust, openness, and closeness to others. Co-administration of MDMA with the dopamine reuptake inhibitor bupropion prolonged, but did not reduce subjective effects of MDMA, supporting that dopamine does not have a part in MDMA effects on mood [564].

MDMA produces a robust increase in the neurohormone oxytocin [29], a finding first seen in a naturalistic study that reported elevated levels of oxytocin in clubgoers with detectable blood MDMA levels when compared to clubgoers without detectable levels of MDMA [32], as described in Section 4.3.5 Neurobiological Effects. It is likely that all neuroendocrine changes are part of a signaling cascade downstream of monoamine release. Exogenous oxytocin increases trust and improves accuracy of emotion perception, and increased cortisol, in some

circumstances, may serve as a signal to seek affiliation or to increase positive mood [565-568]. However, studies comparing increases in empathy or prosocial effects of MDMA with intranasal oxytocin have failed to find indications that the two substances produce similar effects, with MDMA producing greater feelings of sociability and emotional empathy than oxytocin [63, 569]. Peripheral oxytocin has been suggested to be a reliable indicator of central oxytocin, but peripheral effects of oxytocin need to be ruled out when assessing central effects [570]. The potential significance of elevated oxytocin in producing changes in social cognition are discussed in Section 5.3.8.3 Social Effects, and include potentially therapeutic effects, such as increased feelings of closeness to others or greater ability to detect expressions of positive mood in others.

MDMA acutely increases cortisol, prolactin, and adrenocorticotropic hormone concentrations in a dose dependent manner [9, 12, 19, 30, 47, 118, 526, 572-574], whereas growth hormone levels are unchanged by up to 125 mg MDMA [9]. Increases in cortisol and prolactin peak at about 2 hours after MDMA administration [9, 47]. A second dose of 100 mg MDMA, given 4 hours after an initial 100 mg, produces a second increase in cortisol during an interval when cortisol levels are declining [575], and a dose of 100 mg MDMA, given 24 hours after an initial dose, stimulates a greater release of cortisol but not prolactin [118]. In a study of the effects of 0.5 and 1.5 mg/kg MDMA in eight people, there was a trend for increased levels of the hormone dehydroepiandrosterone (DHEA) after 0.5 mg/kg MDMA, and a significant increase after 1.5 mg/kg MDMA, with peak levels appearing 2 to 3 hours post-drug [12]. A crossover study comparing the effects of MDMA and methylphenidate found that MDMA increased serum cortisol while methylphenidate did not, and that neither drug altered testosterone levels [574]. These findings suggest a relationship between serotonin release and increased serum cortisol. Pre-treatment with the cortisol synthesis inhibitor metyrapone blocked MDMA-induced increase in cortisol levels in blood without preventing impaired performance on verbal memory tasks or altering the effects of MDMA on mood [572]. A study investigating the emotional effects of MDMA found no correlation between those changes and the MDMA-induced increases in oxytocin, cortisol, and prolactin [573].

The pharmacological basis for reported acute shifts in memory, including impaired visual recall and improved recall for life events, after MDMA administration remains undetermined. Initial findings suggest a relationship between MDMA and activation of temporal areas in the brain and response to positive memories, as well as increases in medial PFC and response to negative memories [36]. It is possible that elevation in cortisol could be tied to specific acute effects on mood or memory. Another study found MDMA-associated changes in inferior parietal lobule and acute impairment in working memory [576]. Animal studies have postulated a role of Ach release triggered by upstream serotonin and dopamine neurons in MDMA-induced shifts in memory described above. A human study revealed no difference in MDMA-induced memory changes following pretreatment with the cortisol synthesis inhibitor metyrapone or the α_7/nAchR7 receptor antagonist memantine, suggesting cortisol is not involved in these effects [572, 577]. It is unclear what contributions, if any, elevated neuroendocrine levels make to the subjective and memory effects of MDMA.

5.3 Safety of MDMA in Humans

Safety data from studies in controlled research settings show that MDMA produces sympathomimetic effects that include statistically significant, self-limiting increases in body temperature, heart rate, and blood pressure that are likely to be transient and well tolerated by healthy individuals [7, 9, 10, 12, 26, 41-47, 526, 527]. Risks posed by elevated blood pressure are addressed in clinical trials by excluding candidates with a history of cardiovascular or cerebrovascular disease or with pre-existing uncontrolled hypertension and by monitoring blood pressure and pulse during MDMA-assisted experimental sessions. Common reactions from

MDMA research studies are transient and diminish as drug effects wane during treatment sessions and over the next 24 hours. In studies conducted with and without sponsor support in controlled clinical settings, with 1180 individuals exposed to MDMA, there have been no published or reported unexpected drug-related SAEs to date, and expected SAEs have been rare and non-life threatening. One subject to date experienced an expected related SAE (increased premature ventricular extrasystoles in MP-8), and 10 unrelated SAEs after drug administration have been reported in MAPS-sponsored clinical trials.

All sponsor-supported data presented in this IB was collected through 01 October 2015. There are three completed (MP-1, MP-2, MP1-E2) and four ongoing Phase 2 studies of MDMA-assisted psychotherapy in people with PTSD that have completed enrollment (MP-8, MP-12, MP-4, MP-9). A Phase 2 study of MDMA-assisted therapy treating social anxiety in autistic adults (MAA-1) and another Phase 2 study of MDMA-assisted psychotherapy treating anxiety associated with life-threatening illness (MDA-1) are ongoing. Safety is addressed and closely monitored through several measures in these studies. Vital signs, concomitant medications, unexpected and expected AEs are collected in all studies. Suicidal ideation and behavior are formally measured with the Columbia Suicide Severity Rating Scale (C-SSRS) in all but MP-1 and MP-2. One completed (MP-1) and two ongoing studies (MP-12, MP-4) measure cognitive function before and after treatment. Psychological distress during psychotherapy sessions is assessed in all studies with the single-item Subjective Units of Distress (SUD) scale.

Partial safety data from the Phase 1 study MT-1 in healthy volunteers is not presented in the current report since data remains blinded. There have been no severe or serious AEs during the study, and there were no clinically significant changes in vital signs. No medical intervention has been required during this study to date.

Physiological effects of MDMA-assisted psychotherapy in sponsored studies are similar to those reported in studies conducted outside of sponsor support, including elevated blood pressure, body temperature, and heart rate. The following common reactions are found in published literature and are collected in the sponsor's Phase 2 clinical trials: anxiety, depressed mood, insomnia, obsessive rumination, restlessness, irritability, headache, disturbance in attention, dizziness, parasthesia, judgment impaired, hypersomnia, nausea, diarrhea, fatigue, asthenia, feeling cold, muscle tightness, decreased appetite, hyperhidrosis, disturbed gait, dry mouth, thirst, sensation of heaviness, somnolence, and nystagmus. These common reactions are transient and diminish as the drug is metabolized during treatment sessions and excreted over the next 24 hours, with the majority of reactions resolving within several days and up to 1 week after dosing. Among spontaneous reports of reactions to MDMA, muscle tightness (jaw), anxiety, decreased appetite, headache, and fatigue were most commonly reported acutely during MDMA-assisted psychotherapy. During the week following treatment, the most frequently reported reactions were anxiety, fatigue, insomnia, depressed mood, and hypersomnia. The half-life of MDMA doses used in these studies is 8 to 9 hours and the majority of AEs have been transient, resolving within 2 to 3 days after MDMA has been metabolized and excreted. Severe anxiety, insomnia, fatigue, nausea, muscle tightness, and depressed mood are commonly reported in PTSD studies supported by the sponsor. These reactions also overlap with symptoms of pre-existing conditions in medical history associated with PTSD (depression, somatic symptoms, insomnia, anxiety), which may influence the reaction frequency observed during clinical trials of MDMA-assisted psychotherapy.

5.3.1 Reproductive and Developmental

All research studies with MDMA, with and without sponsor support, require measures to limit pregnancy risk prior to receiving each dose of MDMA. Women of childbearing potential must

use an effective method of birth control to be enrolled in sponsor-supported studies, and pregnancy tests must be negative prior to each experimental session. There is no information on reproductive and developmental risks reported as there have been no pregnancies in these studies. See Section 4.4.5 Reproductive and Developmental Toxicity for information gathered on reproductive and developmental risks in Ecstasy users.

5.3.2 Immunological Effects

Various groups have studied immunological effects of MDMA in laboratory settings, with none found to be clinically significant from a safety standpoint. Studies in men conducted by researchers in Spain have found 100 mg MDMA to have immunosuppressive and anti-inflammatory effects [117, 557, 575, 578, 579]. Findings included a decline in CD4 cells, smaller CD4/CD8 ratio, attenuated lymphocyte proliferation in response to mitogen, and an increase in natural killer (NK) cells, with effects diminishing but still detectable 24 hours after drug administration. These researchers also found that MDMA decreased production of pro-inflammatory cytokines, including IL-6, IL-1β, TNF-α, and INF-γ, and increased production of anti-inflammatory cytokines, including IL-10 and TGF-ß. Generally, MDMA appeared to decrease the concentration of Th1 cytokines, including IL-2, and increase the amount of Th2 cytokines, including IL-4, measured in blood. Changes of similar magnitude and duration have been previously noted after ingestion of other psychoactive agents, such as alcohol or cocaine [117, 579]. Due to their limited duration, these changes are not likely to have clinical significance beyond several days of possible increased risk of viral upper respiratory infection or similar illness. Interestingly, meta-analysis and meta-regression of 20 studies investigating inflammatory markers in PTSD found an association with increased IL-6, IL-1β, TNF-α, and INF-γ, consistent with chronic low-grade inflammation [184], and any effects of MDMA on these immune markers remains to be tested.

Immunological changes seen after an initial dose of MDMA are enhanced by a second dose of identical size given 4 hours after the first dose [575, 580]. A second dose of identical size given 24 hours after the first dose produced the same immunological effects over the same time course, but with greater intensity than after the first dose [575]. Given this data, it is possible that administering a smaller supplemental dose 1.5 to 2.5 hours after the first dose will slightly enhance the immunological effects set in motion by the initial dose of MDMA. Previous Phase 1 studies mentioned above have not reported any indication of increased risk of illness occurring after MDMA administration.

5.3.3 Thermoregulatory Effects

In the first Phase 1 safety study funded by the sponsor, MDMA was found to cause a significant increase in body temperature in some healthy volunteers [47]. However, these increases were found to be transient and tolerable in a controlled clinical setting. Doses between 1.5 and 2 mg/kg produced only a slight elevation in body temperature that was not clinically significant [10, 556, 559] and this elevation was unaffected by ambient temperature [195]. Studies in MDMA-experienced volunteers given 2 mg/kg MDMA produced slight but statistically significant increases in core body temperature, at mean elevation of 0.6°C [195]. The same study found that ambient temperatures did not affect elevation in core temperature after administration of MDMA, which increased metabolic rate. A supplemental dose twice as large as the initial dose of MDMA elevates body temperature, but not beyond what would be expected after the cumulative dose [328]. While MDMA did not increase or decrease perspiration overall in this study, it was associated with a higher core temperature when perspiration began. Ambient temperature neither attenuated nor amplified the subjective effects of MDMA, with people reporting similar drug effects in warm and cool environments. As expected, people felt warm when the room was warm

and cold when the ambient temperature was cool, and MDMA did not distort perceptions of warmth or cold in either case. Unlike rodents given MDMA at higher mg/kg doses, humans do not exhibit reduced temperature when MDMA is given in a cold environment, and they do not exhibit significant hyperthermia in a warm environment. When compared with placebo, findings from 74 subjects given MDMA found that men exhibited a greater elevation in body temperature than women when given the dose of MDMA in mg/kg [10]. Subsequent studies have not confirmed this gender difference [26], and a report in a sample of 17 men and women reported higher oral temperatures in women [552]. A review of clinical placebo-controlled laboratory studies conducted without sponsor support found that route of measurement has an effect on variability in body temperature findings, with oral and tympanic, but not axillary, temperatures frequently rising above 38°C into moderate hyperthermia ranges at 125 mg MDMA [581]. Thermogenic effects of MDMA are distinct from malignant hyperthermia and are mediated by noradrenergic signaling, which contributes to peripheral effects of MDMA by affecting cutaneous vasoconstriction of blood flow and stimulation of heat production, and are attenuated by norepinephrine blocking drugs [582]. It is notable that subjects in studies in a clinical setting have not engaged in vigorous exercise and have remained either sitting or lying down throughout duration of drug effects. It may be the case that heat dissipation impaired by a hot environment, heat generation increased by exertion, interactions of serotonergic drugs, and potential disturbance of central heat regulation mechanisms contribute to the occurrence of hyperprexia (body temperatures >41°C) in people ingesting Ecstasy in uncontrolled settings. However, one of four naturalistic studies reported that Ecstasy users had a statistically significant increase in body temperature [583], while three others failed to find significant differences in Ecstasy-user body temperature at a club [584-586].

In all sponsor-supported studies to date, oral body temperature readings were taken at baseline, then every 60 to 90 minutes, with some differences in collection methods across studies. Peak values during each experimental session are ascertainable for all studies. Across studies, the final value was either at a relatively set time (MP-8, MP-12, MP1-E2) or as the final reading with time point varying (MP-1). MP-1 and MP-2 reported two pre-drug values (15 minutes and 5 minutes before dosing) and these were averaged. Average post-drug values serve as the final value for MP-2. If body temperature rose 1°C above the pre-drug reading, each duration above the pre-determined cut-off was collected in MP-2, MP-8, MP-12, MP-9, MP-4, MP1-E2, MAA-1, and MDA-1. Clinical signs and symptoms were monitored and more frequent readings were collected in cases where readings were above cut-off. Data presented below is final for completed studies and preliminary for ongoing studies.

Table 3: Pre-Drug, Peak, and Final Body Temperature During Experimental Sessions with Placebo or any MDMA Dose in MAPS-Sponsored Studies Across Populations

Dose	Subjects (Observation)	Pre-drug Min/Max Mean (SD)	Peak Min/Max Mean (SD)	Final Min/Max Mean (SD)	Subjects with BT Above Cut-off (Observations)
0 mg	14 (27)	35.1/37.2 36.4 (0.5)	36.4/37.6 36.9 (0.3)	35.9/37.5 36.6 (0.3)	2 (2)
25 mg	8 (18)	35.8/37.1 36.5 (0.3)	36.0/38.5 37.2 (0.8)	36.0/38.0 36.9 (0.7)	4 (6)
30 mg	7 (15)	35.3/36.9 36.3 (0.5)	36.4/37.9 37.0 (0.4)	35.7/37.2 36.5 (0.4)	4 (6)
40 mg	7 (12)	35.6/37.2 36.4 (0.5)	36.6/37.6 37.1 (0.3)	36.5/37.6 37.0 (0.4)	3 (3)
75 mg	13 (20)	35.9/37.8 36.6 (0.4)	36.3/37.8 37.2 (0.5)	36.1/37.6 36.8 (0.4)	2 (2)
100 mg	25 (42)	33.9/37.5 36.1 (0.8)	35.5/37.9 37.0 (0.47)	34.8/38.0 36.7 (0.7)	8 (12)
125 mg	95 (232) [A]	34.3/37.7 36.5 (0.5) [B]	36.0/38.7 37.3 (0.5)	35.2/38.4 36.9 (0.5)	50 (83)
150 mg	3 (4)	36.6/36.7 36.7 (0.1)	37.3/38.2 37.7 (0.4)	36.8/37.7 37.3 (0.4)	1 (2)

[A] One endpoint temperature was excluded pending queries, and two listings are unavailable for endpoint temperature.
[B] One subject given 125 mg did not have pre-dose values for any vital sign, but post-drug values were collected.

Based on the literature, MDMA is expected to produce elevations in body temperature with possible influence of ambient temperature. Body temperature above 1°C above baseline was detected in 33% (114 of 343) of experimental sessions where MDMA was administered at any dose, and in 46% (72 of 157) of subjects in sponsor-supported trials. Maximum body temperature observed to date was 38.7°C in one MP-2 subject lasting 3 hours, where 125 mg MDMA was administered as the initial dose. This subject had no risk factors reported in medical history and temperature elevation was not clinically significant. Maximum duration above 1°C elevation was 9.2 hours in one MP-9 subject where 125 mg MDMA was administered as the initial dose. This subject experienced a maximum of 38.0°C temperature, which dropped to 37.6°C at final reading. By contrast, elevation of body temperature above 1°C was observed in 7% (2 of 27) of experimental sessions and in 14% (2 of 14) of subjects receiving inactive placebo. Perspiration was reported in 21% to 25% of experimental sessions with active dose MDMA, and was generally mild. Adjustments were made to the ambient temperature and to air circulation in the room, but no subjects required medical intervention to decrease body temperature, and values returned to baseline as drug effects waned. In conclusion, controlled setting for treatments with MDMA-assisted psychotherapy are optimized with the capacity to control ambient temperature for subject comfort, though there is no evidence that this will significantly influence or is needed for control of core body temperature.

5.3.4 Cardiovascular Effects

MDMA produces sympathomimetic effects that include elevation in blood pressure and heart rate, first recorded by Downing [44] and replicated by other research teams in the U.S. and Europe [9, 10, 45]. Subsequent trials confirmed that MDMA produced significant increases in heart rate and blood pressure that were likely to be well tolerated by healthy individuals [7, 12, 26, 46]. Most people do not experience elevations that are greater than those seen after moderate

exercise. MDMA has also been found to decrease respiratory sinus arrhythmia, the natural variation in heart rate over the course of each respiratory cycle [587]. Cardiovascular effects of MDMA first appear 30 to 45 minutes after administration [44] and peak between 1 and 2 hours post-drug [11, 45], with effects waning 3 to 5 hours after drug administration. Men given the same mg/kg dose of MDMA as women exhibited a significantly greater elevation in blood pressure and heart rate in a study summarizing and pooling data from a series of human MDMA studies [10]. These studies did not report any discomfort or increased distress accompanying cardiovascular effects.

Elevation in blood pressure above 140/90 occurred in approximately 5% of research subjects receiving a single dose of at least 100 mg of MDMA in Phase 1 research studies [9, 13]. Peiro and colleagues observed elevation in blood pressure above 150/90 as well in all 10 subjects given 50 mg followed 2 hours later by 100 mg MDMA [328]. When compared with 100 mg MDMA and placebo given 4 hours apart, two doses of 100 mg 4 hours apart significantly elevated SBP, while other physiological were not significantly elevated beyond values seen after a single dose. These studies used different dosing regimens than the one used in sponsor-supported studies, which employ an optional supplemental half dose. None of these individuals needed clinical intervention and blood pressure returned to normal as drug effects waned [9, 13, 328].

Greater elevations in blood pressure are seen in individuals with a specific COMT genotype (Val158/Met genotype), and greater elevations in blood pressure and heart rate are seen in individuals with a specific SERT (l/* 5-HTTLPR) genotype [552]. However, the observed increases are not so severe as to suggest contraindication for these genotypes. The α_1- and beta-adrenergic receptor antagonist carvedilol is capable of reducing MDMA-induced elevations in blood pressure, heart rate, and body temperature when administered 1 hour before MDMA without affecting the subjective effects of MDMA, indicating the norepinephrine release is primarily responsible for cardiovascular effects of MDMA [207]. Other concomitant antihypertensive medications either alter some of the effects of MDMA [588] or do not significantly reduce MDMA-induced blood pressure elevation [205].

Norepinephrine release induced by MDMA leads to indirect activation of the AVP system, stimulating secretion of copeptin (CTproAVP), a 39-aminoacid glycopeptide that is a C-terminal part of the precursor pre-proAVP. CTproAVP is secreted into circulation from the posterior pituitary gland in equimolar amounts with AVP. CTproAVP directly reflects AVP concentration and can be used as a surrogate biomarker of AVP secretion. In many studies CTproAVP behavior represents changes in plasma osmolality, stress and various disease states (diabetes, SIADH, heart failure, renal disorders), and is an indicator of osmoregulatory function in the body [365]. Heart failure is commonly associated with hyponatremia, and is also characterized by increased concentrations of basal AVP and CTproAVP [375]. Intra-cardiac pressures, intra-arterial pressures, angiotensin II, pain, and adrenergic (α_2) central nervous stimuli can also influence AVP secretion [364]. Increased CTproAVP concentration is described in several studies as a strong predictor of mortality in patients with chronic heart failure and acute heart failure. [365]. Taken together, the AVP system appears to be the main connection between MDMA and cardiovascular risk as well as hyponatremia.

In all sponsor-supported studies to date, blood pressure readings were taken at baseline, with study-specific differences in data collection times post-drug. Peak values during each experimental session are ascertainable for all studies. The final or endpoint was recorded as the final value, either at a relatively set time (MP-8, MP-12, MP1-E2) or as the final value available, or with timepoint varying (MP-1). MP-1 and MP-2 reported two pre-drug values (15 minutes and 5 minutes before dosing) and these were averaged, whereas all other studies reported single time point pre-drug. Average post-drug values serve as the final value for MP-2. If SBP rose above

160 mmHg or if diastolic blood pressure (DBP) rose above 110 mmHg, each duration above this pre-determined cut-off for more frequent measurement was collected in MP-8, MP-12, MP-9, MP-4, and MP1-E2. In MAA-1, if SBP rose above 180 mmHg or if DBP rose above 110 mmHg, each duration above the pre-determined cut-off was collected. If SBP rose above 180 mmHg and if DBP rose above 120 mmHg, each duration above the pre-determined cut-off is collected in MDA-1. MP-2 criteria for cut-off was exceeding both 160/110 mmHg. Clinical signs and symptoms were monitored and more frequent readings were collected in cases where readings were above cut-off. Data presented below is final for completed studies and preliminary for ongoing studies.

Table 4: Pre-drug, Peak, and Final Systolic Blood Pressure During Experimental Sessions with Placebo or any MDMA Dose in MAPS-Sponsored Studies Across Populations

Dose	Subjects (Observations)	Pre-drug Min/Max Mean (SD)	Peak Min/Max Mean (SD)	Final Min/Max Mean (SD)	Subjects with SBP Above Cut-off (Observations)
0 mg	14 (27)	90/139 118.8 (13.0)	102/159 134.5 (16.3)	83/138 115.2 (13.5)	0
25 mg	8 (18)	110/130 119.9 (5.2)	117/147 133.6 (8.1)	107 /146 119.8 (11.3)	0
30 mg	7 (15)	94/134 114.2 (12.1)	110/155 132.3 (14.0)	98/140 118.5 (11.6)	0
40 mg	7 (12)	100/154 125.9 (14.1)	112/168 137.1 (17.7)	107/148 124.3 (12.1)	2 (2)
75 mg	13 (20)	101/145 124.2 (11.3)	116/179 144.7 (17.5)	107/156 127.8 (12.8)	3 (4)
100 mg	25 (42)	92/155 118.0 (13.4)	100/193 138.2 (22.8)	86/148 119.1 (14.6)	6 (8)
125 mg	94 (232) [A]	95/177 125.3 (14.9)	114/200 152.8 (17.4)	77/170 126.2 (15.7)	43 (78)
150 mg	3 (4)	102/146 128.0 (21.0)	128/185 156.5 (23.3)	117/161 141.0 (19.0)	1 (1)

[A] One subject given 125 mg did not have pre-dose values for any vital sign, but post-drug values were collected.

As described above, MDMA is expected to produce statistically significant but transient, self-limited increases in blood pressure. The supplemental half dose, when administered 1.5 to 2.5 hours after the initial dose, may cause further SBP increases above those resulting from the initial dose of MDMA. In one study (MP-1), 9 of 23 subjects received the supplemental dose, with four in the 125 mg MDMA group, in all subsequent studies, most of the subjects received the optional supplemental dose. A comparison of subjects receiving the supplemental dose to those who only received the initial dose in MP-1 indicate that the supplemental dose did not cause further elevation in blood pressure and heart rate beyond the initial dose, although the sample was underpowered to detect a small effect. Maximum SBP observed to date was 200 mmHg in a single MP-2 subject, lasting 5 hours, where 125 mg MDMA was administered as the initial dose. This subject had a medical history of controlled hypertension, and the traumatic event that caused PTSD was medical malpractice, with a secondary diagnosis of white coat hypertension. This subject was only enrolled after 24-hour monitoring of blood pressure at baseline to confirm this diagnosis. SBP above cut-off was detected in 27% (93 of 343) of experimental sessions where MDMA was administered, and in 35% (55 of 157) of subjects receiving MDMA in sponsor-supported trials. Maximum duration above SBP cut-off was 6 hours in two separate subjects with respective peak values of 172 and 174, where 125 mg MDMA was administered as the initial dose. Doses of 40 mg MDMA and greater were associated with elevations above cut-off. SBP

was elevated in 46% (43 of 94) of subjects and 34% (78 of 232) of experimental sessions where the 125 mg dose was administered. This was not observed in any of the sessions where inactive placebo or 25 mg to 30 mg MDMA was administered, supporting a dose dependent effect of MDMA on blood pressure. Despite elevations in SBP, no clinical signs or symptoms of hypertension were observed. In all cases, final values returned to pre-drug levels with no clinical intervention required. No clinically significant AEs were reported based on elevations in blood pressure.

Table 5: Pre-drug, Peak, and Final Systolic Blood Pressure During Experimental Sessions in Controlled Hypertension Subjects in MAPS-Sponsored PTSD Study MP-8

Dose	Subjects (Observations)	Pre-drug Min/Max Mean (SD)	Peak Min/Max Mean (SD)	Final Min/Max Mean (SD)	Subjects with SBP Above Cut-off (Observations)
30 mg	1 (1)	125/125 125	131/131 131	124/124 124	0
75 mg	1 (2) [A]	133/145 139.0 (8.5)	170/179 174.5 (6.4)	147/147 147 (0)	1 (2)
100 mg	1 (3) [A]	122/140 132.0 (9.2)	179/193 185.0 (7.2)	133/147 140.7 (7.1)	1 (3)
125 mg	2 (6)	124/171 137.2 (18.8)	144/177 160.0 (14.0)	126/158 134.3 (13.9)	2 (3)

[A] The same subject received these doses of MDMA in different stages of the study.

Candidates with hypertension are excluded from participation in all but one of sponsor-supported studies to limit cardiovascular risk during treatments. In MP-8, four subjects with hypertension controlled by medications were permitted to enroll after completion of carotid ultrasound and nuclear exercise test (per protocol) in addition to usual medical screening for the study. Results are depicted above. One subject dropped out after receiving a single experimental session with 30 mg MDMA and did not experience SBP above cut-off. SBP above cut-off was detected in 75% (3 of 4) of subjects and 67% (8 of 12) of experimental sessions where MDMA was administered to this sub-group. The prevalence of these elevations appears higher in this sub-group than the overall sample, although the prevalence could decrease in a larger group. Pre-drug SBP was typically higher in this sub-group, and peak SBP of these subjects was typically at the upper end of the range of the overall sample. Final SBP readings remained 11 to 14 mmHg higher on average than pre-drug SBP readings in the subject who received 75 mg of MDMA in two blinded experimental sessions and 100 mg in three open-label crossover experimental sessions. However, two subjects receiving 125 mg MDMA had final readings that returned to pre-drug values, suggesting this could be an individual case with a medical history of both hypertension and hyperlipidemia. None of the subjects with controlled hypertension experienced AEs of the cardiovascular system.

Table 6: Pre-drug, Peak, and Final Diastolic Blood Pressure During Experimental Sessions with Placebo or any MDMA Dose in MAPS-Sponsored Studies Across Populations

Dose	Subjects (Observations)	Pre-drug Min/Max Mean (SD)	Peak Min/Max Mean (SD)	Final Min/Max Mean (SD)	Subjects with DBP Above Cut-off (Observations)
0 mg	14 (27)	56.5/94 74.6 (9.1)	65/103 84.5 (10.2)	48/100 70.85 (10.9)	0
25 mg	8 (18)	59/84 73.9 (6.2)	76/92 83.2 (5.0)	63/81 72.33 (5.3)	0
30 mg	7 (15)	60/87 74.3 (8.4)	75/99 85.5 (7.5)	68/91 76.7 (6.3)	0
40 mg	7 (12)	69/95 82.7 (8.3)	72/135 90.2 (16.7)	68/96 80.3 (9.4)	1 (1)
75 mg	13 (20)	56/95 75.1 (10.1)	73/118 88.6 (11.2)	59/100 76.1 (10.2)	2 (3)
100 mg	25 (42)	52/93 74.1 (10.6)	62/125 86.9 (15.2)	58/99 74.6 (10.0)	2 (4)
125 mg	95 (232)	54/120 79.1 (9.9)	69/126 92.5 (9.6)	53/104 78.2 (9.8)	6 (8)
150 mg	3 (4)	60/90 78.8 (14.0)	78/108 95.3 (12.6)	67/96 82.0 (12.2)	0

DBP exceeded cut-off in only 5% (16 of 343) of experimental sessions and in 7% (11 of 157) of subjects at any MDMA dose. Maximum duration above DBP cut-off was 5 hours in MP-2 subject 112, with a peak of 114, where 125 mg MDMA was administered as the initial dose. This subject had a high pre-drug DBP reading of 96, and also experienced the highest SBP in sponsor-supported studies to date, as described above. In contrast, 14 subjects participating in 27 experimental sessions with placebo did not experience any elevations in blood pressure above cut-off. In experimental sessions with 25 mg to 30 mg MDMA, elevations in blood pressure above cut-off were not observed either, supporting a dose-dependent effect of MDMA on blood pressure. In all cases, final values returned to pre-drug levels with no clinical intervention required. No clinically significant AEs were reported based on elevations in blood pressure.

Table 7: Pre-drug, Peak, and Final Diastolic Blood Pressure During Experimental Sessions in Controlled Hypertension Subjects in MAPS-Sponsored PTSD Study MP-8

Dose	Subjects (Observations)	Pre-drug Min/Max Mean (SD)	Peak Min/Max Mean (SD)	Final Min/Max Mean (SD)	Subjects with DBP Above Cut-off (Observations)
30 mg	1 (1)	85/85 85	86/86 86	77/77 77	0
75 mg	1 (2) [A]	89/95 92 (4.2)	113/118 115.5 (1.8)	91/100 95.5 (6.4)	1 (2)
100 mg	1 (3) [A]	77/91 83.7 (7.0)	121/125 123.0 (2.0)	82/99 90.7 (8.5)	1 (3)
125 mg	2 (6)	82/101 87.8 (8.4)	91/110 98.5 (7.5)	84/93 86.0 (7.5)	0 (0)

[A] The same subject received these doses of MDMA in different stages of the study.

DBP above cut-off was detected in one of four subjects (25%) and five of 12 (41%) of experimental sessions where MDMA was administered at any dose to subjects with controlled

hypertension. All five cases were in the same subject, who received both 75 mg and 100 mg MDMA and is described above. Of all observations of DBP above cut-off across studies and populations, 31% (5 of 16) of experimental sessions were attributed to this subject, suggesting that pre-existing risk factors are associated with elevations in blood pressure. However, this subject did not experience any AEs of the cardiovascular system and DBP resolved back to baseline at final reading in all cases.

In all sponsor-supported studies to date, heart rate readings were taken at baseline, with study-specific differences in data collection times post-drug. Peak values during each experimental session are ascertainable for all studies. The final or endpoint value was recorded as the final value, either at a relatively set time (MP-8, MP-12, MP1-E2) or as the final value available, with time point varying (MP-1). MP-1 and MP-2 reported two pre-drug values (15 minutes and 5 minutes before dosing) and these were averaged, whereas all other studies reported single time point pre-drug. Average post-drug values serve as the final value for MP-2. If heart rate rose above 110 bpm, each duration above the pre-determined cut-off was collected in MP-8, MP-12, MP-9, MP-4, and MP1-E2. Duration of pulse above cut-off was not collected in MP-2. Clinical signs and symptoms were monitored and more frequent readings were collected in cases where readings were above cut-off.

Table 8: Pre-drug, Peak, and Final Heart Rate During Experimental Sessions with Placebo or any MDMA Dose in MAPS-Sponsored Studies Across Populations

Dose	Subjects (Observations)	Pre-drug Min/Max Mean (SD)	Peak Min/Max Mean (SD)	Final Min/Max Mean (SD)	Subjects with HR Above Cut-off (Observations)
0 mg	14 (27)	45/111 69.9 (16.3)	54/108 81.2 (14.0)	45/92 70.7 (11.8)	0
25 mg	8 (18)	45/94 69.9 (13.7)	50/124 84.1 (19.8)	51/90 71.7 (12.3)	0
30 mg	7 (15)	45/91 67.1 (14.6)	54/102 81.1 (16.0)	50/89 72.7 (13.0)	0
40 mg	7 (12)	66/110 80.8 (14.3)	69/126 90.7 (15.6)	56/120 83.4 (18.7)	1(1)
75 mg	13 (20)	54/85 72.2 (8.8)	58/123 93.2 (16.9)	57/102 80.9 (13.2)	2 (4)
100 mg	25 (42)	42/114 68.5 (13.5)	63/139 96.6 (17.5)	55/103 78.6 (11.7)	6 (10)
125 mg [A]	95 (232)	36/122 74.9 (13.9)	63/160 104.7 (18.07)	47/135 85.0 (15.1)	51 (90)
150 mg	3 (4)	69/96 79.3 (11.7)	83/125 105.8 (17.3)	74/112 94.5 (15.8)	1 (1)

[A] A single value was not recorded for final readings in subjects receiving 125 mg.

Heart rate elevation above the pre-determined cut-off was detected in 31% (106 of 343) experimental sessions at any MDMA dose, and in 39% (61 of 157) of subjects receiving MDMA. Maximum peak pulse was 160 bpm reported in a subject who received 125 mg MDMA, with pulse remaining above cut-off for 60 minutes. At final reading 3.75 hours later, pulse had returned to below cut-off levels of 93 bpm. The maximum duration above cut-off was 9.5 hours in MP-1 subject 218, were 125 mg MDMA was administered as the initial dose. This subject experienced a peak pulse of 121, which dropped at final reading to 119. Subject 218 had no cardiovascular risk factors in medical history. In cases where blood pressure or heart rate was above cut-off, vitals were monitored more frequently. No subjects receiving MDMA in sponsor-

supported clinical trials have required any clinical interventions for elevated blood pressure or pulse, as all values returned to normal as the effects of MDMA diminished.

The values presented above suggest a dose-dependent action on SBP and heart rate, which is supported in the literature in healthy controls [7, 9, 12, 589]. Peak body temperature and values above cut-off do not appear to be strongly related to MDMA dose, with values above cut-off occurring at every dose, including inactive placebo. While peak DBP is higher after doses of 100 mg or greater, very few reports of DBP elevated above cut-off occurred during MDMA administration, suggesting that this is a less common response than elevated SBP or pulse.

On average, cardiovascular vital signs returned to baseline or near-baseline values by final reading, which is the case across all doses of MDMA. Blood pressure and pulse readings were used to assess AEs described in Section 5.3.9, but they were not the source of the event. There are far fewer observations of elevated DBP than SBP. None of the subjects have required medical intervention after elevations above cut-off, and the elevations were self-limiting and none were clinically significant.

Vital signs for subjects in the study of social anxiety in people on the autism spectrum appear to be similar to those made in people with PTSD receiving equivalent doses of MDMA. Only one measurement rose above pre-determined cut-off values in this sample (pulse above 110, for approximately 1 hour). Comparatively small sample size and use of somewhat lower doses may explain this difference. Differences in age may be involved, with the average age of MAA-1 subjects examined in the IB being 30.65, while mean age in PTSD studies is in the early to mid-40s [43, 590]. No subjects in this study have required any medical interventions.

5.3.5 Osmoregulatory Effects

The neuroendocrine hormone copeptin, described in Section 5.3.4 Cardiovascular Effects as correlating with AVP in blood, was detected in women acutely after 125 mg MDMA administration [561], and this finding was reproduced in another study reporting that 47.5 mg MDMA caused an acute rise in AVP and a small decrease in plasma sodium, at a time of day when it would not be expected to change, in an all-male sample. [251]. The sponsor-supported study MAA-1 includes AVP assessments in peripheral plasma samples before, during, and after MDMA-assisted psychotherapy. This study is ongoing and results are pending analysis.

5.3.6 Hepatic Effects

The first two sponsor-supported Phase 2 studies (MP-1, MP-2) assessed liver function after completion of two or three blinded experimental sessions. Values that differ from established, age-appropriate norms were evaluated for clinical significance. Laboratory assessments of liver function were not conducted after experimental sessions in subsequent sponsor-supported studies and no AEs related to liver function have been reported in these studies.

Table 9: List of All Clinically Significant Changes in Laboratory Values in Two Subjects from MP-2

Laboratory Value	Abnormal Test Value	Value at Baseline	Normal Value/Range	Condition
Bilirubin	2.8	2.2	<2.5 mg/dL	125 mg
ESR	32	2.4	<10 mm	125 mg

Two subjects in the MP-2 study reported two clinically significant abnormalities. One was an elevation in bilirubin in a subject with a family history of elevated bilirubin (probably Gilbert's

syndrome), with the elevation occurring after open-label treatment with 125 mg to 150 mg initial dose of MDMA. Bilirubin levels can be indicative of decreased liver function, but the liver enzymes were normal at that time, supporting the interpretation that the bilirubin levels were slightly elevated compared to baseline due to hereditary factors. The other abnormal laboratory value, an elevation in erythrocyte sedimentation rate (ESR), a marker of inflammation, occurred in a subject with a medical history of breast cancer. This value was recorded 3 months after the last administration of MDMA as an AE unrelated to the study drug.

Table 10: Average ALT Values at Baseline and 2-Month Follow-up After Two Experimental Sessions in Subjects from MP-1

Timepoint	Placebo	125 mg
Baseline	25.6 (13.4) N=8	22.75 (12.89) N=12 [A]
Primary Endpoint After Two Experimental Sessions	26.4 (13.5) N=8	19.7 (12.7) N=13

[A] ALT value for one subject not recorded at baseline.

No clinically significant changes in liver function occurred in MP-1. Values for laboratory tests were within the normal range in MP-1. An independent t-test of differences between baseline and 2-month follow-up alanine aminotransferase (ALT) in placebo and MDMA subjects in MP-1 detected a trend toward a change that implied improved liver function that failed to reach statistical significance. Phase 1 studies conducted outside of sponsor support involving administration of MDMA to healthy volunteers have not published any results of liver function after MDMA administration. There have been no reported adverse effects on the liver from these studies.

5.3.7 Neurobiological Effects

Early investigations in healthy volunteers used PET to detect changes of brain activity after MDMA and found decreased left amygdalar activity and increased frontal activity [28]. PET brain scans 75 minutes after administration of 1.7 mg/kg MDMA found increased regional cerebral blood flow (rCBF) in ventromedial prefrontal, inferior temporal, and cerebellar areas and decreased rCBF in the left amygdala [28]. In a different study, arterial spin labeling has also found decreased cerebral blood flow (CBF) in the right amygdala and hippocampus after MDMA administration [27]. The decreased CBF correlated with drug intensity ratings after 100 mg MDMA. Blood oxygen level dependent (BOLD) MRI scans of resting-state functional connectivity in the same sample detected complementary decreases in medial PFC-hippocampal coupling and increases in right amygdala-hippocampal coupling, although the relationship did not achieve statistical significance [27]. Decreased activity in the amygdala may be indicative of reduced reactions to potential threats [591]. MDMA (100 mg) increased subjective ratings of positive mood in response to positive memories and decreased negative response to negative memories. Attenuated activity in the left anterior temporal area was detected after MDMA during worst memory recall. [36].

During a task that required keeping a visual target cue in mind, visual attention, and response inhibition, brain imaging detected changes in parietal activity after 75 mg MDMA compared with placebo [576]. MDMA increased activity in frontal areas and decreased activity in occipital sites as measured via functional MRI (fMRI) [592]. Reduced resting-state cerebral blood flow in right amygdala and hippocampus after MDMA was associated with greater intensity of self-reported subjective effects [27]. Subjects given MDMA exhibited similar brain activity when reading or encoding a word list, suggesting that they were investing similar effort into both tasks. Ten Ecstasy user subjects receiving a minimum of two doses of 1 to 1.25 mg/kg or 2.25 to 2.5 mg/kg

MDMA exhibited signal decreases in bilateral visual cortex, caudate, superior parietal, and dorsolateral frontal regions 10 to 21 days later, with increased rCBF measured in two subjects at a later time point. However, a comparison between heavy Ecstasy users and non-user controls failed to find differences in baseline rCBF [593], and a report assessing changes before and after initial Ecstasy use found increased rCBF in only one area of the prefrontal cortex [266], suggesting that the changes seen by Chang and colleagues are a transient effect. EEG recorded 2 hours after MDMA administration showed the following changes in EEG activity: overall increase in beta activity, reduction in alpha activity, localized decreases in alpha and delta in frontal areas, and increased frontotemporal beta signal [594]. The authors reported the EEG patterns after MDMA were similar to those seen with serotonergic and noradrenergic drugs, as well as, but to a lesser extent, dopaminergic drugs.

The sponsor is undertaking a small BOLD fMRI pilot study investigating brain activity in people with PTSD before and after MDMA-assisted psychotherapy, as a substudy of a sample of people enrolled in MP-8. Brain activity is recorded while the subject is listening to a neutral and a personalized trauma-related scripts. Preliminary findings are pending analysis.

Monoamine neurotransmitters are known to modulate sleep architecture and alertness. In a trial with 2 mg/kg MDMA given 6 hours prior to preparing for sleep, MDMA was found to increase Stage 1 sleep and produce fewer periods of REM sleep without increasing daytime sleepiness [281]. Sample size of seven in this study suggests that findings should be accepted with caution. PTSD patients suffer from poor sleep quality. Disturbed REM or non-REM sleep is a contributing factor to maladaptive stress and trauma responses and chronic sleep disruption associated with nightmares caused by PTSD may be an indicator of efficacy of PTSD treatments. The sponsor is collecting secondary outcomes in PTSD studies with the Pittsburg Sleep Quality Index. Results are pending analysis from ongoing studies.

5.3.8 Neuropsychological Effects

MDMA alters mood, perception, and cognition in healthy volunteers, with effects on emotion and social behavior. At doses of at least 1 mg/kg (approximately 70 mg) and higher, active doses of MDMA alter mood and cognition, and produce slight alterations in perception [10, 529]. Acute subjective effects peak 90 to 120 minutes after oral administration and return to pre-drug levels 3 to 6 hours later [13, 595, 596]. Sub-acute effects assessed in controlled and naturalistic studies may occur 1 to 3 days after drug administration, but are no longer apparent seven to 14 days later [12, 324, 597]. Most of the therapeutic effects of MDMA are thought to result from changes in affect, cognition, and social interaction.

At least four research teams published relevant findings in studies of healthy volunteers during 2013 and 2014, examining the effects of MDMA on social cognition with several experimental paradigms assessing brain activity during episodic memory recall and assessing contributions of oxytocin and cortisol to the acute effects of MDMA. Findings include reduced reactivity to simulated social exclusion, reduced negative emotional response to self-selected "worst" memories, increased use of language related to interpersonal closeness, increased emotional empathy and increases in perceived partner empathy. One study reported greater social language after MDMA than with the psychostimulant methamphetamine [37], and another reported greater emotional empathy after MDMA and another psychostimulant, methylphenidate [34]. Taken together, this research lends greater support to the view that MDMA possesses unique psychological effects, distinct from psychostimulants that can be beneficial when combined with psychotherapy. As an entactogen, MDMA can promote increased trust, greater ability to face and cope with emotionally distressing memories, thoughts or feelings and greater emotional empathy toward the self as well as others.

When combined with psychotherapy, MDMA permits people to confront and consider emotionally intense memories, thoughts, or feelings, and perhaps through changes in mood and perception, increase empathy and compassion for others and oneself [41, 62, 527]. In a sub-study of MP-8, the Self Compassion Scale [598] was administered before and 2 months after MDMA-assisted psychotherapy. Preliminary results in this small sub-study (N=7) are trending upward; subjects were low in self-compassion with mean total score of 2.4±0.63 prior to the study and experienced an increase to moderate self-compassion with mean total score of 2.8±0.84. In this assessment, self-kindness and a sense of common humanity increased, while self-judgment and feelings of isolation decreased on average within-subjects.

A Phase 1 study of the effects of MDMA-assisted psychotherapy on mood and social cognition in healthy volunteers who completed training in performing manualized MDMA-assisted psychotherapy is underway. Findings will include effect on mood and interpersonal closeness. The ongoing MAA-1 study in autistic adults is measuring symptoms of social anxiety, with secondary measures of emotion identification in the self and others, emotion regulation, alexithymia, and empathy. In this study, biomarkers associated with social behavior, including oxytocin, AVP, and cortisol, will also be assessed before, during, and after MDMA-assisted therapy. Taken together, findings from ongoing studies will assist the sponsor in evaluating how neuropsychological effects contribute to clinical development of MDMA-assisted psychotherapy.

5.3.8.1 Cognitive Function

MDMA does not affect responses on tasks requiring attention and response to visual stimuli or visually presented words [13, 28], but has been shown to interfere with performance on digit-symbol substitution, a measure of attention, psychomotor speed and visual memory [8]. A dose of 75 mg improved visual tracking speed, but impaired estimating the position of a blocked (occluded) object in a study of acute effects on skills used for driving cars [595]. A series of studies conducted in the Netherlands examined the effects of MDMA on skills needed for automobile driving reported transient and selective changes in verbal and visual attention, and memory after 75 or 100 mg MDMA [599-602]. MDMA caused difficulty learning or remembering lists of words and difficulty recalling object position within an array of objects. MDMA did not cause impairment in spotting scene changes and reduced weaving in a driving simulation. MDMA was associated with an excessively cautious response to the actions of another car in an assessment of actual driving [603]. While these studies have added to the literature of MDMA's cognitive effects, people in sponsor-supported studies are advised to never operate a vehicle while under the influence of MDMA or any other psychoactive substance.

MDMA acutely improved performance on one measure of impulsivity while failing to affect performance on other impulsivity measures [600]. The causes of these changes are unclear but may relate to changes in attention, salience of visual objects, and altered time perception. Changes in visuospatial recall and driving skills are likely associated with serotonin release or indirect action on serotonin receptors, as the noradrenergic and dopaminergic drug methylphenidate (Ritalin) did not produce similar changes [599, 602, 603]. A study on performance monitoring compared the effects of ethanol, MDMA, and both substances combined, found that MDMA had no effect on performance monitoring and no interaction when ethanol and MDMA are administered concurrently [604]. Administration of a $5HT_{2A}$ receptor antagonist, but not a $5HT_{1A}$ antagonist, reduced impaired performance on a word learning and recall task after MDMA, suggesting that interference is due in part to direct or indirect activation of these receptors [233]. Changes in cognitive function and psychomotor skills occurred during peak drug effects, but were not detectable 24 hours later.

Acute effects on cognitive function are not assessed in sponsor-supported studies. In three MAPS-sponsored studies, MP-1, MP-4, and MP-12, long-term effects on cognitive function was assessed by administering the Repeatable Battery for Assessment of Neuropsychological Status (RBANS), a relatively brief measure that assesses memory, attention and processing speed, visual-spatial and constructional abilities, and expressive language [605]; and the Paced Auditory Serial Addition Task (PASAT), a measure of auditory processing speed and mental flexibility [606, 607]. These instruments were given prior to and 1 to 2 months after psychotherapy assisted with either MDMA or comparator or placebo.

In MP-1, no significant differences in cognitive function were detected at the 2-month follow-up between subjects who received two sessions with 125 mg of MDMA compared to subjects who received placebo, as measured by RBANS and PASAT [41]. These findings suggest that MDMA did not impair cognitive function in this sample or that the effect was too small to attain statistical significance in this small pilot study. Two ongoing studies (MP-12 and MP-4) include these measures to assess reproducibility of this finding. Since both MP-4 and MP-12 were ongoing as of the data cut-off, available data pooled across studies are presented below by dose.

Table 11: Neurocognitive Function - RBANS Mean Total Scores at Baseline, Primary Endpoint, End of Stage 1, and End of Stage 2 for MP-1, MP-4, and MP-12 as of 01 October 2015

Dose	Baseline Mean (SD)	Primary Endpoint Mean (SD)	End of Stage 1 Mean (SD)	End of Stage 2 Mean (SD)
0 mg	100.9 (15.38) N=10	106.9 (15.15) N=10	---	119.0 N=1
40 mg	94.7 (5.20) N=6	102.0 (10.58) N=3	---	101.3 (5.51) N=3
100 mg	95.0 (17.87) N=6	104.9 (15.75) N=7	101.5 (18.97) N=6	---
125 mg	102.9 (15.88) N=27	103.1 (12.70) N=22	99.5 (9.33) N=6	---

On average, RBANS scores trend towards improvement after treatment with placebo and 40 mg to 100 mg initial dose of MDMA, whereas scores stay the same after treatment with 125 mg initial dose of MDMA. The trend towards improvement could be a practice effect from repeated assessments, although stimuli were varied across these, or could possibly be correlated with PTSD symptom reduction. One to three additional treatments with open-label active dose MDMA do not appear to worsen cognitive function based on preliminary End of Stage 1 and End of Stage 2 results. The significance of these pooled findings is yet to be determined.

Table 12: Neurocognitive Function - PASAT Trial 1 and Trial 2 Mean Raw Total Scores at Baseline, Primary Endpoint, End of Stage 1, and End of Stage 2 for MP-1, MP-4, and MP-12 as of 01 October 2015

PASAT Trial 1				
Dose	**Baseline Mean (SD)**	**Primary Endpoint Mean (SD)**	**End of Stage 1 Mean (SD)**	**End of Stage 2 Mean (SD)**
0 mg	42.1 (12.59) N=10	43.7 (12.03) N=10	---	37.0 N=1
40 mg	43.6 (10.36) N=5	53.3 (4.16) N=3	---	52.7 (5.03) N=3
100 mg	44.3 (12.44) N=6	46.7 (9.74) N=7	49.3 (9.09) N=6	---
125 mg	44.1 (11.12) N=27	49.1 (8.48) N=22	53.0 (6.36) N=6	---
PASAT Trial 2				
0 mg	34.2 (11.21) N=10	38.6 (11.66) N=10	---	45.0 N=1
40 mg	34.0 (13.36) N=5	43.0 (10.39) N=3	---	45.7 (8.15) N=3
100 mg	31.2 (12.67) N=6	29.0 (13.37) N=7	38.0 (10.33) N=6	---
125 mg	32.6 (9.62) N=27	35.4 (8.42) N=21	42.0 (11.8) N=6	---

On average, PASAT scores stay about the same after treatment with placebo and 100 mg initial dose of MDMA and trend towards improvement after treatment with 40 and 125 mg initial dose of MDMA. The trend towards improvement could be a practice effect from repeated assessments or could be correlated with PTSD symptom reduction. One to three additional treatments with open-label active dose MDMA do not appear to worsen cognitive function and continued to trend towards improvement on average based on preliminary End of Stage 1 and End of Stage 2 results. Cognitive function tests such as the PASAT are also known to be subject to individual variability, as they require basic proficiency with mathematical skills that are influenced by education level. The significance of these pooled findings is yet to be determined, but it does not appear that MDMA-assisted psychotherapy is negatively impacting cognitive function.

5.3.8.2 Perceptual Effects

MDMA causes slight changes in visual or auditory perception, including changes in the brightness or colors, sounds seeming closer or farther away, and simple visual distortions [7, 8, 10, 12]. Subjects also experienced altered time perception, and changes in meaning or significance of perceptions after MDMA [13]. On average, subjects maintained insight of their experience, with little indication that MDMA produces any strong alterations to the sense of self or control over the experience [11, 12]. Three healthy volunteers reported developing minimal to mild unusual beliefs or delusions under the influence of 1.5 mg/kg MDMA. Findings from a study with a small sample (five per group), perceptual alteration may be more pronounced after 2 mg versus 1 mg [596]. These beliefs resolved within a few hours, or by the next day at the latest. These subjects were aware that these beliefs were unusual [12]. Women reported experiencing all subjective effects of MDMA more intensely compared to men, but especially those related to perceptual changes [10]. The perceptual effects of MDMA appear to be the result of direct or indirect action on $5HT_{2A}$ receptors, as co-administration of the $5HT_{2A}$ antagonist ketanserin reduced reported perceptual alterations, as well as eliminated slight elevations in body temperature after 1.5 mg/kg MDMA [559], while co-administration with the $5HT_{1A}$ antagonist

pindolol did not affect perceptual alteration [231]. The effects of MDMA upon perception have not been studied within sponsor-supported studies.

5.3.8.3 Social Effects

In controlled laboratory settings, an established measure of accurate facial expression reading found that MDMA improved detection of expressions of positive mood and reduced accuracy in detecting expressions of negative mood [30]. Despite initial findings in naturalistic studies suggesting that Ecstasy increased accuracy of assessing some emotional expressions, particularly fearful ones [608], an fMRI study found that 0.75 and 1.5 mg/kg MDMA reduced signaling in the amygdala in response to angry faces when compared with placebo without changing the response to faces showing fear [26]. These researchers also detected increased activity in the ventral striatum in response to happy faces. Taken together, these findings suggest that MDMA changes the way emotional facial expressions are processed or the response to them. Complementing these findings are results demonstrating that MDMA enhanced the accuracy of recognizing facial expressions of positive mood and impaired mind reading for facial expressions of negative mood, but had no effect on mind reading for neutral faces [30]. Enhanced mind reading of positive emotions may facilitate therapeutic relationships in MDMA-assisted psychotherapeutic settings. In addition, and contrary to the finding in the early naturalistic study described above, there is some evidence showing that MDMA produces selective difficulty in recognizing faces expressing fear [588]. Further investigation corroborates this finding, showing that MDMA reduced recognition accuracy of fear significantly more in women than in men, and reduced recognition accuracy of sadness in women, but not in men. The same study found MDMA-induced increases in both implicit and explicit emotional empathy in men, but not in women [19].

Findings in placebo-controlled trials suggest that MDMA enhances positive response to positive social stimuli. Wardle and colleagues observe this effect simultaneously with a decrease in positive response to positive stimuli with no social content, which suggests that the contrast in valuation of social and non-social emotional stimuli contributes to MDMA's prosocial effects [38]. MDMA also reduces the impact of rejection on mood and self-esteem [609], which manifests more strikingly at lower doses of MDMA than reduction in perceived social rejection, suggesting complex social and behavioral effects from MDMA. Moreover, results from Kirkpatrick and colleagues show a behavioral preference for social activities over non-social ones, with subjects reporting increased desire for only the social activity after 1.5 mg/kg MDMA [610].

In a study by Bedi and colleagues, MDMA induced changes in semantic speech content with natural language learning software. Through natural language processing (NLP), researchers found speech patterns after MDMA were distinct from those produced after methamphetamine and placebo [37]. Proximity of speech to the concepts of *friend*, *support*, *intimacy*, *rapport*, and *empathy* was increased in the MDMA drug condition, which may bear some significance for the use of MDMA in therapy. MDMA did not affect the overall structure of subjects' speech. These findings were confirmed in an additional sample through a standardized dictionary method and machine learning, indicating that MDMA increased the use of social words, as well as words connoting positive and negative emotions [240]. There is some evidence that the increases in affiliative and prosocial feelings are separable from romantic or sexual feelings. Men and women did not seek to prolong viewing of images with explicit sexual content after MDMA, and they did not impute increased romantic feelings to images of heterosexual couples [611].

While the hormone oxytocin is implicated in social interactions and bonding, evidence indicates that oxytocin alone does not explain MDMA's prosocial effects. One investigation found a positive correlation in subjective effects ratings between intranasal oxytocin and oral MDMA, but

only at the lower of the two oxytocin doses tested [63]. Using pindolol to block 5-HT_{1A} receptor mediation of oxytocin's effects, Kuypers and colleagues determined that MDMA increased emotional empathy while oxytocin did not produce similar effects on measures of empathy and social interaction [569]. Studies examining the prosocial effects of MDMA, in relation to oxytocin, should be considered in the context of previous findings that showed no discernable subjective effects were found for intranasal oxytocin [612]. A single nucleotide polymorphism in the oxytocin receptor gene was found to predict subjective responses to MDMA, suggesting that this question remains worthy of further study [613]. Two studies have found that MDMA increased AVP [251, 561]. Neither study reported analysis or findings concerning any relationship between AVP levels and the subjective, emotional or social effects of MDMA.

Studies in healthy controls comparing doses between 0.75 and 1 mg/kg and 1.5 to 2 mg/kg suggest that the higher dose produces greater prosocial effects than the lower dose, while the lower dose may increase self-reported loneliness and use of empathy-related language [35, 39, 596, 609]. However, higher doses also produce a greater degree of stimulation and anxiety. It is notable that the first study investigating the impact of variation in an oxytocin receptor gene reported that those with one variation did not exhibit an increase in sociability after 1.5 mg/kg without a statistically significant difference in response at 0.75 mg/kg [613].

5.3.8.4 Emotional Effects

MDMA increases positive mood and anxiety [8, 10-12] on measures of alteration in consciousness and subjective effects. There is evidence that increases in positive mood and anxiety increase with dose [8, 12, 35, 614]. MDMA users report feeling more talkative and friendly after receiving MDMA. Self-reported interpersonal closeness was noted during a study in healthy volunteers [13]. Subsequent research confirmed the occurrence of increased interpersonal closeness after MDMA [29, 30, 35, 91, 558]. Researchers using two items within an instrument designed to assess drug effects and a visual analog scale rating closeness to others failed to detect increased feelings of empathy after 1.5 mg/kg MDMA [12], possibly due to the low sensitivity of these measures. In another investigation, the SSRI paroxetine was pre-administered to healthy volunteers before administering MDMA. The researchers found that MDMA increased feelings of being social and closeness to others, and paroxetine reduced these effects, indicating a significant role of the serotonergic system for the prosocial effects of MDMA [91]. People have reported feeling anxious or experiencing negative derealization while under the influence of MDMA, including increased anxiety related to loss of control and experiences of racing or blocked thoughts [8, 10, 13].

People receiving active doses of MDMA experience euphoria, positive mood, vigor, and positively experienced derealization, consonant with early retrospective reports, but also report experiencing anxiety, tension, and dysphoria, as well as concern over losing control over the self [8, 10-12]. More surprisingly, subjects report increased positive mood even after a dose of 25 mg [614]. It is uncertain whether the increases in positive and negative mood occur simultaneously or at different times throughout the duration of MDMA effects; evidence from two different teams suggests that peaks in negative mood may precede peaks in positive mood [11, 563]. MDMA may have a greater impact on mood in women than in men. Women report greater elevation in negative mood despite reaching plasma concentrations of MDMA and metabolites similar to those of men [552]. A second dose of MDMA 2 hours after the first does not increase subjective effects beyond that of an initial dose, interpreted by Peiro and colleagues as indications of tolerance to these effects [328]. When two 100 mg doses are given 4 hours apart, most subjective effects are comparable to those after a single dose, despite there being double the amount of plasma MDMA [546]. It is notable that the second dose in this study was identical to the first

dose, in contrast to sponsor-supported studies, wherein the second dose is half the size of the initial dose.

5.3.8.5 Suicidal Ideation, Behavior, and Depression

There is high incidence of positive suicidal ideation and behavior in populations of people with PTSD, especially those suffering from chronic, treatment-resistant PTSD [615, 616]. The FDA has responded to concerns over the occurrence of treatment emergent suicidal ideation or behavior by requiring clinical trials of psychiatric drugs to measure suicidality via the C-SSRS, a clinician-administered guided interview [617]. A score of 4 or 5 on the suicidal ideation category is considered serious, as well as a score of 1 or greater on the behavior category, and individuals with serious ideation or behavior are closely followed until levels return to normal or additional interventions are recommended. In order to determine if suicidal ideation and behavior worsens or improves after treatment in ongoing MAPS-sponsored trials (MP-4, MP-8, MP-9, MP-12, MAA-1, MDA-1, and MT-1), the C-SSRS is given repeatedly throughout a study, including lifetime incidence, baseline, before/during/after drug administration, endpoints when other measures are administered, and follow-up visits. Findings concerning suicidal ideation or behavior have not been formally measured in the first two sponsor-supported studies or reported in studies of healthy volunteers. Due to the nature of the therapeutic method, wherein a person may re-experience emotions associated with the traumatic event in order to reprocess the memory in a new, less detrimental way, thoughts of ending one's life may surface during this process. However, evidence from clinical studies indicates that these thoughts are most often transient, returning to normal, or even improve during the acute period following MDMA treatment. C-SSRS scores have also escalated during the preparatory sessions (before any drug administration), which is thought to be either a result of discussing traumatic experiences, or subjects tapering off long-prescribed medications, such as SSRIs and benzodiazepines, which have been documented elsewhere to induce suicidal ideation or behavior during withdrawal [618-620]. During both non-drug and MDMA-assisted psychotherapy sessions, subjects are asked to think about and discuss their experiences, thoughts, and emotions related to their condition. They may experience intense emotional responses to recalling and speaking about this material. As MDMA is only administered in combination with psychotherapy, the distress associated with psychotherapy is unavoidable, and is considered a necessary part of the therapeutic process that requires proper facilitation and support from therapists.

In Tables 13 through 17 below, suicidal ideation and behavior are summarized for subjects in MP-4, MP-8, MP-9, MP-12, MDA-1, and MAA-1 according to suggestions made in the C-SSRS Scoring and Data Analysis Guide [621]. A positive response for suicidal ideation is counted when a subject responds "yes" to any one of the five suicidal ideation questions (Categories 1 to 5) on the C-SSRS (i.e. a score >0 for suicidal ideation score). Serious suicidal ideation is a suicidal ideation score of 4 or 5. A positive response for suicidal behavior occurs when a subject responds "yes" to any one of the five suicidal behavior questions (Categories 6 to 10) on the C-SSRS (i.e. a score >0 for suicidal behavior score). Lifetime scores account for all suicidal ideation and behavior prior to enrollment according to subject recall and medical records. Pre-drug exposure represents measures collected on the Since Last Visit C-SSRS after enrollment during preparatory sessions and before first drug administration in experimental session 1 upon completion of tapering off psychiatric medications. Frequencies are event-based, calculated based on percentage of observations in which subjects would have the opportunity to report, as the C-SSRS is collected multiple times with each exposure to MDMA.

Table 13: Summary of Baseline Positive and Serious Responses on C-SSRS for Studies MP-4, MP-8, MP-9, MP-12, MAA-1, and MDA-1 as of 01 October 2015

Condition		Lifetime [A] N (%)	Pre-drug Exposure [B] N (%)
PTSD			
Blinded	PI	3 (75%)	3 (38%)
Placebo	SI	2 (50%)	0 (0)
(0 mg)	PB	2 (50%)	0 (0)
	O	4	8
	N	4	4
Blinded	PI	11 (79%)	5 (15%)
Comparator Doses	SI	3 (21%)	0 (0)
(25-40 mg)	PB	6 (43%)	0 (0)
	O	14	33
	N	14	13
Blinded	PI	41 (93%)	28 (29%)
Active Doses	SI	19 (43%)	0 (0)
(75-125 mg)	PB	19 (43%)	2 (2%)
	O	44	97
	N	44	44
Social Anxiety in Autistic Adults			
Blinded	PI	2 (100%)	0 (0)
Placebo	SI	0 (0)	0 (0)
(0 mg)	PB	1 (50%)	0 (0)
	O	2	3
	N	2	2
Blinded	PI	2 (100%)	0 (0)
Active Doses	SI	1 (50%)	0 (0)
(75-125 mg)	PB	1 (50%)	0 (0)
	O	2	6
	N	2	3
Anxiety Associated with a Life-threatening Illness			
Blinded	PI	1 (50%)	3 (38%)
Placebo	SI	1 (50%)	0 (0)
(0 mg)	PB	0 (0)	1 (13%)
	O	2	8
	N	2	2
Blinded	PI	1 (50%)	0 (0)
Active Dose	SI	0 (0)	0 (0)
(125 mg)	PB	1 (50%)	0 (0)
	O	2	8
	N	2	2

PI=Positive Ideation, SI=Serious Ideation, PB=Positive Behavior, O=Observations, N=Number of Subjects
[A] Lifetime accounts for all suicidal ideation and behavior prior to study Visit 1, according to participant recall and medical records
[B] Pre-drug exposure represents measures taken during Preparatory Sessions and before drug administration in Experimental Session 1

Based on lifetime results, most subjects across populations and dose groups had a history of suicidal ideation. In the PTSD sample, 39% of subjects had a history of serious ideation and 43% had positive behavior, which is consistent with the literature. Although samples were small, non-PTSD samples also have evidence of suicidal ideation and behavior, although prevalence may change as these studies enroll more subjects. Two PTSD subjects randomized to active dose and one autistic subject randomized to placebo exhibited suicidal behavior prior to any MDMA administration.

Table 14: C-SSRS Positive and Serious Responses During Experimental Sessions and 1-Day Post-Drug for Studies MP-4, MP-8, MP-9, and MP-12 as of 01 October 2015

Condition		Session 1 N (%)			Session 2 N (%)			Session 3 N (%)		
		Pre-drug [A]	During-drug [B]	Integration Day 1	Pre-drug [A]	During-drug [B]	Integration Day 1	Pre-drug [A]	During-drug [B]	Integration Day 1
PTSD										
Blinded	PI	1 (25%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	---	---	---
Placebo	SI	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)			
(0 mg)	PB	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)			
	N	4	4	4	4	4	4			
Blinded	PI	1 (7%)	1 (8%)	0 (0)	0 (0)	0 (0)	1 (8%)	1 (33%)	0 (0)	0 (0)
Comparator	SI	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Doses	PB	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
(25-40 mg)	N	14	13	13	12	11	12	3	2	2
Blinded	PI	9 (21%)	3 (7%)	5 (12%)	9 (21%)	7 (17%)	2 (5%)	4 (11%)	6 (17%)	3 (9%)
Active Doses	SI	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
(75-125 mg)	PB	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	N	44	43	43	42	42	42	35	35	35
Open-label	PI	0 (0)	1 (6%)	2 (11%)	1 (5%)	0 (0)	0 (0)	1 (6%)	0 (0)	0 (0)
Stage 2	SI	0 (0)	1 (6%)	1 (5%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Active Dose	PB	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
(100-125 mg)	N	19	18	19	19	17	19	18	17	17

PI=Positive Ideation, SI=Serious Ideation, PB=Positive Behavior, N=Number of Subjects

[A] Pre-drug measurement taken day of experimental session prior to drug administration.

[B] During-drug observation measured at experimental session endpoint, approximately 6 hours after drug administration.

In a PTSD sample with prevalent lifetime history of suicidal ideation, subjects randomized to either dose group reported pre-drug suicidal ideation in blinded experimental sessions. More active dose subjects reported pre-drug positive ideation, likely due to oversampling. During blinded session 1, numbers of comparator and active dose subjects reporting positive ideation were equivalent, with only active dose subjects reporting positive ideation the next day and none serious. As active dose subjects went deeper in the therapeutic process, reports of positive ideation 6 hours post-drug increased to 17% in the blinded session 2, with no reports from comparator subjects. No subjects reported positive suicidal behavior 6 hours post-drug as they were under continuous clinical observation during treatment and for 24 hours after. 5% of active dose subjects and 8% of comparator dose subjects experienced positive ideation the next day, with none serious. Active dose session 3 was similar to the second. Interestingly, open-label experimental sessions had fewer reports of positive and serious ideation, suggesting a protective effect of receiving comparator dose sessions prior to active dose, which could be attributed to developing the therapeutic alliance.

Table 15: C-SSRS Positive and Serious Responses During Experimental Sessions and 1-Day Post-Drug for Studies MAA-1 and MDA-1 as of 01 October 2015

Condition		Session 1 N (%)			Session 2 N (%)			Session 3 N (%)		
		Pre-drug [A]	During-drug [B]	Integration Day 1	Pre-drug [A]	During-drug [B]	Integration Day 1	Pre-drug [A]	During-drug [B]	Integration Day 1
Social Anxiety in Autistic Adults										
Blinded	PI	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	---	---	---
Placebo	SI	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)			
(0 mg)	PB	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)			
	N	2	2	2	2	2	2			
Blinded	PI	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	---	---	---
Active Doses	SI	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)			
(75-125 mg)	PB	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)			
	N	3	3	3	3	3	3			
Open-label	PI	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	---	---	---
Stage 2	SI	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)			
Active Dose	PB	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)			
(100-125 mg)	N	2	2	2	2	2	1			
Anxiety Associated with a Life-threatening Illness										
Blinded	PI	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	---	---	---
Placebo	SI	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)			
(0 mg)	PB	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)			
	N	2	2	2	1	1	1			
Blinded	PI	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Active Dose	SI	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
(125 mg)	PB	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	N	2	2	2	1	2	2	1	1	1

PI=Positive Ideation, SI=Serious Ideation, PB=Positive Behavior, N=Number of Subjects

[A] Pre-drug measurement taken day of experimental session prior to drug administration.

[B] During-drug observation measured at experimental session endpoint, approximately 6 hours after drug administration.

Despite prevalent lifetime history of suicidal ideation with 50% of subjects reporting serious ideation, five autistic subjects in MAA-1 reported no suicidal ideation or behavior before, during, or after experimental sessions regardless of MDMA dose. Although prevalence was about half of the PTSD and autistic subject samples, subjects with anxiety associated with a life-threatening illness also did not report suicidal ideation or behavior before, during, or after experimental sessions. These results may vary as more subjects are treated, but appear encouraging.

Table 16: C-SSRS Positive Responses During Telephone Contact Following Experimental Sessions for Studies MP-4, MP-8, MP-9, MP-12, MAA-1, and MDA-1 as of 01 October 2015

Condition		Session 1 N (%)		Session 2 N (%)		Session 3 N (%)	
		Day 2	Day 7	Day 2	Day 7	Day 2	Day 7
PTSD							
Blinded Placebo (0 mg)	PI	0 (0)	0 (0)	0 (0)	0 (0)	---	---
	SI	0 (0)	0 (0)	0 (0)	0 (0)		
	PB	0 (0)	0 (0)	0 (0)	0 (0)		
	N	4	4	4	4		
Blinded Comparator Doses (25-40 mg)	PI	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	SI	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	PB	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	N	14	14	12	12	2	2
Blinded Active Doses (75-125 mg)	PI	5 (12%)	6 (15%)	8 (20%)	6 (15%)	4 (12%)	4 (12%)
	SI	0 (0)	0 (0)	0 (0)	1 (3%)	0 (0)	1 (3%)
	PB	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	N	42	41	42	39	34	33
Open-label Stage 2 Active Doses (100-125 mg)	PI	3 (16%)	0 (0)	1 (5%)	0 (0)	0 (0)	0 (0)
	SI	2 (11%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	PB	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	N	19	18	19	19	17	18
Social Anxiety in Autistic Adults							
Blinded Placebo (0 mg)	PI	0 (0)	0 (0)	0 (0)	0 (0)	---	---
	SI	0 (0)	0 (0)	0 (0)	0 (0)		
	PB	0 (0)	0 (0)	0 (0)	0 (0)		
	N	2	2	2	2		
Blinded Active Doses (75-125 mg)	PI	0 (0)	0 (0)	0 (0)	0 (0)	---	---
	SI	0 (0)	0 (0)	0 (0)	0 (0)		
	PB	0 (0)	0 (0)	0 (0)	0 (0)		
	N	3	3	3	3		
Open-label Stage 2 Active Dose (100-125 mg)	PI	0 (0)	0 (0)	0 (0)	0 (0)	---	---
	SI	0 (0)	0 (0)	0 (0)	0 (0)		
	PB	0 (0)	0 (0)	0 (0)	0 (0)		
	N	2	2	2	2		
Anxiety Associated with a Life-threatening Illness							
Blinded Placebo (0 mg)	PI	0 (0)	0 (0)	0 (0)	0 (0)	---	---
	SI	0 (0)	0 (0)	0 (0)	0 (0)		
	PB	0 (0)	0 (0)	0 (0)	0 (0)		
	N	2	2	1	1		
Blinded Active Dose (125 mg)	PI	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	SI	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	PB	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	N	2	2	2	2	1	1

PI=Positive Ideation, SI=Serious Ideation, PB=Positive Behavior, N=Number of Subjects

Reports of positive ideation during treatment continued during the week after experimental sessions in 12% to 20% of subjects randomized to active dose MDMA. Lack of reports in comparator dose subjects suggests a dose-dependent effect. Prevalence increased after the second experimental session as seen during experimental sessions, likely due to enhancement of the therapeutic process with each exposure bringing up disturbing traumatic thoughts. As MDMA is only administered in the context of psychotherapy, and PTSD subjects have a lifetime history of suicidal ideation, these effects are expected. In contrast, autistic adults and those with anxiety associated with a life-threatening illness reported no suicidal ideation or behavior.

Table 17: C-SSRS Positive Responses at Endpoints After Treatment for Studies MP-4, MP-8, MP-9, MP-12, MAA-1, and MDA-1 as of 01 October 2015

Condition		Primary/ Secondary Endpoint N (%)	End of Stage 1/ End of Stage 2 N (%)	Long-term Follow-up N (%)
PTSD				
Blinded Placebo (0 mg)	PI	0 (0)	---	---
	SI	0 (0)		
	PB	0 (0)		
	N	2		
Blinded Comparator Doses (25-40 mg)	PI	1 (8%)	0 (0)	1 (14%)
	SI	0 (0)	0 (0)	0 (0)
	PB	0 (0)	0 (0)	0 (0)
	N	12	2	7
Blinded Active Doses (75-125 mg)	PI	13 (36%)	7 (23%)	5 (31%)
	SI	1 (3%)	0 (0)	1 (6%)
	PB	0 (0)	0 (0)	0 (0)
	N	36	30	16
Open-label Stage 2 Active Doses (100-125 mg)	PI	0 (0)	1 (8%)	---
	SI	0 (0)	0 (0)	
	PB	0 (0)	0 (0)	
	N	7	13	
Social Anxiety in Autistic Adults				
Blinded Placebo (0 mg)	PI	---	0 (0)	0 (0)
	SI		0 (0)	0 (0)
	PB		0 (0)	0 (0)
	N		2	2
Blinded Active Doses (75-125 mg)	PI	---	1 (17%)	0 (0)
	SI		0 (0)	0 (0)
	PB		0 (0)	0 (0)
	N		6	3
Anxiety Associated with a Life-threatening Illness				
Blinded Placebo (0 mg)	PI	0 (0)	---	---
	SI	0 (0)		
	PB	0 (0)		
	N	1		
Blinded Active Dose (125 mg)	PI	0 (0)	0 (0)	---
	SI	0 (0)	0 (0)	
	PB	0 (0)	0 (0)	
	N	1	1	

PI=Positive Ideation, SI=Serious Ideation, PB=Positive Behavior, N=Number of Subjects

About a third of active dose PTSD subjects and one comparator dose PTSD subject continued to experience suicidal ideation at the primary endpoint 1 month after treatment, but this was only serious in one case. The prevalence of suicidal ideation remained consistent at long-term follow-up, and was comparable to the pre-drug preparatory period after medication washout. Only one

autistic subject reported positive ideation during the study as a result of ending the therapeutic relationship to date.

Only five cases of suicidal ideation have been considered clinically significant across sponsor-supported studies in 122 people. Two AEs were rated serious and were not related to study drug. One SAE was reported 12 days after treatment with 30 mg MDMA and lasted 6 days, concurrent with a major depressive episode that was triggered by external trauma cues, and was treated with prescription medication and hospitalization. The other SAE was reported 9 months after treatment during the long-term follow-up period, lasted 3 days and resulted in hospitalization. Three AEs of suicidal ideation were reported during the treatment period (2 in MP-12, 1 in MAA-1), one moderate AE started on the day of an active dose experimental session and lasted 1 week, one mild AE started 1 month after the last active dose experimental session and lasted 2 days, one moderate AE started 27 days after active dose treatment, lasted 12 days and resolved after treatment with prescription medication and therapy. All cases resolved without development of suicidal behavior.

Overall the incidence of serious suicidal ideation or behavior in sponsor-supported studies is low, occurring in only a few subjects post-MDMA treatment, and returning to non-life-threatening scores while subjects were closely monitored. Given that severe PTSD sufferers are known to experience suicidal ideation and behavior, it is difficult to identify a single cause of the increase in suicidal thinking or behavior (i.e. exacerbation of PTSD symptoms or from MDMA-stimulated effects). A large percentage of people enrolled in the studies reported suicidal ideation and behavior during sometime in their lives prior to study enrollment, which may reflect a manifestation of PTSD or co-morbid affective disorders. When positive serious ideation or behavior occurred after enrollment, the investigators made follow-up observations of C-SSRS to ensure subject safety, and tracked scores until they returned to non-serious levels.

The Beck Depression Inventory-II (BDI-II) is a widely used self-administered measure of depression and includes an item on suicidal ideation. Subjects' depression levels were evaluated at baseline and at endpoints throughout the study, as a secondary measure of effectiveness of treatment. Tables 18 through 20 below show mean BDI-II scores for subjects in MP-4, MP-8, MP-9, MP-12, and MAA-1. Scores of 13 or lower indicate minimal, 14 to 19 mild, 20 to 28 moderate, 29 and above indicate severe depression symptoms.

Table 18: Mean BDI-II Scores at Baseline, Primary Endpoint, and End of Stage 1 by Dose for Studies MP-4, MP-8, MP-9, and MP-12 as of 01 October 2015

Condition	Baseline	Primary Endpoint	End of Stage 1
0 mg	32.5 (6.4) N=2	28.5 (9.2) N=2	---
25 mg	17.0 (0.0) N=2	15.5 (5.0) N=2	---
30 mg	30.4 (13.7) N=7	25.8 (12.2) N=6	20.0 (15.9) N=3
40 mg	23.8 (6.2) N=6	12.8 (6.9) N=5	---
75 mg	24.7 (12.6) N=7	10.3 (6.7) N=6	7.0 (5.7) N=2
100 mg	29.3 (14.2) N=8	21.9 (16.7) N=7	12.7 (9.1) N=7
125 mg	32.2 (11.0) N=30	15.8 (13.5) N=30	10.4 (12.0) N=19

As depression is not the primary indication in sponsor-supported studies, only a subset of subjects presented with clinically significant co-morbid depression at baseline, which contributes to variation within each dose group. Statistical tests have yet to be conducted, but scores appear to be trending downward in most active MDMA dose groups, indicating an improvement in depression symptoms on average.

Table 19: Mean BDI-II Scores at Secondary Endpoint, End of Stage 2, and 12-month Follow-up for Studies MP-4, MP-8, MP-9, and MP-12 as of 01 October 2015

Condition Stage 1/Stage 2	Secondary Endpoint	End of Stage 2	12-month Follow-up
0 mg/125 mg	---	---	---
30 mg/125 mg	16.5 (11.1) N=6	19.5 (13.0) N=6	17.2 (13.9) N=5
40 mg/125 mg	6.8 (6.2) N=5	9.6 (9.0) N=5	0.5 (0.7) N=2
75 mg/125 mg	9.8 (11.4) N=6	6.0 (6.3) N=5	11.2 (10.1) N=5
125 mg	---	---	12.3 (11.5) N=13

Stage 2 crossover data after initial treatment with placebo or comparator shows that depression scores are in the minimal to mild range on average after active dose treatment. Most subjects receive active dose treatments in either Stage 1 or Stage 2 and continue to long-term follow-up in PTSD studies. Depression scores remain in the minimal to mild range at 12-month follow-up, suggesting that improvements in depression observed during treatment are durable on average.

Table 20: Mean BDI-II Scores After MDMA or Placebo in MAA-1 as of 01 October 2015

Condition	Baseline Mean (SD)	1 Day Post Session 1 Mean (SD)	2 Weeks Post Session 1 Mean (SD)	1 Month Post Session 1 Mean (SD)
Placebo	3.0 (1.4) N=2	1.5 (2.1) N=2	0.0 (0.0) N=2	0.0 (0.0) N=2
MDMA (75-125 mg)	25.0 (18.1) N=3	4.7 (3.5) N=3	6.7 (9.8) N=3	11.7 (17.6) N=3
Condition		**1 Day Post Session 2 Mean (SD)**	**2 Weeks Post Session 2 Mean (SD)**	**1 Month Post Session 2 Mean (SD)**
Placebo		0.0 (0.0) N=2	0.0 (0.0) N=2	0.0 (0.0) N=2
MDMA (75-125 mg)		7.0 (3.5) N=3	5.0 (6.3) N=3	2.0 (2.8) N=2

MDMA does not worsen symptoms of depression in people exhibiting moderate to severe co-morbid depression, and may have an acute antidepressant effect in this sub-group. In most cases, symptom scores declined or remained at similar levels after MDMA-assisted psychotherapy. Some subjects experienced transient positive suicidal ideation during treatment, with these scores declining throughout the course of psychotherapy, as discussed in Section 5.3.8.5 Suicidal Ideation, Behavior, and Depression above. Taken together with C-SSRS findings that do not suggest a general increase in suicidality, improvements in depression scores indicate that MDMA-assisted psychotherapy does not exacerbate or provoke symptoms of suicidality or depression.

5.3.9 Adverse Events

5.3.9.1 Commonly Reported Adverse Events

Common AEs of MDMA reported in non-sponsor supported Phase 1 studies in healthy volunteers include elevation in blood pressure and heart rate, increased anxiety or dysphoria, and dilated pupils [8-10, 12]. Some reports indicated decreased rather than increased alertness [8]. Other common AEs reported in controlled studies of MDMA include reduced appetite, dizziness, tight jaw, bruxism (tooth-grinding), disturbance in attention, impaired gait or balance, dry mouth, and thirst. Subjects in some studies also reported or exhibited changes in cognition, such as increases in speed of thought or thought blocking, facilitated imagination or recall [13], and unusual thoughts or ideas [12]. Other less commonly reported events include parasthesia (unusual body sensations) such as tingling, or feeling hot or cold. MDMA can produce anxiety in healthy volunteers [10, 12, 13]. These effects are transient and recede as drug effects wane. One study found that women were more likely than men to experience the most commonly reported adverse effects of MDMA, though men were more likely than women to experience the specific AEs of nausea and sweating [10]. Kirkpatrick and colleagues examined a pooled sample of 220 healthy volunteers from three laboratories and failed to find gender differences in subjective or cardiovascular effects [589].

The most commonly reported AEs from Phase 1 studies published between 1986 and 2012 were used to develop a list of common reactions, or Spontaneously Reported Reactions, to record daily occurrence, duration and severity [12, 13, 28, 44, 62, 205, 208, 527, 556, 559, 560, 563]. Based on the reports summarized in Table 18, 24 reactions were identified to be tracked during sponsor-supported studies MP-1 and MP-2, and three were added after examining data from the first sponsor-supported study in a PTSD sample (MP-1). The investigators noted that subjects in MP-1 reported greater incidence of Diarrhea and Muscle Tightness, which were added to the list, and further observation led to the addition of Judgment Impaired. The following 27 reactions listed by preferred terms were tracked in MP-4, MP-8, MP-9, MP-12, MAA-1, MDA-1, and MT-1: decreased appetite, diarrhea, dry mouth, judgment impaired, muscle tightness (jaw), muscle tightness, disturbance in attention, thirst, restlessness, disturbed gait, depressed mood, dizziness, hyperhidrosis, feeling cold, obsessive ruminations, sensation of heaviness, somnolence, nystagmus, parasthesia, nausea, anxiety, irritability, insomnia, asthenia, fatigue, hypersomnia, and headache.

Table 21: Mean Percentage of Subjects Reporting Commonly Reported Reactions During MDMA or Placebo Treatment Collected from 12 Phase 1 Studies Conducted Outside of Sponsor Support

Treatment Group		Placebo	MDMA		
Subjects		57	174		
Reaction	**Preferred Term**	**Mean%**	**Mean%**	**Min%**	**Max%**
Anxiety	Anxiety	0%	19%	14%	50%
Difficulty concentrating	Disturbance in attention	16%	53%	3%	88%
Dizziness	Dizziness	2%	43%	21%	75%
Drowsiness	Somnolence	50%	26%	14%	50%
Dry mouth	Dry mouth	N/A	64%	57%	88%
Fatigue	Fatigue	26%	15%	7%	50%
Feeling cold	Feeling cold	4%	43%	23%	75%
Weakness	Asthenia	0%	16%	3%	36%
Headache	Headache	0%	11%	0%	50%
Heavy legs	Sensation of heaviness	0%	38%	38%	38%
Impaired balance/gait	Disturbed gait	0%	44%	10%	71%
Insomnia	Insomnia	0%	17%	0%	31%
Jaw clenching/tight	Muscle tightness (jaw)	0%	60%	44%	76%
Lack of appetite	Decreased appetite	2%	68%	50%	97%
Lack of energy	Decreased energy	14%	14%	3%	50%
Muscle ache/tension	Muscle tightness	N/A	20%	0%	50%
Nausea	Nausea	4%	21%	8%	36%
Nystagmus	Nystagmus	N/A	23%	3%	80%
Parasthesia	Parasthesia	0%	22%	3%	75%
Ruminations	Obsessive ruminations	23%	38%	38%	38%
Perspiration	Hyperhidrosis	0%	40%	0%	50%
Restlessness	Restlessness	0%	46%	29%	69%
Sensitivity to cold	Feeling cold	7%	38%	38%	38%
Thirst	Thirst	4%	48%	38%	63%
Restless legs	Restless legs syndrome	0%	45%	44%	46%
Palpitations	Palpitations	0%	37%	21%	63%
Hot flashes	Feeling hot	0%	23%	23%	23%
Trismus	Trismus	N/A	21%	3%	57%
Inner tension	Tension	0%	18%	3%	50%
Urge to urinate	Micturition urgency	8%	15%	15%	15%
Tremor	Tremor	0%	22%	3%	56%
Forgetfulness	Memory impairment	0%	15%	3%	38%
Brooding	Obsessive rumination	0%	12%	3%	29%

In sponsor-supported Phase 2 studies, researchers record any spontaneous (unsolicited) report of common reactions on the day of each experimental session and 7 days after. The same severity coding system for AEs was employed throughout all studies, based on limitation in daily function. Table 19 and Table 20 above display data from 342 experimental sessions, with each subject receiving between one and six experimental sessions at different doses across Stage 1 and Stage 2. More subjects received the 100 mg to 125 mg initial dose due to additional open-label experimental sessions offered to subjects randomized to comparator and medium dose in blinded experimental sessions.

Table 22: Percentage of Observations of Most Commonly Reported Spontaneously Reported Reactions During Experimental Sessions in Studies MP-1, MP-2, MP-4, MP-8, MP-9, MP-12, MDA-1, MAA-1, and MP1-E2 as of 01 October 2015

Dose Subjects	Placebo (N=12)	25 mg (N=7)	30 mg (N=7)	40 mg (N=6)	75 mg (N=7)	100-125 mg (N=100)	150 mg (N=3)
Schedule	1-2 doses 3-5 weeks apart	1-3 doses 3-5 weeks apart	1-3 doses 3-5 weeks apart	1-2 doses 3-5 weeks apart	1-3 doses 3-5 weeks apart	1-3 doses 3-5 weeks apart	1-2 doses 3-5 weeks apart
Sessions	24	19	15	11	14	255	4
Muscle Tightness (jaw)							
Mild	2 (8%)	1 (5%)	---	1 (9%)	4 (29%)	62 (24%)	---
Moderate	3 (13%)	---	---	2 (18%)	1 (7%)	73 (29%)	1 (25%)
Severe	---	---	---	---	---	6 (2%)	1 (25%)
Total	5 (21%)	1 (5%)	0 (0%)	3 (27%)	5 (36%)	141 (55%)	2 (50%)
Anxiety							
Mild	1 (4%)	---	---	2 (18%)	4 (29%)	48 (19%)	1 (25%)
Moderate	9 (38%)	---	7 (47%)	2 (18%)	1 (7%)	61 (24%)	---
Severe	4 (17%)	---	1 (7%)	---	1 (7%)	13 (5%)	---
Total	14 (58%)	0 (0%)	8 (53%)	4 (36%)	6 (43%)	122 (48%)	1 (25%)
Decreased Appetite							
Mild	1 (4%)	2 (11%)	3 (20%)	---	4 (29%)	63 (25%)	---
Moderate	1 (4%)	1 (5%)	---	---	---	40 (16%)	1 (25%)
Severe	---	1 (5%)	---	---	---	3 (1%)	---
Total	2 (8%)	4 (21%)	3 (20%)	0 (0%)	4 (29%)	106 (42%)	1 (25%)
Headache							
Mild	5 (21%)	1 (5%)	6 (40%)	3 (27%)	10 (71%)	57 (22%)	1 (25%)
Moderate	7 (29%)	---	1 (7%)	1 (9%)	---	37 (15%)	---
Severe	---	---	---	---	---	1 (<1%)	---
Total	12 (50%)	1 (5%)	7 (47%)	4 (36%)	10 (71%)	95 (37%)	1 (25%)
Fatigue							
Mild	3 (13%)	4 (21%)	6 (40%)	---	2 (14%)	32 (13%)	---
Moderate	7 (29%)	---	2 (13%)	3 (27%)	2 (14%)	52 (20%)	---
Severe	---	---	---	---	---	3 (1%)	---
Total	10 (42%)	4 (21%)	8 (53%)	3 (27%)	4 (28%)	87 (34%)	0 (0%)
Muscle Tightness							
Mild	1 (4%)	---	5 (33%)	1 (9%)	1 (7%)	44 (17%)	---
Moderate	2 (8%)	---	2 (13%)	2 (18%)	2 (14%)	25 (10%)	---
Severe	---	---	---	---	---	---	---
Total	3 (13%)	0 (0%)	7 (47%)	3 (27%)	3 (21%)	69 (27%)	0 (0%)
Nausea							
Mild	2 (8%)	2 (11%)	1 (7%)	---	2 (14%)	34 (13%)	1 (25%)
Moderate	1 (4%)	---	2 (13%)	---	---	28 (11%)	---
Severe	---	---	---	---	---	6 (2%)	---
Total	3 (13%)	2 (11%)	3 (20%)	0 (0%)	2 (14%)	68 (27%)	1 (25%)
Feeling Cold							
Mild	2 (8%)	1 (5%)	7 (47%)	---	4 (29%)	47 (18%)	---
Moderate	1 (4%)	---	1 (7%)	---	2 (14%)	20 (8%)	---
Severe	---	---	---	---	---	1 (<1%)	---
Total	3 (13%)	1 (5%)	8 (53%)	0 (0%)	6 (43%)	68 (27%)	0 (0%)

Source: Table 31

The sponsor has analyzed the cumulative frequency of AEs commonly reported during each experimental session, collected as Spontaneously Reported Reactions. Most spontaneously reported reactions were rated as mild in studies across populations. The most frequently reported

acute and sub-acute reactions related to 255 experimental sessions with 100 mg to 125 mg initial dose of MDMA in 100 people across Phase 2 studies were muscle tightness (jaw) (141 reports during 55% of sessions at any severity, 2% severe), anxiety (122 reports during 48% of sessions at any severity, 5% severe), decreased appetite (106 reports during 42% of sessions at any severity, 1% severe), headache (95 reports during 37% of sessions at any severity, <1% severe), fatigue (87 reports during 34% of sessions at any severity, 1% severe), muscle tightness (69 reports during 27% of sessions at any severity, none severe), and nausea (68 reports during 27% of sessions at any severity, 2% severe). The next most common reactions reported during 9% to 25% of experimental sessions with a 100 mg to 125 mg initial dose of MDMA in order of frequency are: hyperhidrosis, restlessness, dizziness, insomnia, thirst, disturbed gait, dry mouth, disturbance in attention, depressed mood, and nystagmus, described in Table 31. The highest initial dose of 150 mg MDMA was only administered during four experimental sessions in MP-2, and was associated with reports of insomnia (3), muscle tightness (jaw) (2), dizziness (2), disturbed gait (2), dry mouth (2), and thirst (2), but it should be noted that this group is small. The following reactions were reported during less than 9% of experimental sessions with 100 mg to 125 mg initial dose of MDMA on the day of drug administration: feeling cold, obsessive ruminations, sensation of heaviness, somnolence, parasthesia, diarrhea, judgment impaired, irritability, asthenia, and hypersomnia. These reactions may be of less concern than previously proposed in the scientific literature on MDMA.

In studies where a low dose of MDMA (25 mg to 40 mg) was administered in 20 subjects across 45 sessions, infrequent reports of fatigue (15), anxiety (12), headache (12), muscle tightness (10), and feeling cold (9) were observed. In comparison, 12 subjects who received an inactive placebo in 24 experimental sessions reported anxiety (14), insomnia (12), headache (12), fatigue (10), and muscle tightness (jaw) (5) during experimental sessions. Taking into consideration that the 100 mg to 125 mg MDMA dose has been administered by far the most frequently, the sponsor concludes that the frequency of spontaneously reported reactions are likely to be most accurate in the 100 mg to 125 mg dose experimental sessions that have been administered to date in these studies. The higher number of experimental sessions at this dose meant that there was greater opportunity to report reactions. While 100 mg to 125 mg MDMA was associated with more reactions overall, these reactions were self-limiting and generally did not persist beyond the 7-day window after experimental sessions, unless associated with medical history.

Table 23: Percentage of Observations of Most Commonly Reported Spontaneously Reported Reactions During Telephone Contact on Day 1-7 After Experimental Sessions in Studies MP-1, MP-2, MP-4, MP-8, MP-9, MP-12, MDA-1, MAA-1, and MP1-E2 as of 01 October 2015

Dose Subjects	Placebo (N=12)	25 mg (N=7)	30 mg (N=7)	40 mg (N=6)	75 mg (N=7)	100-125 mg (N=100)	150 mg (N=3)
Schedule	1-2 doses 3-5 weeks apart	1-3 doses 3-5 weeks apart	1-3 doses 3-5 weeks apart	1-2 doses 3-5 weeks apart	1-3 doses 3-5 weeks apart	1-3 doses 3-5 weeks apart	1-2 doses 3-5 weeks apart
Observations	168	133	105	77	98	1785	21
Anxiety							
Mild	26 (15%)	4 (3%)	25 (24%)	8 (10%)	5 (5%)	239 (13%)	---
Moderate	35 (21%)	---	10 (10%)	3 (4%)	1 (1%)	172 (10%)	---
Severe	2 (1%)	---	---	---	---	24 (1%)	---
Total	63 (38%)	4 (3%)	35 (33%)	11 (14%)	6 (6%)	435 (24%)	0 (0%)
Fatigue							
Mild	23 (14%)	16 (12%)	20 (19%)	3 (4%)	27 (28%)	245 (14%)	2 (10%)
Moderate	27 (16%)	8 (6%)	8 (8%)	4 (5%)	1 (1%)	163 (9%)	14 (67%)
Severe	1 (1%)	1 (1%)	---	---	---	13 (1%)	2 (10%)
Total	51 (30%)	25 (19%)	28 (27%)	7 (9%)	28 (29%)	421 (24%)	18 (86%)
Insomnia							
Mild	19 (11%)	17 (13%)	8 (8%)	5 (6%)	6 (6%)	158 (9%)	---
Moderate	29 (17%)	13 (10%)	9 (9%)	5 (6%)	2 (2%)	88 (5%)	---
Severe	1 (1%)	8 (6%)	1 (1%)	5 (6%)	---	8 (<1%)	---
Total	49 (29%)	38 (29%)	18 (17%)	15 (19%)	8 (8%)	254 (14%)	0 (0%)
Depressed Mood							
Mild	13 (8%)	14 (11%)	4 (4%)	3 (4%)	---	114 (6%)	3 (14%)
Moderate	8 (5%)	11 (8%)	4 (4%)	---	---	101 (6%)	---
Severe	---	---	---	---	---	17 (1%)	---
Total	21 (13%)	25 (19%)	8 (8%)	3 (4%)	0 (0%)	232 (13%)	3 (14%)
Hypersomnia							
Mild	15 (9%)	8 (6%)	9 (9%)	3 (4%)	17 (17%)	145 (8%)	2 (10%)
Moderate	9 (5%)	7 (5%)	1 (1%)	3 (4%)	---	63 (4%)	---
Severe	---	---	1 (1%)	---	---	---	---
Total	24 (14%)	15 (11%)	11 (10%)	6 (8%)	17 (17%)	208 (12%)	2 (10%)
Disturbance in Attention							
Mild	11 (7%)	---	2 (2%)	2 (3%)	---	141 (8%)	---
Moderate	11 (7%)	---	2 (2%)	2 (3%)	---	38 (2%)	---
Severe	---	---	---	---	---	3 (<1%)	---
Total	22 (13%)	0 (0%)	4 (4%)	4 (5%)	0 (0%)	182 (10%)	0 (0%)
Decreased Appetite							
Mild	---	10 (8%)	2 (2%)	1 (1%)	2 (2%)	89 (5%)	---
Moderate	---	2 (2%)	---	1 (1%)	---	67 (4%)	---
Severe	---	3 (2%)	---	---	---	1 (<1%)	---
Total	0 (0%)	15 (11%)	2 (2%)	2 (3%)	2 (2%)	157 (9%)	0 (0%)
Dizziness							
Mild	5 (3%)	6 (5%)	---	---	1 (1%)	122 (7%)	---
Moderate	---	1 (1%)	---	---	---	19 (1%)	---
Severe	---	---	---	---	---	2 (<1%)	---
Total	5 (3%)	7 (5%)	0 (0%)	0 (0%)	1 (1%)	143 (8%)	0 (0%)

Dose Subjects	Placebo (N=12)	25 mg (N=7)	30 mg (N=7)	40 mg (N=6)	75 mg (N=7)	100-125 mg (N=100)	150 mg (N=3)
Schedule	1-2 doses 3-5 weeks apart	1-3 doses 3-5 weeks apart	1-3 doses 3-5 weeks apart	1-2 doses 3-5 weeks apart	1-3 doses 3-5 weeks apart	1-3 doses 3-5 weeks apart	1-2 doses 3-5 weeks apart
Observations	168	133	105	77	98	1785	21
Irritability							
Mild	12 (7%)	3 (2%)	5 (5%)	---	4 (4%)	69 (4%)	---
Moderate	9 (5%)	---	3 (3%)	3 (4%)	---	48 (3%)	---
Severe	---	---	---	---	---	2 (<1%)	---
Total	21 (13%)	3 (2%)	8 (8%)	3 (4%)	4 (4%)	119 (7%)	0 (0%)
Headache							
Mild	9 (5%)	13 (10%)	1 (1%)	3 (4%)	4 (4%)	76 (4%)	---
Moderate	5 (3%)	13 (10%)	---	3 (4%)	---	33 (2%)	---
Severe	---	---	---	---	---	3 (<1%)	---
Total	14 (8%)	26 (20%)	1 (1%)	6 (8%)	4 (4%)	112 (6%)	0 (0%)
Muscle Tightness (jaw)							
Mild	2 (1%)	---	---	6 (8%)	2 (2%)	90 (5%)	---
Moderate	1 (1%)	---	---	4 (5%)	---	20 (1%)	---
Severe	---	---	---	---	---	2 (<1%)	---
Total	3 (2%)	0 (0%)	0 (0%)	10 (13%)	2 (2%)	112 (6%)	0 (0%)

Source: Table 32

The sponsor has analyzed the cumulative frequency of Spontaneously Reported Reactions reported during 7 days following each experimental session. The most frequently reported reactions related to 255 experimental sessions with 100 mg to 125 mg initial dose of MDMA in 100 people across Phase 2 studies were anxiety (24% of observations, 1% severe), fatigue (24% of observations, 1% severe), insomnia (14% of observations, <1% severe), depressed mood (13% of observations, 1% severe), hypersomnia (12% of observations, none severe), disturbance in attention (10% of observations, <1% severe), decreased appetite (9% of observations, <1% severe), dizziness (8% of observations, <1% severe), irritability (7% of observations, <1% severe), headache (6% of observations, <1% severe), muscle tightness (jaw and elsewhere) (6% of observations, <1% severe). The next most common reactions reported during the week after experimental sessions with 100 mg to 125 mg initial dose of MDMA in less than 6% of daily telephone contacts, in order of frequency, are: muscle tightness, nausea, obsessive ruminations, restlessness, asthenia, feeling cold, diarrhea, dry mouth, judgment impaired, disturbed gait, hyperhidrosis, sensation of heaviness, somnolence, nystagmus, parasthesia, and thirst, as described in Table 32. The highest initial dose of 150 mg MDMA was only administered during four experimental sessions in MP-2, and was associated with reports of fatigue (86% of observations), depressed mood (14% of observations), hypersomnia (10% of observations), and dry mouth (5% of observations) during the week following experimental sessions.

In studies where a low dose of 25 mg to 40 mg initial dose of MDMA was administered, infrequent reports of insomnia (22% of observations), fatigue (19% of observations), anxiety (16% of observations), depressed mood (11% of observations), headache (10% of observations), hypersomnia (10% of observations), muscle tightness (6% of observations), nausea (6% of observations), and decreased appetite (6% of observations). The following reactions were observed in 4% or less of daily telephone contact observations, in order of frequency: obsessive ruminations, irritability, muscle tightness (jaw), disturbance in attention, restlessness, dizziness, feeling cold, diarrhea, somnolence, judgment impaired, asthenia, thirst, dry mouth, hyperhidrosis, and sensation of heaviness. In comparison, 12 subjects who received an inactive placebo in 24 experimental sessions reported anxiety (38% of observations), fatigue (30% of observations),

insomnia (29% of observations), hypersomnia (14% of observations), depressed mood (13% of observations), disturbance in attention (13% of observations), and irritability (13% of observations) were reported during daily contact for 1 week following each experimental session. Headache, nausea, muscle tightness, somnolence, obsessive rumination, dizziness, muscle tightness (jaw), diarrhea, disturbed gait, and hyperhidrosis were reported in less than 10% of observations during daily telephone contact. While 100 mg to 125 mg MDMA was associated with more reactions overall, these reactions were self-limiting and generally did not persist beyond the 7-day window after experimental sessions.

Any reactions that continued beyond the 7-day window were tracked as unexpected AEs until they returned to baseline levels. In all studies to date, 18 severe reactions lasted beyond the 7-day window: insomnia (2 lasting up to 26 days), anxiety (6 lasting up to 53 days), restlessness (2 lasting up to 18 days), obsessive rumination (1 lasting 4 days) and depressed mood (4 lasting up to 51 days), headache (1 lasting 13 days), muscle tightness (jaw) (1 lasting 20 days), and muscle tightness (1 lasting 20 days). These reactions were tracked as AEs until resolution and subjects experiencing them were provided with prescription medication and additional therapy. Among the subset of AEs collected as commonly reported severe reactions, severe anxiety, insomnia, fatigue, nausea, muscle tightness, and depressed mood were reported in 4% or more subjects. Severe anxiety was reported the most during both inactive placebo (22%) and MDMA experimental sessions (5% to 10%, depending on dose). These reactions also overlap with symptoms of pre-existing conditions in medical history associated with PTSD (depression, somatic symptoms, insomnia, anxiety) and anxiety disorders, which can be exacerbated by processing traumatic content and may influence the frequency and duration of reactions observed in sponsored-supported clinical trials of MDMA-assisted psychotherapy.

5.3.9.2 Adverse Events

The sponsor has analyzed cumulative frequency of AEs through the data cut-off period, which included 122 subjects treated with MDMA at any dose in 10 MAPS-sponsored studies conducted under U.S. IND. See Table 24 below for distribution by severity and relationship. There have been no Safety Reports to date under this IND.

Table 24: Overview of All Adverse Events Post-Drug by Severity and Relationship in MAPS-Sponsored Studies Across Populations as of 01 October 2015

	Related AEs (% by severity)	All AEs (% by severity)
Mild AEs	58 (34%)	117 (36%)
Moderate AEs	100 (59%)	181 (56%)
Severe AEs	12 (7%)	28 (9%)
Any Severity	170 (100%)	326 (100%)

In data collected from all studies described above, there were 170 possibly or probably related AEs out of 326 at any severity after MDMA administration. Since MDMA is administered as an adjunct to psychotherapy, judging relationship to study drug is a known challenge for this combined therapy. In the context of complex medical histories associated with the PTSD diagnosis, somatic symptoms may wax and wane independent of treatment. In addition, it is known that processing trauma during psychotherapy for PTSD, with our without concomitant pharmacological treatment, can temporarily increase symptoms as an expected aspect of the therapeutic process. This is borne out by the high incidence of spontaneously reported reactions and AEs in the placebo group. Possibly or probably related AEs were more often moderate than mild or severe. Multiple severe AEs were rarely reported by the same subject. In Table 25 below,

body systems of AEs reported by 2% or more of subjects are displayed, with distribution and frequency of severe AEs by body system.

Table 25: Body Systems of All Adverse Events Post-Drug Reported by 2% or More of Subjects in MAPS-Sponsored Studies Across Populations

Dose	**Placebo (0 mg)**		**Comparator Dose (25-40 mg)**		**Active Dose (75-150 mg)**		**Any MDMA Dose (25-150 mg)**	
Schedule	1-2 doses 3-5 weeks apart		1-3 doses 3-5 weeks apart		1-6 doses 3-5 weeks apart		1-6 doses 3-5 weeks apart	
Subjects	14		24		141		122	
Sessions	27		49		306		355	
Relationship to Drug	PR	NR	PR	NR	PR	NR	PR	NR
Cardiac Disorders	---	---	---	---	2 (1%)	1 (1%)	2 (2%)	1 (1%)
Severe					(0)	(0)	(0)	(0)
Ear and Labyrinth Disorders	---	---	1 (4%)	---	1 (1%)	1 (1%)	2 (2%)	1 (1%)
Severe			(0)		(0)	(0)	(0)	(0)
Eye Disorders	---	---	---	---	9 (6%)	1 (1%)	9 (7%)	1 (0%)
Severe					(0)	(0)	(0)	(0)
Gastrointestinal Disorders	1 (7%)	---	1 (4%)	---	17 (12%)	13 (9%)	18 (15%)	13 (11%)
Severe	(0)		(0)		1 (1%)	(0)	1 (1%)	(0)
General Disorders and Administration Site Conditions	4 (29%)	---	4 (17%)	4 (17%)	21 (15%)	10 (7%)	25 (20%)	14 (11%)
Severe	(0)		(0)	1 (4%)	(0)	(0)	(0)	1 (1%)
Infections and Infestations	1 (7%)	4 (29%)	---	5 (21%)	6 (4%)	12 (9%)	6 (5%)	17 (14%)
Severe	(0)	(0)		(0)	(0)	2 (1%)	(0)	2 (1%)
Injury, Poisoning, and Procedural Complications	---	1 (7%)	---	---	2 (1%)	7 (5%)	2 (2%)	7 (6%)
Severe		(0)			(0)	1 (1%)	(0)	1 (1%)
Metabolism and Nutrition Disorders	---	---	---	1 (4%)	2 (1%)	2 (1%)	2 (2%)	3 (2%)
Severe				(0)	(0)	(0)	(0)	(0)
Musculoskeletal and Connective Tissue Disorders	8 (57%)	2 (14%)	1 (4%)	---	20 (14%)	13 (9%)	21 (17%)	13 (11%)
Severe	1 (7%)	(0)	(0)		(0)	1 (1%)	(0)	1 (1%)
Neoplasms Benign, Malignant, and Unspecified	---	---	---	---	---	2 (1%)	---	2 (2%)
Severe						2 (1%)		2 (2%)
Nervous System Disorders	1 (7%)	3 (21%)	3 (13%)	1 (4%)	12 (9%)	9 (6%)	15 (12%)	10 (8%)
Severe	(0)	1 (7%)	2 (8%)	(0)	(0)	(0)	2 (2%)	(0)
Psychiatric Disorders	9 (64%)	2 (14%)	11 (46%)	7 (29%)	47 (33%)	44 (31%)	58 (48%)	51 (42%)
Severe	1 (7%)	(0)	2 (8%)	3 (13%)	7 (5%)	5 (4%)	9 (7%)	8 (7%)
Renal and Urinary Disorders	---	---	---	---	2 (1%)	---	2 (2%)	---
Severe					(0)		(0)	

Dose	Placebo (0 mg)		Comparator Dose (25-40 mg)		Active Dose (75-150 mg)		Any MDMA Dose (25-150 mg)	
Schedule	1-2 doses 3-5 weeks apart		1-3 doses 3-5 weeks apart		1-6 doses 3-5 weeks apart		1-6 doses 3-5 weeks apart	
Subjects	14		24		141		122	
Sessions	27		49		306		355	
Reproductive System and Breast Disorders	---	---	---	---	---	4 (3%)	---	4 (3%)
Severe						1 (1%)		1 (1%)
Respiratory, Thoracic, and Mediastinal Disorders	1 (7%)	---	2 (8%)	---	2 (1%)	9 (6%)	4 (3%)	9 (7%)
Severe	(0)		(0)		(0)	(0)	(0)	(0)
Skin and Subcutaneous Tissue Disorders	1 (7%)	1 (7%)	---	1 (4%)	4 (3%)	3 (2%)	4 (3%)	4 (3%)
Severe	(0)	(0)		(0)	(0)	(0)	(0)	(0)
Vascular Disorders	---	---	---	---	---	3 (2%)	---	3 (2%)
Severe						(0)		(0)

PR=Possibly or probably related, NR=Not related

Across all body systems, most related AEs reported at any dose of MDMA were psychiatric disorders (48% of MDMA versus 64% of placebo subjects), followed by general disorders and administration site conditions (20% of MDMA versus 29% of placebo subjects), musculoskeletal and connective tissue disorders (17% of MDMA versus 57% of placebo subjects), gastrointestinal disorders (15% of MDMA versus 7% of placebo subjects), nervous system disorders (12% of MDMA versus 7% of placebo subjects), eye disorders (7% of MDMA versus none of placebo subjects), and infections and infestations (5% of MDMA versus 7% of placebo subjects). See Table 26 below for details of related AEs under each system organ class. Based on comparison of frequencies, taking into account that sample sizes are heavily weighted towards active dose MDMA due to study design, gastrointestinal disorders, nervous system disorders, and eye disorders appear to be associated with more MDMA subjects over placebo. Based on the elimination half-life of 7 to 9 hours for active doses of MDMA, it is difficult to judge relationship of AEs reported after the 7-day safety window as they may also be related to the therapeutic process or medical history. Investigators tended to be more conservative and judged events to be related based on known pharmacodynamics of MDMA, for example with gastrointestinal disorders and the distribution of serotonin receptors in the gut [622].

A majority of the AEs were psychiatric disorders. Given study inclusion criteria requiring a pre-existing diagnosis of chronic anxiety or PTSD and the fact that subjects were receiving MDMA, a drug that is known to increase general anxiety in an average of 19% healthy volunteers across multiple Phase 1 studies, these AEs are expected. However, the frequency of psychiatric disorders in the small group of subjects who received inactive placebo was even higher than the active doses, suggesting that these AEs may, at least in part, be related to exacerbation of medical history diagnoses during the study independent of MDMA administration.

Related AEs reported in 3% or less of MDMA subjects were: respiratory, thoracic and mediastinal disorders, skin and subcutaneous tissue disorders, cardiac, ear and labyrinth, injury, poisoning and procedural complications, metabolism and nutrition disorders, renal and urinary disorders. It is noteworthy that, although there was one related, moderate, expected cardiac AE that was deemed serious because it led to overnight monitoring of increased ventricular extrsystoles, no severe cardiac, renal and urinary, or vascular disorders were reported, and they were also the least frequently reported types of AEs after any MDMA dose, in contrast to reports of cardiovascular toxicity, hyperthermia, ARF, hyponatremia, and neurotoxicity in epidemiological settings, as described in Section 4.5 Serious Reports, Mortality, and Morbidity in Animals and Epidemiological Settings and in Table 2. The difference in frequency suggests that AEs in these body systems are likely to be rare in a controlled clinical setting with proper medical screening, and that they may receive disproportionate coverage in the scientific literature on epidemiological studies due to significant impact on the body. In Table 26 below, preferred terms of AEs possibly or probably related to comparator and active doses of study drug are presented for a more detailed view.

Table 26: Related Adverse Events in Sponsor Supported Studies of MDMA-Assisted Psychotherapy Across Populations Organized by Body System as of 01 October 2015

Dose	Comparator Dose (25-40 mg)	Active Dose (75-150 mg)	Any MDMA Dose (25-150 mg)
Schedule	1-2 doses 3-5 weeks apart	1-6 doses 3-5 weeks apart	1-6 doses 3-5 weeks apart
Subjects	22	121	122
Sessions	45	306	355
Cardiac Disorders			
Palpitations	---	1 (1%)	1 (1%)
Ventricular extrasystoles	---	1 (1%)	1 (1%)
Ear and Labyrinth Disorders			
Tinnitus	1 (5%)	---	1 (1%)
Eye Disorders			
Visual impairment	---	5 (4%)	5 (4%)
Vitreous floaters	---	1 (1%)	1 (1%)
Dry eyes/abnormal sensation in eye	---	1 (1%)	1 (1%)
Vision blurred	---	2 (2%)	2 (2%)
Gastrointestinal Disorders			
Diarrhea	1 (5%)	4 (3%)	5 (4%)
Dyspepsia	---	3 (2%)	3 (2%)
Abdominal pain	---	3 (2%)	3 (2%)
Nausea	---	2 (2%)	2 (2%)
Oropharyngeal blistering	---	1 (1%)	1 (1%)
Vomiting	---	4 (3%)	4 (3%)
General Disorders and Administration Site			
Asthenia	---	1 (1%)	1 (1%)
Fatigue	4 (18%)	9 (7%)	13 (11%)
Feeling abnormal	---	1 (1%)	1 (1%)
Feeling hot	---	2 (2%)	2 (2%)
Irritability	---	1 (1%)	1 (1%)
Pain (body aching, body tension)	---	4 (3%)	4 (3%)
Pyrexia	---	1 (1%)	1 (1%)
Chills	---	1 (1%)	1 (1%)
Infections and Infestations			
Pharyngitis streptococcal	---	1 (1%)	1 (1%)
Upper respiratory infection	---	3 (2%)	3 (2%)
Urinary tract Infection	---	2 (2%)	2 (2%)
Injury, Poisoning, and Procedural Complications			
Contusion	---	1 (1%)	1 (1%)
Skin abrasion	---	1 (1%)	1 (1%)
Metabolism and Nutrition Disorders			
Anorexia	---	1 (1%)	1 (1%)
Decreased appetite	---	1 (1%)	1 (1%)

Dose	Comparator Dose (25-40 mg)	Active Dose (75-150 mg)	Any MDMA Dose (25-150 mg)
Schedule	1-2 doses 3-5 weeks apart	1-6 doses 3-5 weeks apart	1-6 doses 3-5 weeks apart
Subjects	22	121	122
Sessions	45	306	355
Musculoskeletal and Connective Tissue Disorders			
Arthralgia (joint)	---	1 (1%)	1 (1%)
Back pain	---	2 (2%)	2 (2%)
Joint stiffness	---	1 (1%)	1 (1%)
Muscle spasms	---	1 (1%)	1 (1%)
Muscle tightness	1 (5%)	7 (6%)	8 (7%)
Muscle twitches	---	1 (1%)	1 (1%)
Musculoskeletal pain (shoulder)	---	3 (2%)	3 (2%)
Myalgia	---	3 (2%)	3 (2%)
Neck pain	---	1 (1%)	1 (1%)
Nervous System Disorders			
Burning sensation (fingers, thighs)	---	2 (2%)	2 (2%)
Dizziness	---	1 (1%)	1 (1%)
Hangover (feeling hungover)	---	1 (1%)	1 (1%)
Headache	1 (5%)	3 (2%)	4 (3%)
Hypersomnia	1 (5%)	3 (2%)	4 (3%)
Hypoaesthesia facial	---	1 (1%)	1 (1%)
Migraine headache	1 (5%)	---	1 (1%)
Myoclonus	---	1 (1%)	1 (1%)
Tension headache	---	1 (1%)	1 (1%)
Psychiatric Disorders			
Agitation	---	1 (1%)	1 (1%)
Anxiety	4 (18%)	22 (18%)	26 (21%)
Bruxism	---	2 (2%)	2 (2%)
Depressed mood	3 (14%)	4 (3%)	7 (6%)
Derealization	---	1 (1%)	1 (1%)
Dissociation	---	1 (1%)	1 (1%)
Disturbance in attention	---	1 (1%)	1 (1%)
Flashback	---	1 (1%)	1 (1%)
Hypnagogic hallucination	---	1 (1%)	1 (1%)
Hypnopompic hallucination	---	1 (1%)	1 (1%)
Intentional self-injury	---	1 (1%)	1 (1%)
Irritability	---	2 (2%)	2 (2%)
Negative thoughts	1 (5%)	---	1 (1%)
Obsessive Rumination	1 (5%)	1 (1%)	1 (1%)
Panic attack	---	4 (3%)	1 (1%)
Restlessness	---	1 (1%)	1 (1%)
Suicidal ideation	---	1 (1%)	1 (1%)
Tic (teeth tapping)	---	1 (1%)	1 (1%)
Time perception altered	1 (5%)	---	1 (1%)
Trichotillomania	1 (5%)	---	1 (1%)
Renal and Urinary Disorders			
Nocturia	---	1 (1%)	1 (1%)
Dysuria	---	1 (1%)	1 (1%)

Dose	Comparator Dose (25-40 mg)	Active Dose (75-150 mg)	Any MDMA Dose (25-150 mg)
Schedule	1-2 doses 3-5 weeks apart	1-6 doses 3-5 weeks apart	1-6 doses 3-5 weeks apart
Subjects	22	121	122
Sessions	45	306	355
Respiratory, Thoracic, and Mediastinal Disorders			
Cough	1 (5%)	---	1 (1%)
Nasal congestion	1 (5%)	2 (2%)	3 (2%)
Sinus headache	---	1 (1%)	1 (1%)
Skin and Subcutaneous Tissue Disorders			
Petechiae	---	2 (2%)	2 (2%)
Pruritis	---	2 (2%)	2 (2%)

The most frequently reported possibly or probably related AEs were anxiety (18% in active versus 18% comparator subjects), fatigue (7% active versus 18% comparator subjects), muscle tightness (6% active versus 5% comparator subjects), and visual impairment (4% active versus none of comparator subjects). Subjective effects of MDMA are known to have a dose response relationship, so AEs with equivalent frequencies across comparator versus active doses of MDMA suggest an absence of dose response and possible relationship to medical history or therapeutic process. Since more individuals received active dose MDMA due to unequal group sizes weighted towards the active MDMA doses, and the partial crossover offered to comparator dose and placebo subjects, a greater number of AEs is expected with active doses of MDMA beyond any expected dose response relationship. In addition, frequencies in comparator dose subjects are based on a small sample of 22 subjects who received 45 experimental sessions.

Muscle tightness in the body as well as specific to the jaw was frequently reported as an unsolicited reaction during experimental sessions, as described in Table 22. During the 7-day safety window, these reactions were much less frequently reported, as described in Table 23 and Table 32. Among related AEs reported during and after drug administration, somatic symptoms were more frequently experienced in active dose subjects, such as pain associated with body tension (3% of active dose subjects versus none of comparator subjects), muscle tightness (6% of active dose versus 5% of comparator dose subjects), musculoskeletal pain in the shoulder (2% of active dose subjects versus none of comparator), back pain (2% of active dose subjects versus none of comparator), and myalgia (2% of active dose subjects versus none of comparator). As previously discussed in Section 5.3.9.2 Adverse Events, it is difficult to judge relationship between study drug and conditions associated with medical history diagnoses. Pain and somatic symptoms can be directly related to traumatic events, such as physical or sexual assault, a motor vehicle accident, or combat [623]. A meta-analytic review and several large studies have found a robust association between PTSD and somatic symptoms, suggesting that PTSD itself may be a contributing factor beyond combat exposure, sexual, or physical abuse that lead to the PTSD [624-627].

Although MDMA is not a classic hallucinogen, as classified by chemical structure and mechanism of action, data from sponsor-supported studies suggest that in a clinical population mild psychoactive effects, such as hypnagogic and hypnopompic hallucinations and visual distortions may be observed in some individuals. Hallucinogenic subjective effects were not actively solicited during therapy sessions, as was done in Phase 1 studies of healthy volunteers [8, 10, 11, 556]. Any unsolicited reports were collected as spontaneously reported reactions or AEs in sponsor-supported studies.

Table 27: Severe Related Adverse Events in Sponsor Supported Studies of MDMA-Assisted Psychotherapy Across Populations as of 01 October 2015

Indication	PTSD	Healthy	Anxiety	Social Anxiety	Total
Population	All	Therapists	Life-Threatening Illness	Autistic Adults	
Subjects	107	7	4	9	127
Sessions	365	7	8	19	399
Psychiatric					
Re-experiencing Episode	1	---	---	---	1 (1%)
Panic Attack	2	---	---	---	2 (2%)
Depressed Mood	2	---	---	---	2 (2%)
Obsessive Rumination	1	---	---	---	1 (1%)
Anxiety	3	---	---	---	3 (2%)
Nervous System					
Headache	1	---	---	---	1 (1%)
Gastrointestinal					
Abdominal Cramps/Pain	1	---	---	---	1 (1%)
General					
Restlessness	1	---	---	---	1 (1%)
Musculoskeletal & Connective Tissue					
Musculoskeletal Chest Pain	1	---	---	---	1 (1%)

The sponsor has analyzed the cumulative frequency of AEs and found the most frequent severe possibly or probably related AEs to be anxiety or distress (N=3, 2% of subjects), depressed mood (N=2, 2% of subjects), and panic attacks (N=2, 2% of subjects) in sponsor-supported PTSD studies. The following severe related AEs were observed in 1% of subjects: re-experiencing episode, obsessive rumination, restlessness, headache, abdominal cramps/pain, and musculoskeletal chest pain. Severe related AEs were treated with prescription medications and followed by additional phone contact and psychotherapy to ensure that the subjects returned to baseline or were stabilized. It is noteworthy that no severe related AEs were reported in non-PTSD populations in sponsor-supported studies, which could also be attributed to small sample sizes.

5.3.9.3 Serious Adverse Events

Eleven SAEs have occurred across five sponsor-supported studies. These include one expected related SAE and 10 unrelated SAEs after drug administration. See Table 28 below for a summary of these SAEs.

Table 28: Serious Adverse Events in Sponsor-Supported Studies of MDMA-Assisted Psychotherapy Across Populations as of 01 October 2015

Dose		Comparator Dose (30 mg)	Active Dose (100 mg)	Active Dose (125 mg)
System Organ Class Preferred Term	**Relationship**			
Gastrointestinal Disorders				
Appendicitis	None			1
Injury, Poisoning, and Procedural Complications				
Fractured Clavicle (auto accident)	None			1
Lower Limb Fracture	None		1	
Nervous System Disorder				
Vasovagal Syncope	None			1
Neoplasms Benign, Malignant, and Unspecified				
Brain Metastasis (frontal brain syndrome)	None			1
Breast Cancer	None			1
Reproductive System and Breast Disorders				
Ovarian Cyst Ruptured	None		1	
Psychiatric Disorders				
Suicidal Ideation	None	1		1
Major Depressive Episode	None			1
Cardiac Disorders				
Increase in Ventricular Extrasystoles	Probably			1

One related serious adverse reaction has occurred within all sponsor-supported studies to date. Subject 0811 experienced an increase in frequency of ventricular extrasystoles (PVC's), a form of arrhythmia, on the day of his third and final experimental session with open-label 125 mg MDMA. The subject had no other signs and no symptoms of cardiac distress. In the absence of any symptoms of coronary insufficiency, the investigator judged the only medical measure necessary to be withholding the supplemental dose of MDMA. This was the final drug administration in Stage 2. No similar events occurred during the first two 125 mg experimental sessions, nor the two blinded experimental sessions with 30 mg MDMA in Stage 1. There was no evidence of acute cardiac damage or ischemia or underlying heart disease. At baseline during screening, the subject had one PVC on baseline electrocardiogram (EKG), but the EKG was otherwise normal. The subject had a family history of his father having had a coronary artery bypass graft, which had prompted the subject to consult a cardiologist several years before study enrollment, and the cardiologist's note indicated that he did not suspect cardiovascular disease or see the need for further workup. Based on the medical history and clinical presentation of this subject, the investigator judged the SAE to be a moderate exacerbation probably related to drug administration. The event required overnight monitoring in the hospital, but did not lead to any adverse sequelae. He was given one dose of 25 mg metoprolol by the hospital physician but did not require any ongoing treatment. Serial cardiac isoenzymes, an echocardiogram and a nuclear stress test performed during the overnight hospital admission failed to show evidence of cardiovascular or other cardiac disease. Full recovery occurred 1 day after MDMA administration. Arrhythmia is described in sections 4.5 and 5.3.4 as an expected adverse effect of MDMA.

5.3.10 Abuse Potential

When reviewing the effects of MDMA in a sample of 74 largely drug-naïve subjects in a study conducted outside of sponsor support, Liechti and colleagues stated that "none of the subjects expressed any interest in taking MDMA as a recreational drug" after receiving MDMA in a

controlled research setting [10]. When assessed in terms of willingness to choose money over receiving the drug, subjects previously experienced with Ecstasy provided similar responses to 2 mg/kg MDMA and 20 mg d-amphetamine, a sign of having reinforcing effects [596]. A study that enrolled subjects with a history of Ecstasy use (4 to 40 occasions) found that only self-reported feelings of playfulness were associated with subjects' desire to take MDMA in a controlled research setting [39].

The sponsor has assessed abuse potential of MDMA in Phase 2 clinical trials with collection of self-report information on Ecstasy use during long-term follow-up in all studies. In addition, one study (MP-2) incorporated random and scheduled drug testing during long-term follow-up. One subject in MP-1 who had received two experimental sessions with active dose MDMA reported the use of Ecstasy in an attempt to recreate the therapeutic setting but found the experience unsatisfactory, and after this experience indicated no desire to repeat it. No other subjects in this study reported using Ecstasy after completing the study [42]. In sponsor-supported study MP-2, drug screens specific for MDMA performed 2 months, 6 months, and 12 months after the final experimental session were negative, suggesting that study subjects did not seek out MDMA or Ecstasy after taking part in the study. Although MDMA does not demonstrate signals associated with known abuse liability patterns, the drug will only be administered in a clinic setting under continuous observation on an intermittent schedule, which further limits abuse potential.

5.4 Efficacy of MDMA Across Populations

5.4.1 PTSD

Ongoing and completed sponsor-supported studies of MDMA-assisted therapies employ recognized clinician-administered gold-standard measures of the condition or symptoms. The primary outcome measure of efficacy for studies of MDMA-assisted psychotherapy for PTSD to date is the Clinician Administered PTSD Scale (CAPS) following DSM-IV, an established semi-structured interview conducted by a trained clinician [628-630]. The Global Severity CAPS score encompasses frequency and intensity scores for three symptom domains; re-experiencing, avoidance and hyperarousal. An independent rater that does not see the subjects during any of the psychotherapy sessions administers the CAPS at baseline and at the primary endpoint, 1 or 2 months after blinded MDMA-assisted psychotherapy sessions. Secondary endpoints include an assessment 1 to 2 months after a third experimental session and 12 months after the last treatment.

Analyses of the CAPS at the primary endpoint after two experimental sessions in MP-1 found subjects receiving MDMA-assisted psychotherapy experienced a clinically and statistically significant decline in PTSD symptoms compared to placebo-assisted psychotherapy [41]. Global CAPS scores declined for all subjects over time (overall baseline mean Global CAPS=79.1±21.7, and 2 months after the second experimental session, mean Global CAPS=38.2±30.3), indicating a clinically significant drop of 40.9 points, and a 52% reduction in symptoms. People in the MDMA and placebo conditions began the study with similar CAPS scores, while CAPS scores after experimental sessions were lower for people in the MDMA condition through 2 months after the second experimental session (Placebo=59.1±28.9 versus MDMA, 25.4±23.95). Placebo subject scores dropped 20.5 points 2 months after the second experimental session while MDMA subject CAPS scores dropped 53.3 points, or a 26% drop in PTSD symptoms for controls versus a 68% drop in PTSD symptoms for MDMA subjects.

The second study of MDMA-assisted psychotherapy (MP-2) found results similar to the MP-1 study, but improvement after three blinded experimental sessions with 125 mg MDMA was numerically but not statistically superior to the 25 mg MDMA comparator dose [43]. CAPS

scores declined over time for the eight subjects given 125 mg MDMA (baseline mean=66.4±13.6 versus 3 weeks after the third experimental session mean=50.7±19.7), indicating a drop of 15.7 points, or a 23.5% decrease in scores. On the other hand, CAPS scores increased slightly over time for the four subjects given comparator dose (baseline mean=63.2±7.9 versus 3 weeks after the third experimental session mean=66.5±7.5), indicating an increase of 2.3 points, or a 5.2% increase in CAPS scores.

Table 29 and Table 30 below show pooled mean Global CAPS Scores for completed (MP-1, MP-2) and ongoing sponsor-supported studies (MP-4, MP-8, MP-9, MP-12). Since data collection is still in progress, formal analyses have yet to be executed, but data trends appear similar to published reports, with a medium to large effect size of active dose MDMA-assisted psychotherapy depending on number of experimental sessions completed. Table 29 below depicts mean Global CAPS scores for each condition at Baseline, 1 to 2 months after the second experimental session (Primary Endpoint), and 1 to 2 months after the third experimental session (End of Stage 1). Placebo and comparator groups cross over to Stage 2 after the Primary Endpoint, therefore CAPS is not administered at the End of Stage 1 for these groups. Active dose groups (100 mg and 125 mg) do not crossover, hence no data for Stage 2 endpoints. Long-term follow-up data collection is ongoing.

Table 29: Mean Global CAPS Scores in Stage 1 of Sponsor-Supported Studies of MDMA-Assisted Psychotherapy for PTSD as of 01 October 2015

Dose	Baseline Mean (SD)	Primary Endpoint Mean (SD)	End of Stage 1 Mean (SD)
0 mg	83.6 (21.11) N=10	62.9 (27.04) N=10	---
25 mg	70.4 (10.01) N=8	61.2 (8.18) N=6	66.5 (7.55) N=4
30 mg	87.4 (14.12) N=7	73.5 (24.58) N=6	62.7 (36.12) N=3
40 mg	91.0 (17.89) N=7	80.6 (18.81) N=5	---
75 mg	82.4 (17.32) N=7	24.0 (18.79) N=6	18.5 (9.19) N=2
100 mg	94.4 (20.17) N=9	71.0 (30.85) N=7	40.9 (20.92) N=7
125 mg	84.13 (19.01) N=56	46.0 (31.46) N=53	42.4 (27.21) N=34

Across studies, CAPS scores are downward trending at the primary endpoint after two experimental sessions of MDMA-assisted psychotherapy. Formal pooled analyses to determine statistical significance have not been conducted as data collection is ongoing. Primary endpoint results after active doses of 75 mg to 125 mg initial dose, with an optional supplemental half-dose administered 1.5 to 2.5 hours later, appear lower than placebo or comparator dose results after two experimental sessions. Two-month follow-up results at the End of Stage 1 after a blinded or open-label third experimental session demonstrate signals of efficacy that should be further explored in a blinded three session treatment model of MDMA-assisted psychotherapy.

Table 30: Mean Global CAPS Scores in Stage 2 and Long-term Follow-up of Sponsor-Supported Studies of MDMA-Assisted Psychotherapy for PTSD as of 01 October 2015

Condition Stage 1/Stage 2	Last Stage 1 Observation Mean (SD)	Secondary Endpoint Mean (SD)	End of Stage 2 Mean (SD)	12-month Follow-up Mean (SD)
0 mg/125 mg	62.9 (27.04) N=10	33.9 (12.8) N=7	33.6 (18.6) N=5	18.7 (7.6) N=6
25 mg/125 mg	61.2 (8.18) N=6	42.5 (25.3) N=4	36.8 (13.6) N=4	31.5 (19.2) N=4
30 mg/125 mg	73.5 (24.58) N=6	46.5 (20.5) N=6	46.2 (30.5) N=6	59.0 (42.6) N=5
40 mg/125 mg	80.6 (18.81) N=5	38.6 (29.2) N=5	35.2 (31.1) N=5	14.0 (19.8) N=2
75 mg/125 mg	24.0 (18.79) N=6	22.3 (18.9) N=6	22.2 (20.5) N=5	26.8 (21.2) N=5
100 mg	40.9 (20.92) N=7	---	---	37.0 N=1
125 mg	42.4 (27.21) N=34	---	---	34.6 (28.1) N=30

Across studies, CAPS scores are also downward trending at the secondary endpoint after two open-label experimental sessions of MDMA-assisted psychotherapy and are consistent with Stage 1 results. Secondary endpoint results in the crossover set receiving an active dose of 125 mg MDMA after receiving comparator dose or placebo in Stage 1 are in range with subjects receiving 100 mg or 125 mg in Stage 1. Comparison between the 75 mg MDMA results in Stage 1 and the Stage 2 results suggest that this dose is also active and receiving additional 125 mg MDMA sessions does not lead to further improvement in this small sample. Formal analyses to determine statistical significance within-subjects have not been conducted as data collection is ongoing. Twelve-month follow-up results after all subjects have received active dose MDMA in either Stage 1 or Stage 2 suggest that the integration process may continue and lead to further improvement of PTSD symptoms in some subjects.

5.4.2 Social Anxiety in Autistic Adults

The primary outcome measure for the study of social anxiety in people on the autism spectrum is the Liebowitz Social Anxiety Scale (LSAS). This observer-blind measure is an established clinician-administered measure of social anxiety, assessing fear and avoidance in different situations. The LSAS consists of 24 items, with each item rated on a four-point scale (from 0 to 3), with subscales for performance fear, performance avoidance, social fear, and social avoidance. The study is ongoing and efficacy findings will not be presented in this version of the IB.

Data is being collected on the effects of two sessions of MDMA-assisted therapy in people on the autism spectrum with social anxiety symptoms. The study is still blinded; therefore, efficacy data is not presented.

5.4.3 Anxiety Associated with Life-Threatening Illness

MAPS is studying a new indication, the effects of MDMA-assisted psychotherapy on people experiencing anxiety as they face of a potentially life-threatening illness. No data is available at this time.

6.0 Summary of Data and Guidance for the Investigator

MDMA is a psychoactive compound that affects mood, perception, and increases prosocial feelings. The sponsor is investigating use of this compound as an adjunct to psychotherapy for treating PTSD, social anxiety in people on the autism spectrum, and anxiety related to a life-threatening illness. Researchers with and without sponsor support have conducted *in vitro* and *in vivo* non-clinical and clinical studies with MDMA, and additional clinical trials are ongoing. At this time, MDMA is listed as a Schedule I controlled substance in the U.S. and is not permitted for medical use outside of research settings. Psychotherapists in the U.S. began to use MDMA as an adjunct to psychotherapy in the mid to late 1970s, and narrative accounts describe therapeutic use prior to its scheduling. MDMA was administered to thousands of people in a therapeutic setting prior to scheduling, and has been administered to approximately 1180 people in controlled research settings as of 01 October 2015. These studies have demonstrated that MDMA can be safely administered to people with PTSD in a controlled clinical setting.

In comparison to anxiolytics, antidepressants, and atypical antipsychotics, MDMA does not require steady state levels in the blood to function as a catalyst to psychotherapy with rapid onset in some subjects. A limited number of exposures to MDMA, spaced approximately 1 month apart at moderate doses, are sufficient to obtain therapeutic outcomes. This intermittent dosing mitigates AE frequency and improves the risk/benefit ratio of MDMA, which may provide a significant advantage over medications that require daily dosing. Based on the current state of scientific knowledge and the risk/benefit profile of therapeutic doses of MDMA, the sponsor concludes that it appears favorable to pursue the research of MDMA as a medicine used as an adjunct to psychotherapy.

6.1 Pharmacology

The pharmacology of MDMA is complex as it activates multiple signaling cascades in the body. The formulation of the investigational product consists of a gelatin capsule consisting of racemic white crystalline MDMA, at doses ranging from 12.5 mg to 150 mg, compounded with alpha-lactose, and administered orally. Due to a wide range of responses to identical mg/kg dosing between individuals, possibly as a result of inconsistent relationship between body weight and pharmacodynamic activity, the sponsor's human trials use fixed doses between approximately 1 and 4 mg/kg (active fixed doses range from 75 mg to 225 mg cumulative with supplemental dosing, assuming a 60 kg individual) to achieve a more consistent response between subjects. In humans, onset of effects occurs approximately 30 to 60 minutes after administration, and peak effects occur 75 to 120 minutes after administration. Duration of effects lasts 3 to 6 hours, which extends to 6 to 8 hours with supplemental dosing.

The pharmacokinetics of MDMA in humans has been characterized using oral doses of up to 150 mg MDMA in humans. MDMA disposition in the body follows nonlinear pharmacokinetics. MDMA is metabolized in the liver by several enzymes. It is likely that active doses of MDMA saturate CYP2D6 function for an extended period, with function normalizing up to 10 days post-MDMA. The enzymes CYP1A2, COMT, and MAO may also be involved in the metabolism of MDMA. MDMA is metabolized by *N*-demethylation to MDA. The parent compound and MDA are further *O*-demethylenated to HHMA and HHA, respectively. Both HHMA and HHA are subsequently *O*-methylated mainly to HMMA and HMA. These four metabolites, particularly HMMA and HMA, are known to be excreted in the urine as conjugated glucuronide or sulfate metabolites. The elimination half-life of active MDMA doses is 7 to 9 hours. This window should be considered when evaluating relationship of AEs to MDMA.

MDMA is a triple monoamine reuptake inhibitor, which concomitantly promotes carrier-mediated release, inhibits reuptake, and extends duration of serotonin, norepinephrine, and dopamine in the synaptic cleft to increase serotonergic, noradrenergic, and dopaminergic neurotransmission. MDMA appears to alter the conformation of the transporters, enabling monoamines to diffuse out of the neuron rather than being actively transported into the presynaptic neuron. MDMA was found to compete with monoamines for sites on the VMAT2, suggesting MDMA also promotes active release of monoamines from vesicular stores, in addition to inhibiting reuptake. MDMA extends the presence of monoamines in the synaptic cleft by inhibiting MAO-A, an enzyme that breaks down monoamines in the synapse. MDMA has self-limiting subjective and physiological effects. MDMA administration is contraindicated in subjects requiring MAOI medications. Fatalities have been reported after the combination of MAOIs and MDMA in Ecstasy users. Co-administration with an SSRI may eliminate or greatly attenuate the effects of MDMA, and these medications should be tapered in line with the investigator's clinical judgment and an approved study protocol.

MDMA has been shown to acutely decrease activity in the left amygdala and increase blood flow to the PFC in the human brain. The chief mechanism behind its therapeutic effects is likely to be serotonergic, along with some norepinephrine and to a minor extent dopamine-mediated effects. Indirect, but potentially significant effects of MDMA include the release of the hormones cortisol, oxytocin, prolactin, and AVP. MDMA likely stimulates secretion of oxytocin into peripheral blood via indirect activation of $5HT_{1A}$, $5HT_{2C}$, and $5HT_4$ receptor subtypes, as well as AVP secretion via activation of $5HT_{2C}$, $5HT_4$, and $5HT_7$ receptor subtypes. Both oxytocin and AVP are implicated in the widespread regulation of behavioral aspects of mood and also act on different target organs to modulate physiological functions in the body. Taken together, MDMA has been shown to have a diverse array of pharmacodynamic effects in animals and humans.

6.2 Toxicology

The toxicity of MDMA has been investigated in numerous animal and *in vitro* studies published in peer-reviewed journals. Intravenous MDMA doses that cause lethality in 50% of the cases, known as the LD50, are 97 mg/kg in mice, 49 mg/kg in rats, 14 to 18 mg/kg in dogs, and 22 mg/kg in monkeys. LD50 varies between different strains of the same animal species, across the sexes, housing conditions, environmental conditions, social interactions with co-habitating individuals, exercise levels, and water supply. Most preclinical toxicology data is derived from repeated dose studies. Preclinical researchers typically selected doses through use of interspecies scaling, a method of modeling human-equivalent doses in other species, however pharmacokinetic and pharmacodynamic data show this conversion is not appropriate for MDMA. As a result, most research in rodents and primates used doses of MDMA much higher than those consumed by humans, thus translation to human recreational and therapeutic use is limited. Many published epidemiological studies of Ecstasy effects in humans are also subject to the limitations in interpretation due to unknown purity, dose, and quantity of MDMA existing in Ecstasy tablets used in naturalistic settings.

Extensive preclinical toxicological studies report that high or repeated doses of MDMA can increase locomotor activity and signs of serotonin syndrome, which can damage serotonergic axons originating in the brainstem dorsal raphe nuclei, probably as a result of oxidative stress, and this damage is associated with decreases in serotonin production, serotonin metabolites, and SERT site densities. While these findings are consistent across studies, studies in low to moderate Ecstasy users do not report an increase in a biological marker of neuronal injury, and only one of three studies of this marker in humans detected it in heavy users. Retrospective studies in Ecstasy users have found contradictory effects on visual and verbal memory, planning and making decisions, and some types of visual processing. An uncontrolled prospective study of moderate

Ecstasy users failed to find changes in SERT sites or signs of neuronal injury; slight changes in cerebral blood flow in the dorsolateral PFC were found. In the same study, Ecstasy users showed less improvement on a memory task than non-users. Taken together, these findings suggest possible indications of cumulative toxicity in chronic high dose dosing regimens.

MDMA has not been demonstrated to be genotoxic. Consistent with this, despite very high doses of MDMA being tested in preclinical studies, none have reported carcinogenic effects. Risks posed to pregnant women by MDMA are not known. Two of three studies of Ecstasy users suggest that use of Ecstasy and other drugs during pregnancy may be associated with some abnormalities at birth, delays in mental and motor development, but not language or emotional development. Rodent fertility, reproductive, and developmental toxicity studies with MDMA have generally found no abnormalities in gestational duration, neonatal birth weights, or physical appearance when exposure occurs during organogenesis through lactation. However, one study of fertility and developmental toxicity in mice found evidence of toxicity at doses 5 mg/kg s.c. and above when exposure occurred in both genders of a breeding pair at some point between spermatogenesis/ovulation through closure of the hard palate. The results of several behavioral tests indicate that developmental MDMA exposure combined with adult exposure in rats may interfere with some aspects of learning, including visual-spatial memory, and time spent with a novel object. MDMA exposure *in utero* exacerbated hyperthermic response to a subsequent dose to MDMA. A study in neonatal rats suggests two distinct critical periods wherein repeated MDMA doses affected learning versus acoustic startle. In conclusion, MDMA might possess weak reproductive or developmental toxicity with a daily toxic chronic dosing regimen, in contrast to six or less exposures, spaced 1 month apart, tested in clinical trials. All sponsor-supported trials of MDMA exclude pregnant and lactating women, and women who are able to become pregnant must have a negative pregnancy screen before undergoing each experimental session and must agree to use birth control during the period of the protocol. If any subject becomes pregnant during study participation, the sponsor and clinical investigator will follow the pregnancy to outcome.

There have been a number of reports of morbidity and mortality in individuals who use Ecstasy (material represented as containing MDMA, as defined above) around the world in unsupervised and uncontrolled settings, usually involving poly-drug use. These events are relatively rare given the prevalence of Ecstasy use, estimated to be in the millions worldwide. The most common adverse effects in Ecstasy and poly-drug use include hyperthermia, psychiatric problems, hepatotoxicity secondary to hyperthermia, and hyponatremia (see Section 4.4 Toxicology in Animals and Epidemiological Settings and 4.5 Serious Reports, Morbidity, and Mortality in Epidemiological Settings). Fatal dysrhythmias have been reported following heavy MDMA use, resulting in ventricular fibrillation and asystole. Individuals with underlying cardiac and/or pulmonary disease and preexisting conditions such as Wolff-Parkinson-White syndrome are especially at risk for heart failure and fatal arrhythmias when using MDMA. Set and setting likely play a role in the development of some Ecstasy-related adverse reports, such as vigorous exercise, lack of attention to somatic cues, and too little or too much hydration combined with pharmacological action on AVP, resulting in hyperthermia or hyponatremia. Even if ambient temperature does less to moderate the effects of MDMA on body temperature than originally believed based on animal studies, other environmental and behavioral factors, as those related to vigorous exercise, may be involved. Overall, the risks of serious reports appear to be minimal in controlled settings with adequate screening according to eligibility criteria defined in study protocols. None of these events have occurred within the context of human clinical studies with MDMA, likely due to careful screening for pre-existing risk factors and limited exposure in a controlled clinical setting.

6.3 Physiological Effects

MDMA is responsible for a series of dose dependent physiological effects due to enhanced neurochemical release of serotonin, norepinephrine, and dopamine, and for indirect effects on hormone secretion, including oxytocin and AVP, which act on different target organs to modulate physiological functions in the body. Active doses of MDMA (75 mg to 150 mg), alone or followed by a supplemental half-dose 1.5 to 2.5 hours later, are expected to produce statistically significant but transient, self-limited increases in blood pressure, heart rate, and body temperature that are likely to be well tolerated by healthy individuals. The elevation of blood pressure and increased heart rate produced by MDMA, like that produced by other sympathomimetic drugs, can lead to additional complications in people with pre-existing medical conditions that increase risk. In combination with clinical signs and symptoms, elevations in pulse and blood pressure can also lead to cardiac events, such as arrhythmias. No clinical studies have reported clinically important changes in physiological parameters.

Subjects enrolled in controlled Phase 1 single dose MDMA trials conducted without sponsor support had elevations above a pre-determined cut-off of at least 140/90 mmHg (approximately 5% per trial). All subjects in a subsequent trial in a separate sample given a regimen of 50 mg followed by 100 mg 2 hours later had blood pressure elevations above 140/90 mmHg. Based on the literature, effects of the initial dose of MDMA on blood pressure and heart rate are expected to have a linear dose-response relationship, and the supplemental dose may have an effect on SBP elevation. In sponsor-supported studies, SBP above 160 mmHg was detected in 27% of experimental sessions where MDMA was administered at any dose, and in 35% of subjects in sponsor-supported trials overall. The majority of these instances occurred with the 125 mg MDMA dose group. Both peak and longest duration of blood pressure elevation were also observed in the 125 mg MDMA group. Maximum duration of SBP above 160 mmHg was 6 hours in two subjects with peak values of 172 and 174, respectively. MDMA doses of 40 mg and greater were associated with SBP above 160 mmHg, supporting a dose dependent effect of MDMA on blood pressure. DBP above 110 mmHg was observed in only 5% of experimental sessions with MDMA at any dose in 7% of subjects. The majority of these instances occurred with the 125 mg MDMA dose. Maximum duration of DBP above 110 mmHg was 5 hours. Heart rate above 110 bpm was detected in 31% experimental sessions where MDMA was administered at any dose, in 39% of subjects in sponsor-supported trials. Both peak and maximum duration above 110 bpm were observed in 125 mg MDMA sessions. The highest pulse observed was 160 bpm for 1 hour. Maximum duration above 110 bpm was 9.5 hours. A comparison of subjects receiving the supplemental dose to those who only received the initial dose in MP-1 indicate that the supplemental dose did not cause further elevation in blood pressure and heart rate beyond the initial dose.

Candidates with controlled hypertension are excluded from participation in all but one of sponsor-supported studies to limit cardiovascular risk during treatments. In MP-8, the only study that did enroll a sub-group of subjects with controlled hypertension, SBP above 160 mmHg was detected in 75% (3 of 4) of subjects and 67% (8 of 12) of experimental sessions where MDMA was administered to this sub-group. The prevalence of these elevations appears higher in this sub-group than the overall sample, although the prevalence could decrease in a larger group. Pre-drug SBP was typically higher in this sub-group, and peak SBP of these subjects was typically at the upper end of the range of the overall sample. Final SBP readings remained 11 to 14 mmHg higher than pre-drug SBP readings in one of three subjects. The single subject with extended duration of SBP elevation had a medical history of both hypertension and hyperlipidemia. The same subject had DBP above 110 mmHg in each experimental session, suggesting that pre-existing cardiovascular risk factors beyond hypertension itself may be associated with further elevations in

blood pressure, though a larger sample would be needed to establish this. None of the subjects with controlled hypertension experienced AEs of the cardiovascular system.

Literature on epidemiological studies suggest a relationship between Ecstasy dose and likelihood of hyperthermia. Hyperthermia has occurred in people using Ecstasy in unsupervised and non-medical conditions, and though rare, is one of the most frequently reported serious adverse reports occurring in Ecstasy users. Environmental and behavioral factors, as well as thyroid dysregulation, may contribute to case reports and preclinical findings of hyperthermia. Findings from previous Phase 1 trials indicate that MDMA administered in a controlled setting produces a statistically but not clinically significant increase in body temperature (mean elevation of 0.6°C). The supplemental dose may limit elevations in body temperature, since it inhibits metabolism of MDMA to its bioactive metabolite MDA. MDA levels have been demonstrated to correlate with elevation in temperature in rodents. Unlike rodents, ambient temperature does not effect elevation in core temperature in humans. Controlled clinical settings have been sufficient to manage body temperature in humans.

Body temperature greater than 1°C above baseline was detected in 33% of experimental sessions in which MDMA was administered at any dose, in 46% of subjects in sponsor-supported trials, with most of these cases observed in sessions with 125 mg MDMA. In contrast, in 7% of experimental sessions in which inactive placebo was administered, and in 14% of subjects receiving inactive placebo, elevation of body temperature above cut-off was observed. Both peak and longest duration of body temperature elevation were observed in the 125 mg MDMA group. Maximum peak in all sessions was 38.7°C lasting 3 hours, and maximum duration of elevation in all sessions was 9.2 hours, in separate subjects. Vital signs in sponsor-supported Phase 2 studies presented above suggest a dose-dependent action on SBP and pulse, which is consistent with the literature on healthy volunteers. Body temperature and DBP do not appear to be strongly related to MDMA dose. No subjects receiving MDMA in sponsor-supported clinical trials have required any clinical interventions for elevated vital signs, as all values returned to normal as the effects of MDMA diminish.

6.3.1 Immunological Effects

Humans exhibit transient immunological changes after a dose of 100 mg, including reduced numbers of CD4 cells, increased numbers of NK cells, and an increase in levels of immunosuppressive and anti-inflammatory cytokines compared with levels of pro-inflammatory and immunostimulating cytokines. In several respects, these effects are similar to those that occur with other psychoactive substances, so are not unique to MDMA. Immunological effects last for approximately 24 hours after administration, and most arise indirectly from serotonin release. The significance of these immunological effects remains unclear. Previous reports did not show increases in infections after MDMA and data from the study of MDMA-assisted psychotherapy has reported only instances of infection (upper respiratory or urinary tract) within 7 days of MDMA administration. Based on results from trials conducted by the sponsor, the impact of these effects is expected to be modest. The investigators may exclude subjects that might face additional risks from immunosuppression.

6.3.2 Hepatic Effects

Phase 1 studies conducted outside of sponsor support involving administration of MDMA to healthy volunteers have not published any results of liver function after MDMA administration. There have been no reported adverse effects on the liver from these studies. The first two sponsor-supported Phase 2 studies (MP-1, MP-2) assessed liver function after completion of two or three blinded experimental sessions. No clinically or statistically significant changes in liver

function occurred in MP-1. Values for laboratory tests were within the normal range in MP-1. No AEs related to liver function have been reported in subsequent sponsor-supported studies. Only two subjects in the MP-2 study reported two clinically significant hepatic abnormalities, with one likely due to hereditary factors and the other indicating inflammation in a subject with a medical history of breast cancer 3 months after the last administration of MDMA as an AE unrelated to the study drug.

6.4 Suicidal Ideation, Behavior, and Depression

There is high incidence of suicidal ideation and behavior in populations of people with PTSD, especially those suffering from chronic, treatment resistant PTSD. In order to determine if suicidal ideation and behavior worsens or improves after treatment in MAPS-sponsored trials, the C-SSRS is administered repeatedly throughout the study. Due to the nature of the therapeutic method, wherein a person may re-experience emotions associated with the traumatic event in order to reprocess the memory in a new, therapeutic way, thoughts of ending one's life may surface during this process. However, evidence from ongoing studies indicates that these thoughts are most often transient, returning to baseline, or even improving during the acute period following MDMA treatment. C-SSRS scores have escalated during the preparatory sessions (before any drug administration), which is thought to be a result of preparatory discussion of traumatic experiences, and/or of subjects tapering off long-prescribed medications, such as SSRIs and benzodiazepines. Withdrawal of these drugs is known induce suicidal ideation or behavior in some people. During both non-drug and MDMA-assisted psychotherapy sessions, subjects are asked to think about and discuss their experiences, thoughts, and emotions related to their condition. They may experience intense emotional responses to recalling and speaking about this material. As MDMA is only administered in combination with psychotherapy, the distress associated with psychotherapy is unavoidable, and is considered a necessary part of the therapeutic process that requires proper facilitation and support from therapists.

Overall the incidence of serious suicidal ideation or behavior in sponsor-supported studies is low, occurring in only a few subjects post-MDMA treatment, and returning to non-life-threatening scores while subjects are closely monitored. Given that people suffering from severe PTSD are known to experience suicidal ideation and behavior, it is difficult to identify a single cause of the increase in suicidal thinking or behavior (i.e. exacerbation of PTSD symptoms related to medication withdrawal or to the psychotherapeutic process, or from MDMA effects). A large percentage of people enrolled in the studies reported suicidal ideation and behavior during sometime in their lives prior to study enrollment, which may reflect a manifestation of PTSD or co-morbid affective disorders. When positive serious ideation or behavior occurred after study enrollment, the investigators made follow-up observations of C-SSRS to ensure subject safety, and tracked scores until they returned to non-serious levels. Only two incidences of suicidal ideation have been considered clinically significant and tracked as severe AEs, but they were reported during the long-term follow-up period and were not related to study drug.

6.5 Adverse Events

Overall, adverse effects of MDMA are modest and generally have not been associated with serious discomfort in healthy volunteers or in people with PTSD. Risks posed by sympathomimetic effects of MDMA treatments are addressed in MAPS' clinical trials by excluding people with pre-existing cardiovascular disease, cerebrovascular disease or uncontrolled hypertension and by monitoring blood pressure, body temperature, and pulse. Common reactions reported in clinical trials are transient and diminish as drug effects wane during the MDMA session and over the next 24 hours. Once the drug leaves the body, 3 to 4 days post-treatment, most reactions diminish. Reactions are monitored daily for 1 week after each

treatment and followed until resolution. The most common acute reactions at any severity include muscle tension in the jaw, exacerbation of anxiety, decreased appetite, muscle tension, nausea, and feeling cold. Headache and fatigue are commonly reported across MDMA and placebo groups, and are likely to be background events. During the week after each experimental session, the most commonly reported reactions at any severity were anxiety, fatigue, insomnia, depressed mood, hypersomnia, difficulty concentrating, decreased appetite, and dizziness in the active dose MDMA groups across studies, with PTSD studies overrepresented. Of these reactions, only decreased appetite and dizziness were appreciably elevated above the placebo group, and the remaining reactions are likely to be background events. Severe unexpected AEs included abdominal cramps, panic attacks, and the following reactions lasting longer than 7 days: anxiety, headache, low mood, rumination, and restlessness, all reported in studies of MDMA-assisted psychotherapy for PTSD. All subjects fully recovered from these events.

Unexpected and expected SAEs related to administration of MDMA in MAPS-sponsored clinical trials have been rare and none have been life threatening. One probably drug-related expected SAE has occurred to date in this clinical development program. This event was an increase in frequency of ventricular extrasystoles experienced during treatment with 125 mg MDMA, which resolved with full recovery to baseline after the study drug's effects ceased. The subject was hospitalized for observation and recovered fully after the event, with no cardiac damage. Excluding people with cerebrovascular or cardiovascular disease will reduce the likelihood of risks arising from the cardiovascular effects of MDMA.

6.6 Risk Mitigation in MDMA-Assisted Clinical Trials

Investigators must establish subject eligibility prior to enrollment in trials with MDMA, with eligibility established through medical history, physical examination, vital signs, clinical laboratory tests, EKG, psychiatric interview, and assessment of relevant psychiatric symptoms. Additional procedures may be used as indicated, such as exercise tests and carotid ultrasound imaging. If the study is investigating use of MDMA in people with a specific psychiatric condition, then the investigators must also determine whether an individual has the condition and that specified exclusion criteria are absent.

MDMA-assisted psychotherapy clinical trials use questionnaire-based measures and clinical interviews that can cause testing fatigue and/or emotional reactions stemming from discussing trauma or other psychological stressors. Investigators should be experienced in treating the condition under investigation and they should seek to minimize testing fatigue and emotional stress during screening and participation in the study. Subjects enrolled in studies of MDMA-assisted psychotherapy should be prepared to engage in processing their trauma, which requires proper facilitation and support from study therapists. MDMA-assisted psychotherapy will always be performed in controlled clinical settings to mitigate risk. It is best to ensure that the controlled setting for treatments with MDMA-assisted psychotherapy has the capacity to control ambient temperature for subject comfort, though there is no evidence that this will significantly influence or is needed for control of core body temperature. Cardiovascular risk is primarily mitigated through rigorous screening to exclude subjects with uncontrolled cardiovascular risk. During experimental sessions, therapists should monitor for clinical signs and symptoms (severe headache, confusion or focal neurologic signs, vision problems, chest pain, difficulty breathing, or palpitations) and add more frequent vitals measurements only if clinically indicated. Investigators conducting trials of MDMA should be prepared to treat elevated blood pressure with medications if needed, and either to provide appropriate care related to these effects or to transport individuals to an emergency department, if necessary.

Discontinuing pre-study medications and the acute/sub-acute effects of MDMA-assisted psychotherapy can produce shifts in mood and activation, which may transiently increase likelihood of suicidal ideation or behavior. In addition, during treatment of subjects with prevalent lifetime history of suicidal ideation, the active dose of MDMA, which catalyzes the therapeutic process, can be associated with suicidal ideation as a result of processing trauma. To mitigate risk, subjects are kept under continuous clinical observation during experimental sessions. Experimental sessions are followed by an overnight residential stay at the study site to allow the integration process to begin, followed by an integrative psychotherapy session on the following day, daily phone contact for 1 week, with channels of easy access to the treating therapists maintained during the studies. The need for additional support in these studies is continually assessed with the General Well Being and AE monitoring. Due to the psychotherapeutic setting in which MDMA is provided in these studies, exacerbations of symptoms often appear to be related to the therapeutic process rather than directly to the MDMA itself. When assessing potential AEs, investigators should consider baseline severity of conditions and symptoms, therapeutic process, and potential relationship to drug administration throughout the study.

In sponsor-supported studies, 18% of people across active dose and comparator dose groups experienced periods of increased anxiety (2% severe) and 3% experienced panic attacks, all in the active dose MDMA group (2% severe). Psychological distress may arise at any time during an MDMA-assisted psychotherapy session from the time of first drug effects until effects have dissipated approximately 3 to 5 hours after administration. Anxiety or distress during the session may last for as little as 15 minutes or for as long as 5 hours or more and may be related to the therapeutic process itself. In addition, psychological distress could arise following an MDMA session as a result of subjects having difficulty integrating their experience after the effects of MDMA have subsided. In previous Phase 1 and Phase 2 studies, these symptoms have been modest and self-limiting, and have responded well to reassurance from the investigator, with occasional use of benzodiazepines for anxiety after the experimental session. In clinical trials of PTSD treatment, subjects are informed that experimental sessions are intended to include periods of confronting and working through traumatic experiences. Hence signs of psychological distress, anxiety, or other unpleasant psychological reactions are to be expected and may be considered an element of the psychotherapeutic process. In Phase 1 trials with normal healthy volunteers, mild anxiety and depressed mood were reported by some subjects 1 to 3 days after MDMA administration. It is not known whether these reactions resulted from direct effects of MDMA, or from psychological content that may have been accessed during the MDMA experience.

The potential for destabilizing psychological distress can be minimized by:

- Exclusion of people who might be more vulnerable to psychological destabilization if tapered off other psychiatric drugs, such as people diagnosed with bipolar affective disorder-1 or those with psychotic disorders.
- Preparatory non-drug psychotherapy sessions before the experimental session
- An atmosphere of trust during the experimental session
- Close monitoring of the subject
- Daily contact with subjects for the period of 1 week after the experimental session, and availability of therapists at other times as needed.
- Non-drug integrative psychotherapy sessions
- Having subjects remain at the study site for the night of each experimental session to provide an optimal opportunity for rest and reflection following MDMA-assisted sessions, as part of the integration process.
- Availability of qualified personnel, such as a trained attendant during the overnight stay to support rest and integration of the experience.

Every effort is made to help subjects resolve difficult symptoms and to arrive at a more comfortable and relaxed state by the conclusion of the session. Such efforts include empathic listening on the part of the investigators and affect management techniques, such as diaphragmatic breathing by subjects.

At the end of any experimental session, if the subject is still severely agitated or experiencing any other severe psychological distress, the following measures should be taken:

1. If the subject is anxious, agitated, and/or in danger of any self-harm or is suicidal at the end of the MDMA session, the investigators are available to remain with the subject for at least two more hours. During this time, the investigators use affect management techniques reviewed during the introductory sessions and talk with the subject to help him or her gain cognitive perspective about their experience. If this situation should occur during an integrative therapy session, the same approach should be used, and at least one of the investigators will remain available to stay with the subject for at least two additional hours.
2. If a subject remains severely anxious, agitated or in danger of self-harm or suicide, or is otherwise psychologically unstable at the end of this 2-hour stabilization period, the clinical investigator decides between the following options:

    a. A psychiatric nurse, therapeutic assistant, or therapist will stay with the subject until the time of his or her appointment with investigators the next day. The investigators then meet with the subject daily until the period of destabilization has passed.
    b. If a subject experiences severe, persisting emotional distress, such as panic attacks, severe generalized anxiety, or insomnia following an MDMA session, the investigator may prescribe a drug with a short half-life as a "rescue medication." Investigators should not prescribe an SSRI, SNRI, or MAOI in this context unless it is determined that such treatment is clinically necessary and the subject will be terminated from study participation. Residual symptoms are addressed during the frequent follow-up psychotherapy visits with the investigators.
    c. Hospitalization for stabilization. If a subject should become psychotic, or if for any reason the investigators deem it necessary for safety, arrangements are made to stabilize and transfer him or her to the study site inpatient unit or the nearest appropriate inpatient psychiatric facility.

Subjects hospitalized after a severe panic reaction or other adverse psychological reaction would be suspended from further participation in the trial until after recovery or stabilization, at which time the investigator would carefully evaluate the subject's emotional status and decide whether or not the subject may continue the study. For those subjects engaged in an ongoing therapeutic relationship with a psychotherapist or psychiatrist, the subject's outside therapists are involved in the management of any psychiatric complications.

6.7 Abuse Potential

Despite its classification as a Schedule I drug, an examination of findings in humans and animals suggests that MDMA possesses moderate abuse potential that is higher than that reported for "classic hallucinogens" like psilocybin, but lower than that reported for psychostimulants, such as cocaine or methamphetamine. Studies assessing prevalence of problematic Ecstasy use or dependence suggest that a small percentage of individuals, especially those with prior psychological difficulties, may develop problematic Ecstasy use or dependence. In two published studies of MDMA-assisted psychotherapy for people with PTSD, only one of 32 subjects reported

using Ecstasy subsequent to study participation, and several subjects volunteered that they would not seek out Ecstasy outside of a psychotherapeutic setting. Diversion is not an issue for sponsor-supported studies because MDMA will only be administered under the supervision of the clinical investigator and no take-home doses are permitted. MDMA is handled following all regulations pertaining to the handling and dispensing of controlled substances within research studies.

7.0 Conclusion

Based on the current state of scientific knowledge, the risk for subjects meeting criteria for clinical studies who are exposed to MDMA at the single intermittent dosing schedule used in sponsor-supported studies appears to be low. The overall rates of AEs and reactions across phase 2 studies are low and the reactions and AEs are self-limiting. A number of the AEs and expected reactions reported in the studies are likely related to background events representing the underlying illness being treated, or the expected result of psychotherapy addressing traumatic experiences.

Future studies conducted by the sponsor are intended to further develop the safety profile of MDMA in the PTSD subject population. In addition, the sponsor is examining the use of MDMA-assisted psychotherapy in the treatment of anxiety, including social anxiety in people on the autistic spectrum and anxiety resulting from a life-threatening illness. MDMA-assisted psychotherapy appears to be a promising treatment method for chronic PTSD. More clinical trials in larger subject populations are warranted. It is hoped that MDMA, with it's unique pharmacological mechanisms combined with a novel mode of administration in conjunction with psychotherapy, can improve upon first line PTSD and anxiety treatments in terms of side effect profiles, efficacy and duration of effect.

8.0 References

References

1. Beck, J. and M. Rosenbaum, *In Pursuit of Ecstasy: The MDMA Experience*. 1994, Albany, NY: SUNY Press.
2. Solowij, N., W. Hall, and N. Lee, *Recreational MDMA use in Sydney: a profile of 'Ecstacy' users and their experiences with the drug.* Br J Addict, 1992. **87**(8): p. 1161-72.
3. Carlson, R.G., et al., *Drug use practices among MDMA/ecstasy users in Ohio: a latent class analysis.* Drug Alcohol Depend, 2005. **79**(2): p. 167-79.
4. Sumnall, H.R., J.C. Cole, and L. Jerome, *The varieties of ecstatic experience: an exploration of the subjective experiences of ecstasy.* J Psychopharmacol, 2006. **20**(5): p. 670-82.
5. Cole, J.C. and H.R. Sumnall, *Altered states: the clinical effects of Ecstasy.* Pharmacol Ther, 2003. **98**(1): p. 35-58.
6. Shulgin, A.T., *The background and chemistry of MDMA.* J Psychoactive Drugs, 1986. **18**(4): p. 291-304.
7. Kolbrich, E.A., et al., *Physiological and subjective responses to controlled oral 3,4-methylenedioxymethamphetamine administration.* J Clin Psychopharmacol, 2008. **28**(4): p. 432-40.
8. Cami, J., et al., *Human pharmacology of 3,4-methylenedioxymethamphetamine ("ecstasy"): psychomotor performance and subjective effects.* J Clin Psychopharmacol, 2000. **20**(4): p. 455-66.
9. Mas, M., et al., *Cardiovascular and neuroendocrine effects and pharmacokinetics of 3, 4-methylenedioxymethamphetamine in humans.* J Pharmacol Exp Ther, 1999. **290**(1): p. 136-45.
10. Liechti, M.E., A. Gamma, and F.X. Vollenweider, *Gender differences in the subjective effects of MDMA.* Psychopharmacology (Berl), 2001. **154**(2): p. 161-8.
11. Tancer, M. and C.E. Johanson, *Reinforcing, subjective, and physiological effects of MDMA in humans: a comparison with d-amphetamine and mCPP.* Drug Alcohol Depend, 2003. **72**(1): p. 33-44.
12. Harris, D.S., et al., *Subjective and hormonal effects of 3,4-methylenedioxymethamphetamine (MDMA) in humans.* Psychopharmacology (Berl), 2002. **162**(4): p. 396-405.
13. Vollenweider, F.X., et al., *Psychological and cardiovascular effects and short-term sequelae of MDMA ("ecstasy") in MDMA-naive healthy volunteers.* Neuropsychopharmacology, 1998. **19**(4): p. 241-51.
14. de la Torre, R., et al., *Non-linear pharmacokinetics of MDMA ('ecstasy') in humans.* Br J Clin Pharmacol, 2000. **49**(2): p. 104-9.
15. Marks, D.M., C.U. Pae, and A.A. Patkar, *Triple reuptake inhibitors: a premise and promise.* Psychiatry Investig, 2008. **5**(3): p. 142-7.
16. Millan, M.J., *Dual- and triple-acting agents for treating core and co-morbid symptoms of major depression: novel concepts, new drugs.* Neurotherapeutics, 2009. **6**(1): p. 53-77.
17. Bonkale, W.L. and M.C. Austin, *3,4-Methylenedioxymethamphetamine induces differential regulation of tryptophan hydroxylase 2 protein and mRNA levels in the rat dorsal raphe nucleus.* Neuroscience, 2008. **155**(1): p. 270-6.
18. Schenk, S., et al., *Effects of repeated exposure to MDMA on 5HT1a autoreceptor function: behavioral and neurochemical responses to 8-OHDPAT.* Psychopharmacology (Berl), 2013. **227**(2): p. 355-61.
19. Hysek, C.M., et al., *MDMA enhances emotional empathy and prosocial behavior.* Soc Cogn Affect Neurosci, 2014. **9**(11): p. 1645-52.
20. Adori, C., et al., *Recovery and aging of serotonergic fibers after single and intermittent MDMA treatment in Dark Agouti rat.* J Comp Neurol, 2011. **519**(12): p. 2353-78.

21. Han, D.D. and H.H. Gu, *Comparison of the monoamine transporters from human and mouse in their sensitivities to psychostimulant drugs.* BMC Pharmacol, 2006. **6**: p. 6.
22. Liechti, M.E. and F.X. Vollenweider, *Which neuroreceptors mediate the subjective effects of MDMA in humans? A summary of mechanistic studies.* Hum Psychopharmacol, 2001. **16**(8): p. 589-598.
23. Murnane, K.S., et al., *Endocrine and neurochemical effects of 3,4-methylenedioxymethamphetamine and its stereoisomers in rhesus monkeys.* J Pharmacol Exp Ther, 2010. **334**(2): p. 642-50.
24. Setola, V., et al., *3,4-methylenedioxymethamphetamine (MDMA, "Ecstasy") induces fenfluramine-like proliferative actions on human cardiac valvular interstitial cells in vitro.* Mol Pharmacol, 2003. **63**(6): p. 1223-9.
25. Simmler, L.D., et al., *Monoamine transporter and receptor interaction profiles of a new series of designer cathinones.* Neuropharmacology, 2014. **79**: p. 152-60.
26. Bedi, G., et al., *Effects of MDMA on sociability and neural response to social threat and social reward.* Psychopharmacology (Berl), 2009. **207**(1): p. 73-83.
27. Carhart-Harris, R.L., et al., *The Effects of Acutely Administered 3,4-Methylenedioxymethamphetamine on Spontaneous Brain Function in Healthy Volunteers Measured with Arterial Spin Labeling and Blood Oxygen Level-Dependent Resting State Functional Connectivity.* Biol Psychiatry, 2015. **78**(8): p. 554-62.
28. Gamma, A., et al., *3,4-Methylenedioxymethamphetamine (MDMA) modulates cortical and limbic brain activity as measured by [H(2)(15)O]-PET in healthy humans.* Neuropsychopharmacology, 2000. **23**(4): p. 388-95.
29. Dumont, G.J., et al., *Increased oxytocin concentrations and prosocial feelings in humans after ecstasy (3,4-methylenedioxymethamphetamine) administration.* Soc Neurosci, 2009. **4**(4): p. 359-66.
30. Hysek, C.M., G. Domes, and M.E. Liechti, *MDMA enhances "mind reading" of positive emotions and impairs "mind reading" of negative emotions.* Psychopharmacology (Berl), 2012. **222**(2): p. 293-302.
31. Kirkpatrick, M.G., et al., *Plasma oxytocin concentrations following MDMA or intranasal oxytocin in humans.* Psychoneuroendocrinology, 2014. **46**: p. 23-31.
32. Wolff, K., et al., *Vasopressin and oxytocin secretion in response to the consumption of ecstasy in a clubbing population.* J Psychopharmacol, 2006. **20**(3): p. 400-10.
33. Fallon, J.K., et al., *Action of MDMA (ecstasy) and its metabolites on arginine vasopressin release.* Ann N Y Acad Sci, 2002. **965**: p. 399-409.
34. Schmid, Y., et al., *Differential effects of MDMA and methylphenidate on social cognition.* J Psychopharmacol, 2014. **28**(9): p. 847-56.
35. Bedi, G., D. Hyman, and H. de Wit, *Is ecstasy an "empathogen"? Effects of +/-3,4-methylenedioxymethamphetamine on prosocial feelings and identification of emotional states in others.* Biol Psychiatry, 2010. **68**(12): p. 1134-40.
36. Carhart-Harris, R.L., et al., *The effect of acutely administered MDMA on subjective and BOLD-fMRI responses to favourite and worst autobiographical memories.* Int J Neuropsychopharmacol, 2014. **17**(4): p. 527-40.
37. Bedi, G., et al., *A window into the intoxicated mind? Speech as an index of psychoactive drug effects.* Neuropsychopharmacology, 2014. **39**(10): p. 2340-8.
38. Wardle, M.C., M.G. Kirkpatrick, and H. de Wit, *'Ecstasy' as a social drug: MDMA preferentially affects responses to emotional stimuli with social content.* Soc Cogn Affect Neurosci, 2014. **9**(8): p. 1076-81.
39. Wardle, M.C. and H. de Wit, *MDMA alters emotional processing and facilitates positive social interaction.* Psychopharmacology (Berl), 2014. **231**(21): p. 4219-29.
40. Danforth, A., *Findings from a collective case study of the MDMA/Ecstasy experiences of adults on the autism spectrum: Transcripts from Psychedelic Science 2013.* MAPS Bulletin, 2013. **23**(3): p. 30-35.

41. Mithoefer, M.C., et al., *The safety and efficacy of {+/-}3,4-methylenedioxymethamphetamine-assisted psychotherapy in subjects with chronic, treatment-resistant posttraumatic stress disorder: the first randomized controlled pilot study.* J Psychopharmacol, 2011. **25**(4): p. 439-52.
42. Mithoefer, M.C., et al., *Durability of improvement in post-traumatic stress disorder symptoms and absence of harmful effects or drug dependency after 3,4-methylenedioxymethamphetamine-assisted psychotherapy: a prospective long-term follow-up study.* J Psychopharmacol, 2013. **27**(1): p. 28-39.
43. Oehen, P., et al., *A randomized, controlled pilot study of MDMA (+/- 3,4-Methylenedioxymethamphetamine)-assisted psychotherapy for treatment of resistant, chronic Post-Traumatic Stress Disorder (PTSD).* J Psychopharmacol, 2013. **27**(1): p. 40-52.
44. Downing, J., *The psychological and physiological effects of MDMA on normal volunteers.* J Psychoactive Drugs, 1986. **18**(4): p. 335-40.
45. Lester, S.J., et al., *Cardiovascular effects of 3,4-methylenedioxymethamphetamine. A double-blind, placebo-controlled trial.* Ann Intern Med, 2000. **133**(12): p. 969-73.
46. Kirkpatrick, M.G., et al., *A direct comparison of the behavioral and physiological effects of methamphetamine and 3,4-methylenedioxymethamphetamine (MDMA) in humans.* Psychopharmacology (Berl), 2012. **219**(1): p. 109-22.
47. Grob, C.S., et al., *Psychobiologic effects of 3,4-methylenedioxymethamphetamine in humans: methodological considerations and preliminary observations.* Behav Brain Res, 1996. **73**(1-2): p. 103-7.
48. Pacifici, R., et al., *[Immunomodulator properties of ecstasy (MDMA)].* Ann Ist Super Sanita, 2000. **36**(1): p. 69-75.
49. Baggott, M.J., *Preventing problems in Ecstasy users: reduce use to reduce harm.* J Psychoactive Drugs, 2002. **34**(2): p. 145-62.
50. Gore, S.M., *Fatal uncertainty: death-rate from use of ecstasy or heroin.* Lancet, 1999. **354**(9186): p. 1265-6.
51. Hall, A.P. and J.A. Henry, *Acute toxic effects of 'Ecstasy' (MDMA) and related compounds: overview of pathophysiology and clinical management.* Br J Anaesth, 2006. **96**(6): p. 678-85.
52. Liechti, M.E., I. Kunz, and H. Kupferschmidt, *Acute medical problems due to Ecstasy use. Case-series of emergency department visits.* Swiss Med Wkly, 2005. **135**(43-44): p. 652-7.
53. Rogers, G., et al., *The harmful health effects of recreational ecstasy: a systematic review of observational evidence.* Health Technol Assess, 2009. **13**(6): p. iii-iv, ix-xii, 1-315.
54. Rosenson, J., et al., *Patterns of ecstasy-associated hyponatremia in California.* Ann Emerg Med, 2007. **49**(2): p. 164-71, 171 e1.
55. Williams, H., et al., *"Saturday night fever": ecstasy related problems in a London accident and emergency department.* J Accid Emerg Med, 1998. **15**(5): p. 322-6.
56. Freudenmann, R.W., F. Oxler, and S. Bernschneider-Reif, *The origin of MDMA (ecstasy) revisited: the true story reconstructed from the original documents.* Addiction, 2006. **101**(9): p. 1241-5.
57. Shulgin, A. and A. Shulgin, *Pihkal: A Chemical Love Story*. 1st ed. 1991, Berkeley, CA: Transform Press. 1-978.
58. Anderson, G.M.d., et al., *Absolute configuration and psychotomimetic activity.* NIDA Res Monogr, 1978. **22**: p. 8-15.
59. Shulgin, A.T. and D.E. Nichols, *Characterization of three new psychotomimetics*, in *The Pharmacology of Hallucinogens*, R.C. Stillman and R.E. Willette, Editors. 1978, Pergamon: New York.

60. Rudnick, G. and S.C. Wall, *The molecular mechanism of "ecstasy" [3,4-methylenedioxy-methamphetamine (MDMA)]: serotonin transporters are targets for MDMA-induced serotonin release.* Proc Natl Acad Sci U S A, 1992. **89**(5): p. 1817-21.
61. O'Neil, M.J., *The Merck Index: An Encyclopedia of chemicals, drugs and biologicals. Merck Research Laboratories, Merck and Co.* Inc, Whitehouse station, New Jersey, 2006. **319**.
62. Greer, G. and R. Tolbert, *Subjective reports of the effects of MDMA in a clinical setting.* J Psychoactive Drugs, 1986. **18**(4): p. 319-27.
63. Kirkpatrick, M.G., et al., *Effects of MDMA and Intranasal oxytocin on social and emotional processing.* Neuropsychopharmacology, 2014. **39**(7): p. 1654-63.
64. Adamson, S., *Through the gateway of the heart: Accounts of experiences With MDMA and other empathogenic substances*. 1985, San Francisco CA: Four Trees Publications.
65. Grinspoon, L. and J.B. Bakalar, *Can drugs be used to enhance the psychotherapeutic process?* Am J Psychother, 1986. **40**(3): p. 393-404.
66. Nichols, D.E., *Differences between the mechanism of action of MDMA, MBDB, and the classic hallucinogens. Identification of a new therapeutic class: entactogens.* J Psychoactive Drugs, 1986. **18**(4): p. 305-13.
67. Greer, G. and R.J. Strassman, *Information on "Ecstasy".* Am J Psychiatry, 1985. **142**(11): p. 1391.
68. Greer, G.R. and R. Tolbert, *A method of conducting therapeutic sessions with MDMA.* J Psychoactive Drugs, 1998. **30**(4): p. 371-379.
69. Metzner, R. and S. Adamson, *Using MDMA in healing, psychotherapy and spiritual practice*, in *Ecstasy, A Complete Guide: A Comprehensive Look at the Risks and Benefits of MDMA.*, J. Holland, Editor. 2001, Inner Traditions: Rochester VT. p. 182-207.
70. Greer, G. and R. Tolbert, *The therapeutic use of MDMA.*, in *Ecstasy: The clinical, pharmacological and neurotoxicological effects of the drug MDMA.*, S.J. Peroutka, Editor. 1990, Kluver Academic: Boston, MA. p. 21-35.
71. Carlson, R.G., et al., *MDMA/Ecstasy use among young people in Ohio: perceived risk and barriers to intervention.* J Psychoactive Drugs, 2004. **36**(2): p. 181-9.
72. Substance Abuse and Mental Health Services Administration, *Results from the 2013 National Survey on Drug Use and Health: Summary of National Findings , NSDUH Series H-48*. 2014, Substance Abuse and Mental Health Services Administration,: Rockville, MD.
73. Drugs, E.M.C.f. and D. Addiction, *European Drug Report 2014: Trends and Developments*. 2015.
74. Drug Enforcement Agency, *Scheduling of Controlled Substances: Scheduling of 3,4-methylenedioxymethamphetamine (MDMA) into Schedule 1 of the Controlled Substances Act: Remand*, DEA, Editor. 1988, Federal Register: Washington, DC. p. 5156-5160.
75. Lawn, J.C., *On the Matter of MDMA Scheduling*, in *Docket No. 84-48*, Drug_Enforcement_Administration, Editor. 1986: Washington, DC.
76. Seiden, L.S. and K.E. Sabol, *Methamphetamine and methylenedioxymethamphetamine neurotoxicity: possible mechanisms of cell destruction.* NIDA Res Monogr, 1996. **163**: p. 251-76.
77. Baumann, M.H., X. Wang, and R.B. Rothman, *3,4-Methylenedioxymethamphetamine (MDMA) neurotoxicity in rats: a reappraisal of past and present findings.* Psychopharmacology (Berl), 2007. **189**(4): p. 407-24.
78. Baumann, M.H., et al., *Effects of dose and route of administration on pharmacokinetics of (+ or -)-3,4-methylenedioxymethamphetamine in the rat.* Drug Metab Dispos, 2009. **37**(11): p. 2163-70.
79. Mueller, F., et al., *Neuroimaging in moderate MDMA use: A systematic review.* Neurosci Biobehav Rev, 2015.

80. Henry, J.A., K.J. Jeffreys, and S. Dawling, *Toxicity and deaths from 3,4-methylenedioxymethamphetamine ("ecstasy").* Lancet, 1992. **340**(8816): p. 384-7.
81. Cohen, R.S. and J. Cocores, *Neuropsychiatric manifestations following the use of 3,4-methylenedioxymethamphetamine (MDMA: "Ecstasy").* Prog Neuropsychopharmacol Biol Psychiatry, 1997. **21**(4): p. 727-34.
82. Williamson, S., et al., *Adverse effects of stimulant drugs in a community sample of drug users.* Drug Alcohol Depend, 1997. **44**(2-3): p. 87-94.
83. Krystal, J.H., et al., *Chronic 3,4-methylenedioxymethamphetamine (MDMA) use: effects on mood and neuropsychological function?* Am J Drug Alcohol Abuse, 1992. **18**(3): p. 331-41.
84. McCann, U.D., et al., *Serotonin neurotoxicity after (+/-)3,4-methylenedioxymethamphetamine (MDMA; "Ecstasy"): a controlled study in humans.* Neuropsychopharmacology, 1994. **10**(2): p. 129-38.
85. McCann, U.D., et al., *Cognitive performance in (+/-) 3,4-methylenedioxymethamphetamine (MDMA, "ecstasy") users: a controlled study.* Psychopharmacology (Berl), 1999. **143**(4): p. 417-25.
86. Parrott, A.C. and J. Lasky, *Ecstasy (MDMA) effects upon mood and cognition: before, during and after a Saturday night dance.* Psychopharmacology (Berl), 1998. **139**(3): p. 261-8.
87. Ricaurte, G.A., et al., *Toxicodynamics and long-term toxicity of the recreational drug, 3, 4-methylenedioxymethamphetamine (MDMA, 'Ecstasy').* Toxicol Lett, 2000. **112-113**: p. 143-6.
88. Biezonski, D.K. and J.S. Meyer, *The Nature of 3, 4-Methylenedioxymethamphetamine (MDMA)-Induced Serotonergic Dysfunction: Evidence for and Against the Neurodegeneration Hypothesis.* Curr Neuropharmacol, 2011. **9**(1): p. 84-90.
89. Gouzoulis-Mayfrank, E. and J. Daumann, *The confounding problem of polydrug use in recreational ecstasy/MDMA users: a brief overview.* J Psychopharmacol, 2006. **20**(2): p. 188-93.
90. Bouso, J.C., *MDMA/PTSD research in Spain: An update.* MAPS Bulletin, 2003. **13**(1): p. 7-8.
91. Farre, M., et al., *Pharmacological interaction between 3,4-methylenedioxymethamphetamine (ecstasy) and paroxetine: pharmacological effects and pharmacokinetics.* J Pharmacol Exp Ther, 2007. **323**(3): p. 954-62.
92. van Wel, J.H., et al., *Effects of Acute MDMA Intoxication on Mood and Impulsivity: Role of the 5-HT(2) and 5-HT(1) Receptors.* PLoS One, 2012. **7**(7): p. e40187.
93. Lyon, R.A., R.A. Glennon, and M. Titeler, *3,4-Methylenedioxymethamphetamine (MDMA): stereoselective interactions at brain 5-HT1 and 5-HT2 receptors.* Psychopharmacology (Berl), 1986. **88**(4): p. 525-6.
94. Fantegrossi, W.E., et al., *Discriminative stimulus effects of 3,4-methylenedioxymethamphetamine and its enantiomers in mice: pharmacokinetic considerations.* J Pharmacol Exp Ther, 2009. **329**(3): p. 1006-15.
95. Yarosh, H.L., et al., *MDMA-like behavioral effects of N-substituted piperazines in the mouse.* Pharmacol Biochem Behav, 2007. **88**(1): p. 18-27.
96. Fantegrossi, W.E., et al., *3,4-Methylenedioxymethamphetamine (MDMA, "ecstasy") and its stereoisomers as reinforcers in rhesus monkeys: serotonergic involvement.* Psychopharmacology (Berl), 2002. **161**(4): p. 356-64.
97. Fantegrossi, W.E., et al., *Role of dopamine transporters in the behavioral effects of 3,4-methylenedioxymethamphetamine (MDMA) in nonhuman primates.* Psychopharmacology (Berl), 2009.
98. McClung, J., W. Fantegrossi, and L.L. Howell, *Reinstatement of extinguished amphetamine self-administration by 3,4-methylenedioxymethamphetamine (MDMA) and its enantiomers in rhesus monkeys.* Psychopharmacology (Berl), 2010. **210**(1): p. 75-83.

99. Murnane, K.S., et al., *The neuropharmacology of prolactin secretion elicited by 3,4-methylenedioxymethamphetamine ("ecstasy"): a concurrent microdialysis and plasma analysis study.* Horm Behav, 2012. **61**(2): p. 181-90.
100. Spitzer, M., et al., *Enantio-selective cognitive and brain activation effects of N-ethyl-3,4-methylenedioxyamphetamine in humans.* Neuropharmacology, 2001. **41**(2): p. 263-71.
101. Acquas, E., et al., *Differential effects of intravenous R,S-(+/-)-3,4-methylenedioxymethamphetamine (MDMA, Ecstasy) and its S(+)- and R(-)-enantiomers on dopamine transmission and extracellular signal regulated kinase phosphorylation (pERK) in the rat nucleus accumbens shell and core.* J Neurochem, 2007. **102**(1): p. 121-32.
102. Llabres, S., et al., *Molecular basis of the selective binding of MDMA enantiomers to the alpha4beta2 nicotinic receptor subtype: synthesis, pharmacological evaluation and mechanistic studies.* Eur J Med Chem, 2014. **81**: p. 35-46.
103. Navarro, M., et al., *Usefulness of saliva for measurement of 3,4-methylenedioxymethamphetamine and its metabolites: correlation with plasma drug concentrations and effect of salivary pH.* Clin Chem, 2001. **47**(10): p. 1788-95.
104. Kousik, S.M., T.C. Napier, and P.M. Carvey, *The effects of psychostimulant drugs on blood brain barrier function and neuroinflammation.* Front Pharmacol, 2012. **3**: p. 121.
105. Nichols, D.E., *Chromatographic Purity Of 3,4-Methylenedioxymethamphetamine Hydrochloride (MDMA Hydrochloride), Lot 5810-09*. 2006, Purdue University: Lafayette IN. p. 1-6.
106. Hardman, H.F., C.O. Haavik, and M.H. Seevers, *Relationship of the structure of mescaline and seven analogs to toxicity and behavior in five species of laboratory animals.* Toxicol Appl Pharmacol, 1973. **25**(2): p. 299-309.
107. Mechan, A., et al., *Pharmacokinetic profile of single and repeated oral doses of MDMA in squirrel monkeys: relationship to lasting effects on brain serotonin neurons.* Neuropsychopharmacology, 2006. **31**(2): p. 339-50.
108. Wang, X., et al., *(+/-)-3,4-Methylenedioxymethamphetamine administration to rats does not decrease levels of the serotonin transporter protein or alter its distribution between endosomes and the plasma membrane.* J Pharmacol Exp Ther, 2005. **314**(3): p. 1002-12.
109. Gaston, T.R., Rasmussen, G. T., *Identification of 3,4-methylenedioxy-n-methylamphetamine;*. Microgram, 1972. **5**: p. 60-63.
110. Baggott, M., et al., *Chemical analysis of ecstasy pills.* Jama, 2000. **284**(17): p. 2190.
111. Cole, J.C., et al., *The content of ecstasy tablets: implications for the study of their long-term effects.* Addiction, 2002. **97**(12): p. 1531-6.
112. Tanner-Smith, E.E., *Pharmacological content of tablets sold as "ecstasy": results from an online testing service.* Drug Alcohol Depend, 2006. **83**(3): p. 247-54.
113. de la Torre, R. and M. Farre, *Neurotoxicity of MDMA (ecstasy): the limitations of scaling from animals to humans.* Trends Pharmacol Sci, 2004. **25**(10): p. 505-8.
114. Concheiro, M., et al., *Nonlinear pharmacokinetics of (+/-)3,4-methylenedioxymethamphetamine (MDMA) and its pharmacodynamic consequences in the rat.* Drug Metab Dispos, 2014. **42**(1): p. 119-25.
115. Scheidweiler, K.B., et al., *(+/-)-3,4-methylenedioxymethamphetamine and metabolite disposition in plasma and striatum of wild-type and multidrug resistance protein 1a knock-out mice.* J Anal Toxicol, 2011. **35**(7): p. 470-80.
116. Kolbrich, E.A., et al., *Plasma pharmacokinetics of 3,4-methylenedioxymethamphetamine after controlled oral administration to young adults.* Ther Drug Monit, 2008. **30**(3): p. 320-32.
117. Pacifici, R., et al., *Acute effects of 3,4-methylenedioxymethamphetamine alone and in combination with ethanol on the immune system in humans.* J Pharmacol Exp Ther, 2001. **296**(1): p. 207-15.

118. Farre, M., et al., *Repeated doses administration of MDMA in humans: pharmacological effects and pharmacokinetics.* Psychopharmacology (Berl), 2004. **173**(3-4): p. 364-75.
119. Mueller, M., et al., *Direct comparison of (+/-) 3,4-methylenedioxymethamphetamine ("ecstasy") disposition and metabolism in squirrel monkeys and humans.* Ther Drug Monit, 2009. **31**(3): p. 367-73.
120. Mueller, M., et al., *Simultaneous liquid chromatographic-electrospray ionization mass spectrometric quantification of 3,4-methylenedioxymethamphetamine (MDMA, Ecstasy) and its metabolites 3,4-dihydroxymethamphetamine, 4-hydroxy-3-methoxymethamphetamine and 3,4-methylenedioxyamphetamine in squirrel monkey and human plasma after acidic conjugate cleavage.* Forensic Sci Int, 2009. **184**(1-3): p. 64-8.
121. Mueller, M., et al., *Nonlinear pharmacokinetics of (+/-)3,4-methylenedioxymethamphetamine (MDMA, "Ecstasy") and its major metabolites in squirrel monkeys at plasma concentrations of MDMA that develop after typical psychoactive doses.* J Pharmacol Exp Ther, 2008. **327**(1): p. 38-44.
122. Mueller, M., et al., *Metabolism and disposition of 3,4-methylenedioxymethamphetamine ("ecstasy") in baboons after oral administration: comparison with humans reveals marked differences.* J Pharmacol Exp Ther, 2011. **338**(1): p. 310-7.
123. Johnson, M.P., A.J. Hoffman, and D.E. Nichols, *Effects of the enantiomers of MDA, MDMA and related analogues on [3H]serotonin and [3H]dopamine release from superfused rat brain slices.* Eur J Pharmacol, 1986. **132**(2-3): p. 269-76.
124. Cole, J.C. and H.R. Sumnall, *The pre-clinical behavioural pharmacology of 3,4-methylenedioxymethamphetamine (MDMA).* Neurosci Biobehav Rev, 2003. **27**(3): p. 199-217.
125. Fitzgerald, J.L. and J.J. Reid, *Effects of methylenedioxymethamphetamine on the release of monoamines from rat brain slices.* Eur J Pharmacol, 1990. **191**(2): p. 217-20.
126. Kankaanpaa, A., et al., *The acute effects of amphetamine derivatives on extracellular serotonin and dopamine levels in rat nucleus accumbens.* Pharmacol Biochem Behav, 1998. **59**(4): p. 1003-9.
127. Verrico, C.D., G.M. Miller, and B.K. Madras, *MDMA (Ecstasy) and human dopamine, norepinephrine, and serotonin transporters: implications for MDMA-induced neurotoxicity and treatment.* Psychopharmacology (Berl), 2007. **189**(4): p. 489-503.
128. Cozzi, N.V., et al., *Inhibition of plasma membrane monoamine transporters by beta-ketoamphetamines.* Eur J Pharmacol, 1999. **381**(1): p. 63-9.
129. Partilla, J.S., et al., *Interaction of amphetamines and related compounds at the vesicular monoamine transporter.* J Pharmacol Exp Ther, 2006. **319**(1): p. 237-46.
130. Bogen, I.L., et al., *Short- and long-term effects of MDMA ("ecstasy") on synaptosomal and vesicular uptake of neurotransmitters in vitro and ex vivo.* Neurochem Int, 2003. **43**(4-5): p. 393-400.
131. Gu, X.F. and E.C. Azmitia, *Integrative transporter-mediated release from cytoplasmic and vesicular 5-hydroxytryptamine stores in cultured neurons.* Eur J Pharmacol, 1993. **235**(1): p. 51-7.
132. Leonardi, E.T. and E.C. Azmitia, *MDMA (ecstasy) inhibition of MAO type A and type B: comparisons with fenfluramine and fluoxetine (Prozac).* Neuropsychopharmacology, 1994. **10**(4): p. 231-8.
133. Pilgrim, J.L., et al., *Serotonin toxicity involving MDMA (ecstasy) and moclobemide.* Forensic Sci Int, 2012. **215**(1-3): p. 184-8.
134. Vuori, E., et al., *Death following ingestion of MDMA (ecstasy) and moclobemide.* Addiction, 2003. **98**(3): p. 365-8.
135. Slikker, W., Jr., et al., *Behavioral and neurochemical effects of orally administered MDMA in the rodent and nonhuman primate.* Neurotoxicology, 1989. **10**(3): p. 529-42.
136. Mlinar, B. and R. Corradetti, *Endogenous 5-HT, released by MDMA through serotonin transporter- and secretory vesicle-dependent mechanisms, reduces hippocampal*

excitatory synaptic transmission by preferential activation of 5-HT1B receptors located on CA1 pyramidal neurons. Eur J Neurosci, 2003. **18**(6): p. 1559-71.
137. Rothman, R.B. and M.H. Baumann, *Monoamine transporters and psychostimulant drugs.* Eur J Pharmacol, 2003. **479**(1-3): p. 23-40.
138. Gudelsky, G.A. and B.K. Yamamoto, *Actions of 3,4-methylenedioxymethamphetamine (MDMA) on cerebral dopaminergic, serotonergic and cholinergic neurons.* Pharmacol Biochem Behav, 2008. **90**(2): p. 198-207.
139. Feduccia, A.A., N. Kongovi, and C.L. Duvauchelle, *Heat increases MDMA-enhanced NAcc 5-HT and body temperature, but not MDMA self-administration.* Eur Neuropsychopharmacol, 2010. **20**(12): p. 884-94.
140. Yamamoto, B.K. and L.J. Spanos, *The acute effects of methylenedioxymethamphetamine on dopamine release in the awake-behaving rat.* Eur J Pharmacol, 1988. **148**(2): p. 195-203.
141. Shankaran, M. and G.A. Gudelsky, *Effect of 3,4-methylenedioxymethamphetamine (MDMA) on hippocampal dopamine and serotonin.* Pharmacol Biochem Behav, 1998. **61**(4): p. 361-6.
142. Bradbury, S., et al., *Acquisition of MDMA self-administration: pharmacokinetic factors and MDMA-induced serotonin release.* Addict Biol, 2014. **19**(5): p. 874-84.
143. Acquas, E., et al., *Intravenous administration of ecstasy (3,4-methylendioxymethamphetamine) enhances cortical and striatal acetylcholine release in vivo.* Eur J Pharmacol, 2001. **418**(3): p. 207-11.
144. Nair, S.G. and G.A. Gudelsky, *3,4-Methylenedioxymethamphetamine enhances the release of acetylcholine in the prefrontal cortex and dorsal hippocampus of the rat.* Psychopharmacology (Berl), 2006. **184**(2): p. 182-9.
145. Battaglia, G., et al., *Pharmacologic profile of MDMA (3,4-methylenedioxymethamphetamine) at various brain recognition sites.* Eur J Pharmacol, 1988. **149**(1-2): p. 159-63.
146. Jones, D.C., S.S. Lau, and T.J. Monks, *Thioether metabolites of 3,4-methylenedioxyamphetamine and 3,4-methylenedioxymethamphetamine inhibit human serotonin transporter (hSERT) function and simultaneously stimulate dopamine uptake into hSERT-expressing SK-N-MC cells.* J Pharmacol Exp Ther, 2004. **311**(1): p. 298-306.
147. PDSP, *MDMA receptor binding profiles from Psychoactive Drug Screening Program Database Contract # NO1MH32004 (NIMH PDSP), with data accessed between November 12 and November 14, 2007.* 2007, National Institute of Mental Health.
148. Giannaccini, G., et al., *Short-term effects of 3,4-methylen-dioxy-metamphetamine (MDMA) on 5-HT(1A) receptors in the rat hippocampus.* Neurochem Int, 2007. **51**(8): p. 496-506.
149. Brunner, D. and R. Hen, *Insights into the neurobiology of impulsive behavior from serotonin receptor knockout mice.* Ann N Y Acad Sci, 1997. **836**: p. 81-105.
150. Graeff, F.G., et al., *Role of 5-HT in stress, anxiety, and depression.* Pharmacol Biochem Behav, 1996. **54**(1): p. 129-41.
151. Glennon, R.A. and R. Young, *MDMA stimulus generalization to the 5-HT(1A) serotonin agonist 8-hydroxy-2- (di-n-propylamino)tetralin.* 2000. **66**(3): p. 483-488.
152. Glennon, R.A., et al., *N-Methyl-1-(4-methoxyphenyl)-2-aminopropane (PMMA) and N-Methyl-1-(3,4-methylenedioxyphenyl)-2-aminopropane (MDMA) produce non-identical discriminative stimuli in rats.* Pharmacol Biochem Behav, 2007. **86**(3): p. 477-84.
153. Schechter, M.D., *Discriminative profile of MDMA.* Pharmacol Biochem Behav, 1986. **24**(6): p. 1533-7.
154. Nair, S.G. and G.A. Gudelsky, *3,4-Methylenedioxymethamphetamine (MDMA) enhances the release of acetylcholine by 5-HT4 and D1 receptor mechanisms in the rat prefrontal cortex.* Synapse, 2005. **58**(4): p. 229-35.

155. Kuteykin-Teplyakov, K. and R. Maldonado, *Looking for prosocial genes: ITRAQ analysis of proteins involved in MDMA-induced sociability in mice.* Eur Neuropsychopharmacol, 2014. **24**(11): p. 1773-83.
156. Bankson, M.G. and B.K. Yamamoto, *Serotonin-GABA interactions modulate MDMA-induced mesolimbic dopamine release.* J Neurochem, 2004. **91**(4): p. 852-9.
157. Cordero-Erausquin, M., et al., *Nicotinic receptor function: new perspectives from knockout mice.* Trends Pharmacol Sci, 2000. **21**(6): p. 211-7.
158. Jorgensen, H., et al., *Serotonin receptors involved in vasopressin and oxytocin secretion.* J Neuroendocrinol, 2003. **15**(3): p. 242-9.
159. Forsling, M.L., et al., *The effect of 3,4-methylenedioxymethamphetamine (MDMA, 'ecstasy') and its metabolites on neurohypophysial hormone release from the isolated rat hypothalamus.* Br J Pharmacol, 2002. **135**(3): p. 649-56.
160. Thompson, M.R., et al., *A role for oxytocin and 5-HT(1A) receptors in the prosocial effects of 3,4 methylenedioxymethamphetamine ("ecstasy").* Neuroscience, 2007. **146**(2): p. 509-14.
161. Morley, K.C., J.C. Arnold, and I.S. McGregor, *Serotonin (1A) receptor involvement in acute 3,4-methylenedioxymethamphetamine (MDMA) facilitation of social interaction in the rat.* Prog Neuropsychopharmacol Biol Psychiatry, 2005. **29**(5): p. 648-57.
162. Broadbear, J.H., et al., *Oxytocinergic regulation of endogenous as well as drug-induced mood.* Pharmacol Biochem Behav, 2014. **119**: p. 61-71.
163. Miller, C.A. and J.D. Sweatt, *Covalent modification of DNA regulates memory formation.* Neuron, 2007. **53**(6): p. 857-69.
164. Unternaehrer, E., et al., *Childhood maternal care is associated with DNA methylation of the genes for brain-derived neurotrophic factor (BDNF) and oxytocin receptor (OXTR) in peripheral blood cells in adult men and women.* Stress, 2015. **18**(4): p. 451-61.
165. Koczor, C.A., et al., *Ecstasy (MDMA) Alters Cardiac Gene Expression and DNA Methylation: Implications for Circadian Rhythm Dysfunction in the Heart.* Toxicol Sci, 2015. **148**(1): p. 183-91.
166. Peng, W., et al., *Synaptotagmin I and IV are differentially regulated in the brain by the recreational drug 3,4-methylenedioxymethamphetamine (MDMA).* Brain Res Mol Brain Res, 2002. **108**(1-2): p. 94-101.
167. Pompei, P., et al., *Preprotachykinin A gene expression after administration of 3,4-methylene dioxymethamphetamine (Ecstasy).* Eur J Pharmacol, 2002. **450**(3): p. 245.
168. Sprague, J.E., et al. *Effects of antisense oligonucleotide alteration of MAO-B gene expression on MDMA-induced serotonergic neurotoxicity*. in *Society for Neuroscience*. 1999. Miami, FL.
169. Thiriet, N., et al., *Analysis of ecstasy (MDMA)-induced transcriptional responses in the rat cortex.* Faseb J, 2002. **16**(14): p. 1887-94.
170. Fernandez-Castillo, N., et al., *Active and passive MDMA ('ecstasy') intake induces differential transcriptional changes in the mouse brain.* Genes Brain Behav, 2012. **11**(1): p. 38-51.
171. Martinez-Turrillas, R., et al., *Differential effects of 3,4-methylenedioxymethamphetamine (MDMA, "ecstasy") on BDNF mRNA expression in rat frontal cortex and hippocampus.* Neurosci Lett, 2006. **402**(1-2): p. 126-30.
172. Sandrini, M., et al., *Causal role of prefrontal cortex in strengthening of episodic memories through reconsolidation.* Curr Biol, 2013. **23**(21): p. 2181-4.
173. Llado-Pelfort, L., et al., *5-HT1A receptor agonists enhance pyramidal cell firing in prefrontal cortex through a preferential action on GABA interneurons.* Cereb Cortex, 2012. **22**(7): p. 1487-97.
174. Biezonski, D.K. and J.S. Meyer, *Effects of 3,4-methylenedioxymethamphetamine (MDMA) on serotonin transporter and vesicular monoamine transporter 2 protein and*

gene expression in rats: implications for MDMA neurotoxicity. J Neurochem, 2010. **112**(4): p. 951-62.
175. Kindlundh-Hogberg, A.M., P. Svenningsson, and H.B. Schioth, *Quantitative mapping shows that serotonin rather than dopamine receptor mRNA expressions are affected after repeated intermittent administration of MDMA in rat brain.* Neuropharmacology, 2006. **51**(4): p. 838-47.
176. Salzmann, J., et al., *Analysis of transcriptional responses in the mouse dorsal striatum following acute 3,4-methylenedioxymethamphetamine (ecstasy): identification of extracellular signal-regulated kinase-controlled genes.* Neuroscience, 2006. **137**(2): p. 473-82.
177. Karpova, N.N., *Role of BDNF epigenetics in activity-dependent neuronal plasticity.* Neuropharmacology, 2014. **76 Pt C**: p. 709-18.
178. Young, M.B., et al., *3,4-Methylenedioxymethamphetamine facilitates fear extinction learning.* Transl Psychiatry, 2015. **5**: p. e634.
179. Connor, T.J., et al., *Methylenedioxymethamphetamine (MDMA; Ecstasy) suppresses IL-1beta and TNF-alpha secretion following an in vivo lipopolysaccharide challenge.* Life Sci, 2000. **67**(13): p. 1601-12.
180. Pennock, J.W., et al., *3,4-Methylenedioxymethamphetamine increases susceptibility to genital herpes simplex virus infection in mice.* J Infect Dis, 2009. **200**(8): p. 1247-50.
181. de Paula, V.F., et al., *Methylenedioxymethamphetamine (Ecstasy) decreases neutrophil activity and alters leukocyte distribution in bone marrow, spleen and blood.* Neuroimmunomodulation, 2009. **16**(3): p. 191-200.
182. Boyle, N.T. and T.J. Connor, *MDMA ("Ecstasy") suppresses the innate IFN-gamma response in vivo: A critical role for the anti-inflammatory cytokine IL-10.* Eur J Pharmacol, 2007.
183. Stankevicius, D., et al., *3,4-methylenedioxymethamphetamine (ecstasy) decreases inflammation and airway reactivity in a murine model of asthma.* Neuroimmunomodulation, 2012. **19**(4): p. 209-19.
184. Passos, I.C., et al., *Inflammatory markers in post-traumatic stress disorder: a systematic review, meta-analysis, and meta-regression.* Lancet Psychiatry, 2015. **2**(11): p. 1002-12.
185. Gordon, C.J., *Thermophysiological responses to hyperthermic drugs: extrapolating from rodent to human.* Prog Brain Res, 2007. **162**: p. 63-79.
186. Reveron, M.E., E.Y. Maier, and C.L. Duvauchelle, *Experience-dependent changes in temperature and behavioral activity induced by MDMA.* Physiol Behav, 2006. **89**(3): p. 358-63.
187. Kiyatkin, E.A., et al., *Critical role of peripheral vasoconstriction in fatal brain hyperthermia induced by MDMA (Ecstasy) under conditions that mimic human drug use.* J Neurosci, 2014. **34**(23): p. 7754-62.
188. Dafters, R.I., *Effect of ambient temperature on hyperthermia and hyperkinesis induced by 3,4-methylenedioxymethamphetamine (MDMA or "ecstasy") in rats.* Psychopharmacology (Berl), 1994. **114**(3): p. 505-8.
189. Fantegrossi, W.E., et al., *Pharmacological characterization of the effects of 3,4-methylenedioxymethamphetamine ("ecstasy") and its enantiomers on lethality, core temperature, and locomotor activity in singly housed and crowded mice.* Psychopharmacology (Berl), 2003. **166**(3): p. 202-11.
190. Malberg, J.E. and L.S. Seiden, *Small changes in ambient temperature cause large changes in 3,4-methylenedioxymethamphetamine (MDMA)-induced serotonin neurotoxicity and core body temperature in the rat.* J Neurosci, 1998. **18**(13): p. 5086-94.
191. Gordon, C.J., et al., *Effects of 3,4-methylenedioxymethamphetamine on autonomic thermoregulatory responses of the rat.* Pharmacol Biochem Behav, 1991. **38**(2): p. 339-44.

192. Pedersen, N.P. and W.W. Blessing, *Cutaneous vasoconstriction contributes to hyperthermia induced by 3,4-methylenedioxymethamphetamine (ecstasy) in conscious rabbits.* J Neurosci, 2001. **21**(21): p. 8648-54.
193. Von Huben, S.N., et al., *Impact of ambient temperature on hyperthermia induced by (+/-)3,4-methylenedioxymethamphetamine in rhesus macaques.* Neuropsychopharmacology, 2007. **32**(3): p. 673-81.
194. Bowyer, J.F., et al., *Plasma levels of parent compound and metabolites after doses of either d-fenfluramine or d-3,4-methylenedioxymethamphetamine (MDMA) that produce long-term serotonergic alterations.* Neurotoxicology, 2003. **24**(3): p. 379-90.
195. Freedman, R.R., C.E. Johanson, and M.E. Tancer, *Thermoregulatory effects of 3,4-methylenedioxymethamphetamine (MDMA) in humans.* Psychopharmacology (Berl), 2005. **183**(2): p. 248-56.
196. Crean, R.D., S.A. Davis, and M.A. Taffe, *Oral administration of (+/-)3,4-methylenedioxymethamphetamine and (+)methamphetamine alters temperature and activity in rhesus macaques.* Pharmacol Biochem Behav, 2007. **87**(1): p. 11-9.
197. Crean, R.D., et al., *Effects of (+/-)3,4-methylenedioxymethamphetamine, (+/-)3,4-methylenedioxyamphetamine and methamphetamine on temperature and activity in rhesus macaques.* Neuroscience, 2006. **142**(2): p. 515-25.
198. Banks, M.L., et al., *Ambient temperature effects on 3,4-methylenedioxymethamphetamine-induced thermodysregulation and pharmacokinetics in male monkeys.* Drug Metab Dispos, 2007. **35**(10): p. 1840-5.
199. Schindler, C.W., et al., *Effects of 3,4-methylenedioxymethamphetamine (MDMA) and its main metabolites on cardiovascular function in conscious rats.* Br J Pharmacol, 2014. **171**(1): p. 83-91.
200. Tiangco, D.A., et al., *3,4-Methylenedioxymethamphetamine activates nuclear factor-kappaB, increases intracellular calcium, and modulates gene transcription in rat heart cells.* Cardiovasc Toxicol, 2005. **5**(3): p. 301-10.
201. Vandeputte, C. and J.R. Docherty, *Vascular actions of 3,4-methylenedioxymethamphetamine in alpha(2A/D)- adrenoceptor knockout mice.* Eur J Pharmacol, 2002. **457**(1): p. 45-9.
202. Bexis, S. and J.R. Docherty, *Effects of MDMA, MDA and MDEA on blood pressure, heart rate, locomotor activity and body temperature in the rat involve alpha-adrenoceptors.* Br J Pharmacol, 2006. **147**(8): p. 926-34.
203. Bexis, S. and J.R. Docherty, *Role of alpha2A-adrenoceptors in the effects of MDMA on body temperature in the mouse.* Br J Pharmacol, 2005. **146**(1): p. 1-6.
204. Quinn, S.T., et al., *Blockade of noradrenaline transport abolishes 4-methylthioamphetamine-induced contraction of the rat aorta in vitro.* Auton Autacoid Pharmacol, 2006. **26**(4): p. 335-44.
205. Hysek, C.M., et al., *Effects of the alpha(2)-adrenergic agonist clonidine on the pharmacodynamics and pharmacokinetics of 3,4-methylenedioxymethamphetamine in healthy volunteers.* J Pharmacol Exp Ther, 2012. **340**(2): p. 286-94.
206. Hysek, C.M. and M.E. Liechti, *Effects of MDMA alone and after pretreatment with reboxetine, duloxetine, clonidine, carvedilol, and doxazosin on pupillary light reflex.* Psychopharmacology (Berl), 2012. **224**(3): p. 363-76.
207. Hysek, C.M., et al., *Carvedilol inhibits the cardiostimulant and thermogenic effects of MDMA in humans: Lost in translation.* Br J Pharmacol, 2013. **170**(6): p. 1273-5.
208. Hysek, C.M., et al., *Duloxetine inhibits effects of MDMA ("ecstasy") in vitro and in humans in a randomized placebo-controlled laboratory study.* PLoS One, 2012. **7**(5): p. e36476.
209. Burbach, J., L. Young, and J. Russell, *Oxytocin: synthesis, secretion, and reproductive functions.* Knobil and Neill's physiology of reproduction, 2006. **2**: p. 3055-3128.

210. Tasker, J.G., et al., *Cell biology of oxytocin and vasopressin cells*, in *Hormones, brain and behavior*, Pfaff D.W., et al., Editors. 2002, Academic Press: London. p. 811-842.
211. Hargreaves, G.A., et al., *High ambient temperature increases 3,4-methylenedioxymethamphetamine (MDMA, "ecstasy")-induced Fos expression in a region-specific manner.* Neuroscience, 2007. **145**(2): p. 764-74.
212. Fantegrossi, W.E., et al., *Nantenine: an antagonist of the behavioral and physiological effects of MDMA in mice.* Psychopharmacology (Berl), 2004. **173**(3-4): p. 270-7.
213. Meyer, J.S., et al., *Neural effects of MDMA as determined by functional magnetic resonance imaging and magnetic resonance spectroscopy in awake marmoset monkeys.* Ann N Y Acad Sci, 2006. **1074**: p. 365-76.
214. Karimi, S., M. Jahanshahi, and M.J. Golalipour, *The Effect of MDMA-Induced Anxiety on Neuronal Apoptosis in Adult Male Rats' Hippocampus.* Folia Biol (Praha), 2014. **60**(4): p. 187-91.
215. Isbister, G.K. and N.A. Buckley, *The pathophysiology of serotonin toxicity in animals and humans: implications for diagnosis and treatment.* Clin Neuropharmacol, 2005. **28**(5): p. 205-14.
216. Gillman, P.K., *Ecstasy, serotonin syndrome and the treatment of hyperpyrexia.* Med J Aust, 1997. **167**(2): p. 109, 111.
217. Mueller, P.D. and W.S. Korey, *Death by "ecstasy": the serotonin syndrome?* Ann Emerg Med, 1998. **32**(3 Pt 1): p. 377-80.
218. Ferraz de Paula, V., et al., *Methylenedioxymethamphetamine (Ecstasy) Decreases Neutrophil Activity and Alters Leukocyte Distribution in Bone Marrow, Spleen and Blood.* Neuroimmunomodulation, 2009. **16**(3): p. 191-200.
219. Nash, J.F., Jr., H.Y. Meltzer, and G.A. Gudelsky, *Elevation of serum prolactin and corticosterone concentrations in the rat after the administration of 3,4-methylenedioxymethamphetamine.* J Pharmacol Exp Ther, 1988. **245**(3): p. 873-9.
220. Connor, T.J., J.P. Kelly, and B.E. Leonard, *An assessment of the acute effects of the serotonin releasers methylenedioxymethamphetamine, methylenedioxyamphetamine and fenfluramine on immunity in rats.* Immunopharmacology, 2000. **46**(3): p. 223-35.
221. Balogh, B., et al., *Effects of a single dose of 3,4-methylenedioxymethamphetamine on circadian patterns, motor activity and sleep in drug-naive rats and rats previously exposed to MDMA.* Psychopharmacology (Berl), 2004. **173**(3-4): p. 296-309.
222. Bhattacharya, S.K., A. Bhattacharya, and S. Ghosal, *Anxiogenic activity of methylenedioxymethamphetamine (Ecstasy): an experimental study.* Biogenic Amines, 1998. **7**: p. 217-237.
223. Ho, Y.J., et al., *Acute and long-term consequences of single MDMA administration in relation to individual anxiety levels in the rat.* Behav Brain Res, 2004. **149**(2): p. 135-44.
224. Selken, J. and D.E. Nichols, *Alpha1-adrenergic receptors mediate the locomotor response to systemic administration of (+/-)-3,4-methylenedioxymethamphetamine (MDMA) in rats.* Pharmacol Biochem Behav, 2007. **86**(4): p. 622-30.
225. Mechan, A.O., et al., *A study of the effect of a single neurotoxic dose of 3,4-methylenedioxymethamphetamine (MDMA; "ecstasy") on the subsequent long- term behaviour of rats in the plus maze and open field.* Psychopharmacology (Berl), 2002. **159**(2): p. 167-75.
226. Gurtman, C.G., et al., *Increased anxiety in rats after 3,4-methylenedioxymethamphetamine: association with serotonin depletion.* Eur J Pharmacol, 2002. **446**(1-3): p. 89-96.
227. Clemens, K.J., et al., *MDMA ("ecstasy"), methamphetamine and their combination: long-term changes in social interaction and neurochemistry in the rat.* Psychopharmacology (Berl), 2004. **173**(3-4): p. 318-25.

228. Ando, R.D., et al., *Partial lesion of the serotonergic system by a single dose of MDMA results in behavioural disinhibition and enhances acute MDMA-induced social behaviour on the social interaction test.* Neuropharmacology, 2006. **50**(7): p. 884-96.
229. Thompson, M.R., G.E. Hunt, and I.S. McGregor, *Neural correlates of MDMA ("Ecstasy")-induced social interaction in rats.* Soc Neurosci, 2009. **4**(1): p. 60-72.
230. Hunt, G.E., et al., *MDMA-induced c-Fos expression in oxytocin-containing neurons is blocked by pretreatment with the 5-HT-1A receptor antagonist WAY 100635.* Brain Res Bull, 2011. **86**(1-2): p. 65-73.
231. Hasler, F., et al., *Investigation of serotonin-1A receptor function in the human psychopharmacology of MDMA.* J Psychopharmacol, 2009. **23**(8): p. 923-35.
232. Hysek, C.M., F.X. Vollenweider, and M.E. Liechti, *Effects of a beta-blocker on the cardiovascular response to MDMA (Ecstasy).* Emerg Med J, 2010. **27**(8): p. 586-9.
233. van Wel, J.H., et al., *Blockade of 5-HT(2) Receptor Selectively Prevents MDMA-Induced Verbal Memory Impairment.* Neuropsychopharmacology, 2011. **36**(9): p. 1932-9.
234. Liester, M.B., et al., *Phenomenology and sequelae of 3,4-methylenedioxymethamphetamine use.* J Nerv Ment Dis, 1992. **180**(6): p. 345-52; discussion 353-4.
235. Peroutka, S.J., H. Newman, and H. Harris, *Subjective effects of 3,4-methylenedioxymethamphetamine in recreational users.* Neuropsychopharmacology, 1988. **1**(4): p. 273-7.
236. Halpern, J.H., et al., *Residual neurocognitive features of long-term ecstasy users with minimal exposure to other drugs.* Addiction, 2011. **106**(4): p. 777-86.
237. Hahn, I.-H. *MDMA Toxicity*. Medscape, 2015.
238. Cohen, R.S., *Subjective reports on the effects of the MDMA ('ecstasy') experience in humans.* Prog Neuropsychopharmacol Biol Psychiatry, 1995. **19**(7): p. 1137-45.
239. Litjens, R.P., et al., *Hallucinogen persisting perception disorder and the serotonergic system: a comprehensive review including new MDMA-related clinical cases.* Eur Neuropsychopharmacol, 2014. **24**(8): p. 1309-23.
240. Baggott, M.J., et al., *Intimate insight: MDMA changes how people talk about significant others.* J Psychopharmacol, 2015.
241. Pacifici, R., et al., *Combined immunomodulating properties of 3,4-methylenedioxymethamphetamine (MDMA) and cannabis in humans.* Addiction, 2007. **102**(6): p. 931-6.
242. Parrott, A.C., *MDMA and temperature: a review of the thermal effects of 'Ecstasy' in humans.* Drug Alcohol Depend, 2012. **121**(1-2): p. 1-9.
243. Dafters, R.I., *Hyperthermia following MDMA administration in rats: effects of ambient temperature, water consumption, and chronic dosing.* Physiol Behav, 1995. **58**(5): p. 877-82.
244. Docherty, J.R. and A.R. Green, *The role of monoamines in the changes in body temperature induced by 3,4-methylenedioxymethamphetamine (MDMA, ecstasy) and its derivatives.* Br J Pharmacol, 2010. **160**(5): p. 1029-44.
245. Martin, T.L., D.A. Chiasson, and S.J. Kish, *Does hyperthyroidism increase risk of death due to the ingestion of ecstasy?* J Forensic Sci, 2007. **52**(4): p. 951-3.
246. Sprague, J.E., et al., *Roles of norepinephrine, free Fatty acids, thyroid status, and skeletal muscle uncoupling protein 3 expression in sympathomimetic-induced thermogenesis.* J Pharmacol Exp Ther, 2007. **320**(1): p. 274-80.
247. Droogmans, S., et al., *Possible association between 3,4-methylenedioxymethamphetamine abuse and valvular heart disease.* Am J Cardiol, 2007. **100**(9): p. 1442-5.
248. Farah, R. and R. Farah, *Ecstasy (3,4-methylenedioxymethamphetamine)-induced inappropriate antidiuretic hormone secretion.* Pediatr Emerg Care, 2008. **24**(9): p. 615-7.

249. Esposito, P., et al., *The syndrome of inappropriate antidiuresis: pathophysiology, clinical management and new therapeutic options.* Nephron Clin Pract, 2011. **119**(1): p. c62-73; discussion c73.
250. Laycock, J., *Introduction to vasopressin.* Perspectives on vasopressin. London: World Scientific Publishing Company, Imperial College Press, 2010: p. 1-16.
251. Forsling, M., et al., *Arginine vasopressin release in response to the administration of 3,4-methylenedioxymethamphetamine ("ecstasy"): is metabolism a contributory factor?* J Pharm Pharmacol, 2001. **53**(10): p. 1357-63.
252. Aitchison, K.J., et al., *Ecstasy (MDMA)-induced hyponatraemia is associated with genetic variants in CYP2D6 and COMT.* J Psychopharmacol, 2012. **26**(3): p. 408-18.
253. Henry, J.A. and I.R. Hill, *Fatal interaction between ritonavir and MDMA.* Lancet, 1998. **352**(9142): p. 1751-2.
254. Semple, D.M., et al., *Reduced in vivo binding to the serotonin transporter in the cerebral cortex of MDMA ('ecstasy') users.* Br J Psychiatry, 1999. **175**: p. 63-9.
255. Gouzoulis-Mayfrank, E. and J. Daumann, *Neurotoxicity of methylenedioxyamphetamines (MDMA; ecstasy) in humans: how strong is the evidence for persistent brain damage?* Addiction, 2006. **101**(3): p. 348-61.
256. Buchert, R., et al., *A voxel-based PET investigation of the long-term effects of "Ecstasy" consumption on brain serotonin transporters.* Am J Psychiatry, 2004. **161**(7): p. 1181-9.
257. Gouzoulis-Mayfrank, E., et al., *Memory impairment suggests hippocampal dysfunction in abstinent ecstasy users.* Prog Neuropsychopharmacol Biol Psychiatry, 2003. **27**(5): p. 819-27.
258. Halpern, J.H., et al., *Residual neuropsychological effects of illicit 3,4-methylenedioxymethamphetamine (MDMA) in individuals with minimal exposure to other drugs.* Drug Alcohol Depend, 2004. **75**(2): p. 135-47.
259. Thomasius, R., et al., *Mood, cognition and serotonin transporter availability in current and former ecstasy (MDMA) users.* Psychopharmacology (Berl), 2003. **167**(1): p. 85-96.
260. Daumann, J., Jr., et al., *Neural mechanisms of working memory in ecstasy (MDMA) users who continue or discontinue ecstasy and amphetamine use: evidence from an 18-month longitudinal functional magnetic resonance imaging study.* Biol Psychiatry, 2004. **56**(5): p. 349-55.
261. Gouzoulis-Mayfrank, E., et al., *Memory performance in polyvalent MDMA (ecstasy) users who continue or discontinue MDMA use.* Drug Alcohol Depend, 2005. **78**(3): p. 317-23.
262. Buchert, R., et al., *Reversibility of ecstasy-induced reduction in serotonin transporter availability in polydrug ecstasy users.* Eur J Nucl Med Mol Imaging, 2006. **33**(2): p. 188-99.
263. Selvaraj, S., et al., *Brain serotonin transporter binding in former users of MDMA ('ecstasy').* Br J Psychiatry, 2009. **194**(4): p. 355-9.
264. Kish, S.J., et al., *Low striatal serotonin transporter protein in a human polydrug MDMA (ecstasy) user: a case study.* J Psychopharmacol, 2010. **24**(2): p. 281-4.
265. Erritzoe, D., et al., *In vivo imaging of cerebral serotonin transporter and serotonin(2A) receptor binding in 3,4-methylenedioxymethamphetamine (MDMA or "ecstasy") and hallucinogen users.* Arch Gen Psychiatry, 2011. **68**(6): p. 562-76.
266. de Win, M.M., et al., *A Prospective Cohort Study on Sustained Effects of Low-Dose Ecstasy Use on the Brain in New Ecstasy Users.* Neuropsychopharmacology, 2007. **32**(2): p. 458-470.
267. Chang, L., et al., *Cerebral (1)H MRS alterations in recreational 3, 4-methylenedioxymethamphetamine (MDMA, "ecstasy") users.* J Magn Reson Imaging, 1999. **10**(4): p. 521-6.
268. Cowan, R.L., et al., *Occipital cortical proton MRS at 4 Tesla in human moderate MDMA polydrug users.* Psychiatry Res, 2007.

269. Reneman, L., et al., *Reduced N-acetylaspartate levels in the frontal cortex of 3,4-methylenedioxymethamphetamine (Ecstasy) users: preliminary results.* AJNR Am J Neuroradiol, 2002. **23**(2): p. 231-7.
270. De Win, M., Jager, G., Reneman, L., Booij, J., van den Brink, W., Den Heeten, G., et al., *Ecstasy: Is It Safe for the Brain? First Prospective Study on Effects of Low Doses of Ecstasy on the Brain in New Ecstasy Users, Using a Combination of Advanced MR Imaging Techniques and [123I]ß-CIT SPECT*, in *Radiological Society of North America (RSNA)*. 2006: Chicago, IL.
271. Klomp, A., et al., *The Effects of Ecstasy (MDMA) on Brain Serotonin Transporters Are Dependent on Age-of-First Exposure in Recreational Users and Animals.* PLoS One, 2012. **7**(10): p. e47524.
272. Booij, L., et al., *Brain serotonin synthesis in MDMA (ecstasy) polydrug users: an alpha-[(11) C]methyl-l-tryptophan study.* J Neurochem, 2014. **131**(5): p. 634-44.
273. Bauernfeind, A.L., et al., *Human ecstasy use is associated with increased cortical excitability: an fMRI study.* Neuropsychopharmacology, 2011. **36**(6): p. 1127-41.
274. Salomon, R.M., et al., *MDMA (Ecstasy) association with impaired fMRI BOLD thalamic coherence and functional connectivity.* Drug Alcohol Depend, 2012. **120**(1-3): p. 41-7.
275. Roberts, C.A., et al., *Differences in prefrontal blood oxygenation during an acute multitasking stressor in ecstasy polydrug users.* Psychol Med, 2014: p. 1-12.
276. Jager, G., et al., *Incidental use of ecstasy: no evidence for harmful effects on cognitive brain function in a prospective fMRI study.* Psychopharmacology (Berl), 2007. **193**(3): p. 403-14.
277. Roiser, J.P., et al., *The effect of polymorphism at the serotonin transporter gene on decision-making, memory and executive function in ecstasy users and controls.* Psychopharmacology (Berl), 2006. **188**(2): p. 213-27.
278. Cuyas, E., et al., *The Influence of Genetic and Environmental Factors among MDMA Users in Cognitive Performance.* PLoS One, 2011. **6**(11): p. e27206.
279. Schilt, T., et al., *The effect of Ecstasy on memory is moderated by a functional polymorphism in the cathechol-O-methyltransferase (COMT) gene.* Eur Neuropsychopharmacol, 2009. **19**(2): p. 116-24.
280. Parrott, A.C., *MDMA, serotonergic neurotoxicity, and the diverse functional deficits of recreational 'Ecstasy' users.* Neurosci Biobehav Rev, 2013. **37**(8): p. 1466-1484.
281. Randall, S., et al., *Effects of acute 3,4-methylenedioxymethamphetamine on sleep and daytime sleepiness in MDMA users: a preliminary study.* Sleep, 2009. **32**(11): p. 1513-9.
282. Carhart-Harris, R.L., et al., *Equivalent effects of acute tryptophan depletion on REM sleep in ecstasy users and controls.* Psychopharmacology (Berl), 2009. **206**(2): p. 187-96.
283. Allen, R.P., U.D. McCann, and G.A. Ricaurte, *Persistent effects of (+/-)3,4-methylenedioxymethamphetamine (MDMA, "ecstasy") on human sleep.* Sleep, 1993. **16**(6): p. 560-4.
284. McCann, U.D., S.C. Peterson, and G.A. Ricaurte, *The effect of catecholamine depletion by alpha-methyl-para-tyrosine on measures of cognitive performance and sleep in abstinent MDMA users.* Neuropsychopharmacology, 2007. **32**(8): p. 1695-706.
285. McCann, U.D., et al., *Sleep deprivation differentially impairs cognitive performance in abstinent methylenedioxymethamphetamine ("ecstasy") users.* J Neurosci, 2009. **29**(44): p. 14050-6.
286. McCann, U.D., et al., *Sleep apnea in young abstinent recreational MDMA ("ecstasy") consumers.* Neurology, 2009. **73**(23): p. 2011-7.
287. MacInnes, N., S.L. Handley, and G.F. Harding, *Former chronic methylenedioxymethamphetamine (MDMA or ecstasy) users report mild depressive symptoms.* J Psychopharmacol, 2001. **15**(3): p. 181-6.
288. Parrott, A.C., E. Sisk, and J.J. Turner, *Psychobiological problems in heavy 'ecstasy' (MDMA) polydrug users.* Drug Alcohol Depend, 2000. **60**(1): p. 105-10.

289. Sumnall, H.R. and J.C. Cole, *Self-reported depressive symptomatology in community samples of polysubstance misusers who report Ecstasy use: a meta-analysis.* J Psychopharmacol, 2005. **19**(1): p. 84-92.
290. Milani, R.M., et al., *Gender differences in self-reported anxiety, depression, and somatization among ecstasy/MDMA polydrug users, alcohol/tobacco users, and nondrug users.* Addict Behav, 2004. **29**(5): p. 965-71.
291. Sumnall, H.R., G.F. Wagstaff, and J.C. Cole, *Self-reported psychopathology in polydrug users.* J Psychopharmacol, 2004. **18**(1): p. 75-82.
292. Medina, K.L. and P.K. Shear, *Anxiety, depression, and behavioral symptoms of executive dysfunction in ecstasy users: contributions of polydrug use.* Drug Alcohol Depend, 2007. **87**(2-3): p. 303-11.
293. Fisk, J.E., et al., *Modelling the adverse effects associated with ecstasy use.* Addiction, 2011. **106**(4): p. 798-805.
294. Scott, L.A., et al., *The impact of comorbid cannabis and methamphetamine use on mental health among regular ecstasy users.* Addict Behav, 2012. **37**(9): p. 1058-62.
295. Daumann, J., et al., *Self-reported psychopathological symptoms in recreational ecstasy (MDMA) users are mainly associated with regular cannabis use: further evidence from a combined cross-sectional/longitudinal investigation.* Psychopharmacology (Berl), 2004. **173**(3-4): p. 398-404.
296. Whitaker-Azmitia, P.M. and T.A. Aronson, *"Ecstasy" (MDMA)-induced panic.* Am J Psychiatry, 1989. **146**(1): p. 119.
297. McCann, U.D. and G.A. Ricaurte, *Lasting neuropsychiatric sequelae of (+-)methylenedioxymethamphetamine ('ecstasy') in recreational users.* J Clin Psychopharmacol, 1991. **11**(5): p. 302-5.
298. Pallanti, S. and D. Mazzi, *MDMA (Ecstasy) precipitation of panic disorder.* Biol Psychiatry, 1992. **32**(1): p. 91-5.
299. McCann, U.D. and G.A. Ricaurte, *MDMA ("ecstasy") and panic disorder: induction by a single dose.* Biol Psychiatry, 1992. **32**(10): p. 950-3.
300. Allott, K., et al., *Neuroendocrine and subjective responses to pharmacological challenge with citalopram: a controlled study in male and female ecstasy/MDMA users.* J Psychopharmacol, 2008.
301. Wetherell, M.A. and C. Montgomery, *Basal functioning of the hypothalamic-pituitary-adrenal (HPA) axis and psychological distress in recreational ecstasy polydrug users.* Psychopharmacology (Berl), 2014. **231**(7): p. 1365-75.
302. Frokjaer, V.G., et al., *In abstinent MDMA users the cortisol awakening response is off-set but associated with prefrontal serotonin transporter binding as in non-users.* Int J Neuropsychopharmacol, 2014. **17**(8): p. 1119-28.
303. George, A.M., S. Olesen, and R.J. Tait, *Ecstasy use and depression: a 4-year longitudinal study among an Australian general community sample.* Psychopharmacology (Berl), 2013. **229**(4): p. 713-21.
304. Thomasius, R., et al., *Mood, cognition and serotonin transporter availability in current and former ecstasy (MDMA) users: the longitudinal perspective.* J Psychopharmacol, 2006. **20**(2): p. 211-25.
305. Schilt, T., et al., *Cognition in novice ecstasy users with minimal exposure to other drugs: a prospective cohort study.* Arch Gen Psychiatry, 2007. **64**(6): p. 728-36.
306. White, C., J. Brown, and M. Edwards, *Alterations to global but not local motion processing in long-term ecstasy (MDMA) users.* Psychopharmacology (Berl), 2014.
307. Bedi, G. and J. Redman, *Metamemory in recreational ecstasy polydrug users: what do self-reports of memory failures mean?* J Psychopharmacol, 2008.
308. Bedi, G. and J. Redman, *Ecstasy use and higher-level cognitive functions: weak effects of ecstasy after control for potential confounds.* Psychol Med, 2008. **38**(9): p. 1319-30.

309. Hanson, K.L. and M. Luciana, *Neurocognitive impairments in MDMA and other drug users: MDMA alone may not be a cognitive risk factor.* J Clin Exp Neuropsychol, 2010. **32**(4): p. 337-49.
310. Raj, V., et al., *MDMA (ecstasy) use is associated with reduced BOLD signal change during semantic recognition in abstinent human polydrug users: a preliminary fMRI study.* J Psychopharmacol, 2010. **24**(2): p. 187-201.
311. Roiser, J.P., R.D. Rogers, and B.J. Sahakian, *Neuropsychological function in ecstasy users: a study controlling for polydrug use.* Psychopharmacology (Berl), 2007. **189**(4): p. 505-16.
312. Blagrove, M., et al., *Procedural and declarative memory task performance, and the memory consolidation function of sleep, in recent and abstinent ecstasy/MDMA users.* J Psychopharmacol, 2011. **25**(4): p. 465-77.
313. Kish, S.J., et al., *Decreased cerebral cortical serotonin transporter binding in ecstasy users: a positron emission tomography/[(11)C]DASB and structural brain imaging study.* Brain, 2010. **133**(Pt 6): p. 1779-97.
314. Montgomery, C. and J.E. Fisk, *Ecstasy-related deficits in the updating component of executive processes.* Hum Psychopharmacol, 2008.
315. Hadjiefthyvoulou, F., et al., *Everyday and prospective memory deficits in ecstasy/polydrug users.* J Psychopharmacol, 2011. **25**(4): p. 453-64.
316. van Holst, R.J. and T. Schilt, *Drug-related decrease in neuropsychological functions of abstinent drug users.* Curr Drug Abuse Rev, 2011. **4**(1): p. 42-56.
317. Jager, G., et al., *Assessment of cognitive brain function in ecstasy users and contributions of other drugs of abuse: results from an FMRI study.* Neuropsychopharmacology, 2008. **33**(2): p. 247-58.
318. Indlekofer, F., et al., *Reduced memory and attention performance in a population-based sample of young adults with a moderate lifetime use of cannabis, ecstasy and alcohol.* J Psychopharmacol, 2009. **23**(5): p. 495-509.
319. Schilt, T., et al., *Long-term neuropsychological effects of ecstasy in middle-aged ecstasy/polydrug users.* Psychopharmacology (Berl), 2010. **207**(4): p. 583-91.
320. Morgan, M.J., *Recreational use of "ecstasy" (MDMA) is associated with elevated impulsivity.* Neuropsychopharmacology, 1998. **19**(4): p. 252-64.
321. Quednow, B.B., et al., *Elevated impulsivity and impaired decision-making cognition in heavy users of MDMA ("Ecstasy").* Psychopharmacology (Berl), 2007. **189**(4): p. 517-30.
322. Morgan, M.J., et al., *Elevated impulsivity and impaired decision-making in abstinent Ecstasy (MDMA) users compared to polydrug and drug-naive controls.* Neuropsychopharmacology, 2006. **31**(7): p. 1562-73.
323. Schilt, T., et al., *Decision making as a predictor of first ecstasy use: a prospective study.* Psychopharmacology (Berl), 2009. **203**(3): p. 519-27.
324. Pirona, A. and M.J. Morgan, *An investigation of the subacute effects of ecstasy on neuropsychological performance, sleep and mood in regular ecstasy users.* J Psychopharmacol, 2010. **24**(2): p. 175-85.
325. Hanson, K.L., M. Luciana, and K. Sullwold, *Reward-related decision-making deficits and elevated impulsivity among MDMA and other drug users.* Drug Alcohol Depend, 2008. **96**(1-2): p. 99-110.
326. Mueller, M., et al., *Single oral doses of (+/-) 3,4-methylenedioxymethamphetamine ('Ecstasy') produce lasting serotonergic deficits in non-human primates: relationship to plasma drug and metabolite concentrations.* Int J Neuropsychopharmacol, 2013. **16**(4): p. 791-801.
327. de la Torre, R., et al., *MDMA, methamphetamine, and CYP2D6 pharmacogenetics: what is clinically relevant?* Front Genet, 2012. **3**: p. 235.

328. Peiro, A.M., et al., *Human pharmacology of 3,4-methylenedioxymethamphetamine (MDMA, ecstasy) after repeated doses taken 2 h apart.* Psychopharmacology (Berl), 2013. **225**(4): p. 883-93.
329. Mahmood, I. and J.D. Balian, *Interspecies scaling: a comparative study for the prediction of clearance and volume using two or more than two species.* Life Sci, 1996. **59**(7): p. 579-85.
330. Frith, C.H., et al., *Toxicity of methylenedioxymethamphetamine (MDMA) in the dog and the rat.* Fundam Appl Toxicol, 1987. **9**(1): p. 110-9.
331. Hariri, M., et al., *ASSESSING MUTAGENICITY OF THE DRUG MDMA (ECSTASY) AVAILABLE IN IRAN USING AMES BIOASSAY.* Jundishapur Journal of Natural Pharmaceutical Products, 2010. **5**(1): p. 44-49.
332. Yoshioka, H., et al., *Genotoxicity study of illegal drug MDMA and its nitroso derivative N-MDMA by micronucleus and chromosomal aberration tests using Chinese hamsger lung fibroblast cell line.* Environ Health Prev Med, 2007. **12**(3): p. 129-37.
333. Campbell, N.G., et al., *MDMA administration to pregnant Sprague-Dawley rats results in its passage to the fetal compartment.* Neurotoxicol Teratol, 2006. **28**(4): p. 459-65.
334. St Omer, V.E., et al., *Behavioral and neurochemical effects of prenatal methylenedioxymethamphetamine (MDMA) exposure in rats.* Neurotoxicol Teratol, 1991. **13**(1): p. 13-20.
335. Plessinger, M.A., *Prenatal exposure to amphetamines. Risks and adverse outcomes in pregnancy.* Obstet Gynecol Clin North Am, 1998. **25**(1): p. 119-38.
336. Kwack, S.J., et al., *A One-Generation Reproductive Toxicity Study of 3,4-Methylenedioxy-N-Methamphetamine (MDMA, Ecstasy), an Amphetamine Derivative, in C57BL/6 Mice.* J Toxicol Environ Health A, 2014. **77**(22-24): p. 1431-42.
337. Barenys, M., et al., *MDMA (ecstasy) delays pubertal development and alters sperm quality after developmental exposure in the rat.* Toxicol Lett, 2010. **197**(2): p. 135-42.
338. Barenys, M., et al., *Chronic exposure to MDMA (ecstasy) increases DNA damage in sperm and alters testes histopathology in male rats.* Toxicol Lett, 2009. **191**(1): p. 40-6.
339. Koprich, J.B., N.G. Campbell, and J.W. Lipton, *Neonatal 3,4-methylenedioxymethamphetamine (ecstasy) alters dopamine and serotonin neurochemistry and increases brain-derived neurotrophic factor in the forebrain and brainstem of the rat.* Brain Res Dev Brain Res, 2003. **147**(1-2): p. 177-82.
340. Koprich, J.B., et al., *Prenatal 3,4-methylenedioxymethamphetamine (ecstasy) alters exploratory behavior, reduces monoamine metabolism, and increases forebrain tyrosine hydroxylase fiber density of juvenile rats.* Neurotoxicol Teratol, 2003. **25**(5): p. 509-17.
341. Cohen, M.A., et al., *Learning and memory after neonatal exposure to 3,4-methylenedioxymethamphetamine (ecstasy) in rats: interaction with exposure in adulthood.* Synapse, 2005. **57**(3): p. 148-59.
342. Piper, B.J., J.D. Farelli, and J.S. Meyer, *Dissociation between serotonin neurotoxicity and brain-derived neurotrophic factor induction following neonatal MDMA exposure in rats.* Dev Neurosci, 2009. **31**(1-2): p. 90-4.
343. Piper, B.J. and J.S. Meyer, *Increased responsiveness to MDMA in adult rats treated neonatally with MDMA.* Neurotoxicol Teratol, 2006. **28**(1): p. 95-102.
344. Green, A.R., et al., *Studies on the effect of MDMA ('ecstasy') on the body temperature of rats housed at different ambient room temperatures.* Br J Pharmacol, 2005. **146**(2): p. 306-12.
345. Skelton, M.R., et al., *Distinct periods of developmental sensitivity to the effects of 3,4-(+/-)-methylenedioxymethamphetamine (MDMA) on behaviour and monoamines in rats.* Int J Neuropsychopharmacol, 2012. **15**(6): p. 811-24.
346. Schaefer, T.L., et al., *Cognitive impairments from developmental exposure to serotonergic drugs: citalopram and MDMA.* Int J Neuropsychopharmacol, 2013. **16**(6): p. 1383-94.

347. McElhatton, P.R., et al., *Congenital anomalies after prenatal ecstasy exposure [letter]*. Lancet, 1999. **354**(9188): p. 1441-2.
348. Bateman, D.N., et al., *A case control study to examine the pharmacological factors underlying ventricular septal defects in the North of England.* Eur J Clin Pharmacol, 2004. **60**(9): p. 635-41.
349. Ho, E., L. Karimi-Tabesh, and G. Koren, *Characteristics of pregnant women who use Ecstasy (3, 4- methylenedioxymethamphetamine).* Neurotoxicol Teratol, 2001. **23**(6): p. 561-7.
350. Singer, L.T., et al., *Neurobehavioral outcomes of infants exposed to MDMA (Ecstasy) and other recreational drugs during pregnancy.* Neurotoxicol Teratol, 2012. **34**(3): p. 303-10.
351. Singer, L.T., et al., *Motor delays in MDMA (ecstasy) exposed infants persist to 2years.* Neurotoxicol Teratol, 2016.
352. Greene, S.L., et al., *Multiple toxicity from 3,4-methylenedioxymethamphetamine ("ecstasy").* Am J Emerg Med, 2003. **21**(2): p. 121-4.
353. Mechan, A.O., et al., *The pharmacology of the acute hyperthermic response that follows administration of 3,4-methylenedioxymethamphetamine (MDMA, 'ecstasy') to rats.* Br J Pharmacol, 2002. **135**(1): p. 170-80.
354. Colado, M.I., et al., *Studies on the role of dopamine in the degeneration of 5-HT nerve endings in the brain of Dark Agouti rats following 3,4-methylenedioxymethamphetamine (MDMA or 'ecstasy') administration.* Br J Pharmacol, 1999. **126**(4): p. 911-24.
355. Hughes, J.C., M. McCabe, and R.J. Evans, *Intracranial haemorrhage associated with ingestion of 'ecstasy'.* Arch Emerg Med, 1993. **10**(4): p. 372-4.
356. Kaku, D.A. and D.H. Lowenstein, *Emergence of recreational drug abuse as a major risk factor for stroke in young adults.* Ann Intern Med, 1990. **113**(11): p. 821-7.
357. Perez, J.A., Jr., E.L. Arsura, and S. Strategos, *Methamphetamine-related stroke: four cases.* J Emerg Med, 1999. **17**(3): p. 469-71.
358. Rothwell, P.M. and R. Grant, *Cerebral venous sinus thrombosis induced by 'ecstasy'.* J Neurol Neurosurg Psychiatry, 1993. **56**(9): p. 1035.
359. Gledhill, J.A., et al., *Subarachnoid haemorrhage associated with MDMA abuse [letter]*. J Neurol Neurosurg Psychiatry, 1993. **56**(9): p. 1036-7.
360. Manchanda, S. and M.J. Connolly, *Cerebral infarction in association with Ecstasy abuse.* Postgrad Med J, 1993. **69**(817): p. 874-5.
361. Selmi, F., et al., *Intracerebral haemorrhage due to amphetamine abuse: report of two cases with underlying arteriovenous malformations.* Br J Neurosurg, 1995. **9**(1): p. 93-6.
362. Ho, M.P., J.L. Tsai, and Y.K. Wong, *Subarachnoid hemorrhage and death following coingestion of MDMA with other drugs.* J Chin Med Assoc, 2004. **67**(12): p. 640-3.
363. Johnson, J., et al., *Posterior spinal artery aneurysm rupture after 'Ecstasy' abuse.* J Neurointerv Surg, 2014.
364. Finley, J.J.t., M.A. Konstam, and J.E. Udelson, *Arginine vasopressin antagonists for the treatment of heart failure and hyponatremia.* Circulation, 2008. **118**(4): p. 410-21.
365. Bolignano, D., et al., *Copeptin (CTproAVP), a new tool for understanding the role of vasopressin in pathophysiology.* Clin Chem Lab Med, 2014. **52**(10): p. 1447-56.
366. Dowling, G.P., E.T.d. McDonough, and R.O. Bost, *'Eve' and 'Ecstasy'. A report of five deaths associated with the use of MDEA and MDMA.* Jama, 1987. **257**(12): p. 1615-7.
367. Milroy, C.M., J.C. Clark, and A.R. Forrest, *Pathology of deaths associated with "ecstasy" and "eve" misuse.* J Clin Pathol, 1996. **49**(2): p. 149-53.
368. Montastruc, F., et al., *Valvular heart disease in a patient taking 3,4-methylenedioxymethamphetamine (MDMA, 'Ecstasy').* Br J Clin Pharmacol, 2012. **74**(3): p. 547-8.
369. Baggott, M., L. Jerome, and R. Stuart, *3,4-Methylenedioxymethamphetamine (MDMA); A review of the English-language scientific and medical literature:* , in *First Edition of*

Investigator's Brochure for MDMA. 2001, Multidiscplinary Association for Psychedelic Studies.
370. Brvar, M., et al., *Polydipsia as another mechanism of hyponatremia after 'ecstasy' (3,4 methyldioxymethamphetamine) ingestion.* Eur J Emerg Med, 2004. **11**(5): p. 302-4.
371. Henry, J.A. and J.G. Rella, *Medical risks associated with MDMA use*, in *Ecstasy: A Complete Guide*, J. Holland, Editor. 2001, Inner Traditions: Rochester, VT. p. 71-86.
372. Corona, G., et al., *Moderate hyponatremia is associated with increased risk of mortality: evidence from a meta-analysis.* PLoS One, 2013. **8**(12): p. e80451.
373. Ayus, J.C., S.G. Achinger, and A. Arieff, *Brain cell volume regulation in hyponatremia: role of sex, age, vasopressin, and hypoxia.* Am J Physiol Renal Physiol, 2008. **295**(3): p. F619-24.
374. Lien, Y.H. and J.I. Shapiro, *Hyponatremia: clinical diagnosis and management.* Am J Med, 2007. **120**(8): p. 653-8.
375. Stoiser, B., et al., *Copeptin, a fragment of the vasopressin precursor, as a novel predictor of outcome in heart failure.* Eur J Clin Invest, 2006. **36**(11): p. 771-8.
376. Morgenthaler, N.G., *Copeptin: a biomarker of cardiovascular and renal function.* Congest Heart Fail, 2010. **16 Suppl 1**: p. S37-44.
377. Yalta, K., et al., *Copeptin and cardiovascular disease: a review of a novel neurohormone.* Int J Cardiol, 2013. **167**(5): p. 1750-9.
378. Rohrig, T.P. and R.W. Prouty, *Tissue distribution of methylenedioxymethamphetamine.* J Anal Toxicol, 1992. **16**(1): p. 52-3.
379. Beitia, G., et al., *Ecstasy-induced toxicity in rat liver.* Liver, 2000. **20**(1): p. 8-15.
380. Carvalho, M., et al., *Effect of 3,4-methylenedioxymethamphetamine ("ecstasy") on body temperature and liver antioxidant status in mice: influence of ambient temperature.* Arch Toxicol, 2002. **76**(3): p. 166-72.
381. Varela-Rey, M., et al., *3,4-methylenedioxymethamphetamine ("Ecstasy") stimulates the expression of alpha1(I) procollagen mRNA in hepatic stellate cells.* Biochem Biophys Res Commun, 1999. **259**(3): p. 678-82.
382. Carvalho, M., et al., *Mechanisms underlying the hepatotoxic effects of ecstasy.* Curr Pharm Biotechnol, 2010. **11**(5): p. 476-95.
383. Dykhuizen, R.S., et al., *Ecstasy induced hepatitis mimicking viral hepatitis.* Gut, 1995. **36**(6): p. 939-41.
384. Ellis, A.J., et al., *Acute liver damage and ecstasy ingestion.* Gut, 1996. **38**(3): p. 454-8.
385. Ellis, S.J., *Complications of "ecstasy" misuse.* Lancet, 1992. **340**(8821): p. 726.
386. Nadkarni, G.N., et al., *Serotonin syndrome, disseminated intravascular coagulation, and hepatitis after a single ingestion of MDMA in an Asian woman.* Am J Ther, 2014. **21**(4): p. e117-9.
387. Andreu, V., et al., *Ecstasy: a common cause of severe acute hepatotoxicity.* J Hepatol, 1998. **29**(3): p. 394-7.
388. Carvalho, M., F. Carvalho, and M.L. Bastos, *Is hyperthermia the triggering factor for hepatotoxicity induced by 3,4- methylenedioxymethamphetamine (ecstasy)? An in vitro study using freshly isolated mouse hepatocytes.* Arch Toxicol, 2001. **74**(12): p. 789-93.
389. da Silva, D.D., et al., *Mixtures of 3,4-methylenedioxymethamphetamine (ecstasy) and its major human metabolites act additively to induce significant toxicity to liver cells when combined at low, non-cytotoxic concentrations.* J Appl Toxicol, 2014. **34**(6): p. 618-27.
390. Cerretani, D., et al., *Acute administration of 3,4-methylenedioxymethamphetamine (MDMA) induces oxidative stress, lipoperoxidation and TNFalpha-mediated apoptosis in rat liver.* Pharmacol Res, 2011. **64**(5): p. 517-27.
391. Callahan, B.T., B.J. Cord, and G.A. Ricaurte, *Long-term impairment of anterograde axonal transport along fiber projections originating in the rostral raphe nuclei after treatment with fenfluramine or methylenedioxymethamphetamine.* Synapse, 2001. **40**(2): p. 113-21.

392. Hatzidimitriou, G., U.D. McCann, and G.A. Ricaurte, *Altered serotonin innervation patterns in the forebrain of monkeys treated with (+/-)3,4-methylenedioxymethamphetamine seven years previously: factors influencing abnormal recovery.* J Neurosci, 1999. **19**(12): p. 5096-107.
393. Green, A.R., et al., *The pharmacology and clinical pharmacology of 3,4-methylenedioxymethamphetamine (MDMA, "ecstasy").* Pharmacol Rev, 2003. **55**(3): p. 463-508.
394. O'Callaghan, J.P. and D.B. Miller, *Neurotoxicity profiles of substituted amphetamines in the C57BL/6J mouse.* J Pharmacol Exp Ther, 1994. **270**(2): p. 741-51.
395. Miller, D.B. and J.P. O'Callaghan, *Neurotoxicity of d-amphetamine in the C57BL/6J and CD-1 mouse. Interactions with stress and the adrenal system.* Ann N Y Acad Sci, 1996. **801**: p. 148-67.
396. Molliver, M.E., et al., *Neurotoxicity of MDMA and related compounds: anatomic studies.* Ann N Y Acad Sci, 1990. **600**: p. 649-61; discussion 661-4.
397. Sabol, K.E., et al., *Amphetamine analogs have differential effects on DRL 36-s schedule performance.* Psychopharmacology (Berl), 1995. **121**(1): p. 57-65.
398. Bosch, O.G., et al., *Verbal memory deficits are correlated with prefrontal hypometabolism in (18)FDG PET of recreational MDMA users.* PLoS One, 2013. **8**(4): p. e61234.
399. Taurah, L., C. Chandler, and G. Sanders, *Depression, impulsiveness, sleep, and memory in past and present polydrug users of 3,4-methylenedioxymethamphetamine (MDMA, ecstasy).* Psychopharmacology (Berl), 2014. **231**(4): p. 737-51.
400. Smithies, V., et al., *Dysfunctional overnight memory consolidation in ecstasy users.* J Psychopharmacol, 2014. **28**(8): p. 751-62.
401. Laws, K.R. and J. Kokkalis, *Ecstasy (MDMA) and memory function: a meta-analytic update.* Hum Psychopharmacol, 2007.
402. Zakzanis, K.K., Z. Campbell, and D. Jovanovski, *The neuropsychology of ecstasy (MDMA) use: a quantitative review.* Hum Psychopharmacol, 2007. **22**(7): p. 427-35.
403. Murphy, P.N., et al., *The effects of 'ecstasy' (MDMA) on visuospatial memory performance: findings from a systematic review with meta-analyses.* Hum Psychopharmacol, 2012. **27**(2): p. 113-38.
404. Wagner, D., et al., *A prospective study of learning, memory, and executive function in new MDMA users.* Addiction, 2013. **108**(1): p. 136-45.
405. Wagner, D., et al., *Learning, Memory, and Executive Function in New MDMA Users: A 2-Year Follow-Up Study.* Front Neurosci, 2015. **9**: p. 445.
406. Price, J.S., P. Shear, and K.M. Lisdahl, *Ecstasy exposure & gender: examining components of verbal memory functioning.* PLoS One, 2014. **9**(12): p. e115645.
407. Kuypers, K.P.C., et al., *Verbal memory impairment in polydrug Ecstasy users: A clinical perspective.* PLoS One, 2016. **11**(2): p. e0149438. .
408. Cole, J.C., et al., *The effects of stereotype threat on cognitive function in ecstasy users.* J Psychopharmacol, 2006. **20**(4): p. 518-25.
409. Wareing, M., et al., *Verbal working memory deficits in current and previous users of MDMA.* Hum Psychopharmacol, 2004. **19**(4): p. 225-34.
410. von Geusau, N.A., et al., *Impaired executive function in male MDMA ("ecstasy") users.* Psychopharmacology (Berl), 2004. **175**(3): p. 331-41.
411. Murphy, P.N., et al., *Executive working memory deficits in abstinent ecstasy/MDMA users: a critical review.* Neuropsychobiology, 2009. **60**(3-4): p. 159-75.
412. Hoshi, R., et al., *Neurocognitive function in current and ex-users of ecstasy in comparison to both matched polydrug-using controls and drug-naive controls.* Psychopharmacology (Berl), 2007. **194**(3): p. 371-9.

413. McGuire, P.K., H. Cope, and T.A. Fahy, *Diversity of psychopathology associated with use of 3,4-methylenedioxymethamphetamine ('Ecstasy').* Br J Psychiatry, 1994. **165**(3): p. 391-5.
414. Huizink, A.C., et al., *Symptoms of anxiety and depression in childhood and use of MDMA: prospective, population based study.* Bmj, 2006. **332**(7545): p. 825-8.
415. Fonsart, J., et al., *Sprague-Dawley rats display metabolism-mediated sex differences in the acute toxicity of 3,4-methylenedioxymethamphetamine (MDMA, ecstasy).* Toxicol Appl Pharmacol, 2008.
416. Malpass, A., et al., *Acute toxicity of 3,4-methylenedioxymethamphetamine (MDMA) in Sprague-Dawley and Dark Agouti rats.* Pharmacol Biochem Behav, 1999. **64**(1): p. 29-34.
417. Palenicek, T., et al., *Increased sensitivity to the acute effects of MDMA ("ecstasy") in female rats.* Physiol Behav, 2005. **86**(4): p. 546-53.
418. Davis, W.M., H.T. Hatoum, and I.W. Waters, *Toxicity of MDA (3,4-methylenedioxyamphetamine) considered for relevance to hazards of MDMA (Ecstasy) abuse.* Alcohol Drug Res, 1987. **7**(3): p. 123-34.
419. Green, A.R., E. O'Shea, and M.I. Colado, *A review of the mechanisms involved in the acute MDMA (ecstasy)-induced hyperthermic response.* Eur J Pharmacol, 2004. **500**(1-3): p. 3-13.
420. Cregg, M.T. and J.A. Tracey, *Ecstasy abuse in Ireland.* Ir Med J, 1993. **86**(4): p. 118-20.
421. Armenian, P., et al., *Multiple MDMA (Ecstasy) overdoses at a rave event: a case series.* J Intensive Care Med, 2013. **28**(4): p. 252-8.
422. CDC, *Ecstasy overdoses at a New Year's Eve rave--Los Angeles, California, 2010.* MMWR Morb Mortal Wkly Rep, 2010. **59**(22): p. 677-81.
423. Gowing, L.R., et al., *The health effects of ecstasy: a literature review.* Drug Alcohol Rev, 2002. **21**(1): p. 53-63.
424. Grunau, B.E., M.O. Wiens, and M. Greidanus, *Dantrolene for the treatment of MDMA toxicity.* CJEM, 2010. **12**(5): p. 457-9.
425. Russell, T., et al., *Ecstacy-induced delayed rhabdomyolysis and neuroleptic malignant syndrome in a patient with a novel variant in the ryanodine receptor type 1 gene.* Anaesthesia, 2012. **67**(9): p. 1021-4.
426. Shah, H.V., G.H. Irvine, and M. Bradley, *Rhabdomyolysis of the masseter muscle: case report.* Br J Oral Maxillofac Surg, 2008. **46**(2): p. 138-40.
427. Davies, O., et al., *Full recovery after severe serotonin syndrome, severe rhabdomyolysis, multi-organ failure and disseminated intravascular coagulopathy from MDMA.* Heart Lung, 2014. **43**(2): p. 117-9.
428. Hall, A.P., et al., *An unusual case of Ecstasy poisoning.* Intensive Care Med, 1996. **22**(7): p. 670-1.
429. Logan, A.S., et al., *Survival following 'Ecstasy' ingestion with a peak temperature of 42 degrees C.* Anaesthesia, 1993. **48**(11): p. 1017-8.
430. Singarajah, C. and N.G. Lavies, *An overdose of ecstasy. A role for dantrolene.* Anaesthesia, 1992. **47**(8): p. 686-7.
431. Bedford Russell, A.R., R.H. Schwartz, and S. Dawling, *Accidental ingestion of 'Ecstasy' (3,4-methylenedioxymethylamphetamine).* Arch Dis Child, 1992. **67**(9): p. 1114-5.
432. Nimmo, S.M., et al., *Drug-induced hyperthermia.* Anaesthesia, 1993. **48**(10): p. 892-5.
433. Murthy, B.V., R.G. Wilkes, and N.B. Roberts, *Creatine kinase isoform changes following Ecstasy overdose.* Anaesth Intensive Care, 1997. **25**(2): p. 156-9.
434. Ramcharan, S., et al., *Survival after massive ecstasy overdose.* J Toxicol Clin Toxicol, 1998. **36**(7): p. 727-31.
435. Screaton, G.R., et al., *Hyperpyrexia and rhabdomyolysis after MDMA ("ecstasy") abuse.* Lancet, 1992. **339**(8794): p. 677-8.

436. Montgomery, H. and S. Myerson, *3,4-methylenedioxymethamphetamine (MDMA, or "ecstasy") and associated hypoglycemia.* Am J Emerg Med, 1997. **15**(2): p. 218.
437. Williams, A. and R. Unwin, *Prolonged elevation of serum creatine kinase (CK) without renal failure after ingestion of ecstasy.* Nephrol Dial Transplant, 1997. **12**(2): p. 361-2.
438. Hayner, G.N. and H. McKinney, *MDMA. The dark side of ecstasy.* J Psychoactive Drugs, 1986. **18**(4): p. 341-7.
439. Toth, A.R. and T. Varga, *Myocardium and striated muscle damage caused by licit or illicit drugs.* Leg Med (Tokyo), 2009. **11 Suppl 1**: p. S484-7.
440. Vanden Eede, H., et al., *Rhabdomyolysis in MDMA intoxication: a rapid and underestimated killer. "Clean" Ecstasy, a safe party drug?* J Emerg Med, 2012. **42**(6): p. 655-8.
441. Sadeghian, S., et al., *Two ecstasy-induced myocardial infarctions during a three month period in a young man.* Arch Iran Med, 2007. **10**(3): p. 409-12.
442. Diffley, M., et al., *Catecholaminergic polymorphic ventricular tachycardia found in an adolescent after a methylenedioxymethamphetamine and marijuana-induced cardiac arrest.* Crit Care Med, 2012. **40**(7): p. 2223-6.
443. Hoggett, K., D. McCoubrie, and D.M. Fatovich, *Ecstasy-induced acute coronary syndrome: something to rave about.* Emerg Med Australas, 2012. **24**(3): p. 339-42.
444. Moller, M., et al., *Ecstasy-induced myocardial infarction in a teenager: rare complication of a widely used illicit drug.* Clin Res Cardiol, 2010. **99**(12): p. 849-51.
445. Kapoor, A. and K.S. Jackson, *Seizures presenting in pregnancy: eclampsia or something else?* J Obstet Gynaecol, 2013. **33**(6): p. 630-1.
446. Okunoye, G.O. and P. Dutton, *Acute myocardial infarction in pregnancy following unlicensed use of methylenedioxymethamphetamine ('Ecstasy').* Scott Med J, 2013. **58**(3): p. e4-6.
447. Mizia-Stec, K., et al., *Severe dilated cardiomyopathy as a consequence of Ecstasy intake.* Cardiovasc Pathol, 2008. **17**(4): p. 250-3.
448. Hua, Y.S., et al., *Contraction band necrosis in two ecstasy abusers: a latent lethal lesion associated with ecstasy.* Am J Forensic Med Pathol, 2009. **30**(3): p. 295-7.
449. Sano, R., et al., *A fatal case of myocardial damage due to misuse of the "designer drug" MDMA.* Leg Med (Tokyo), 2009. **11**(6): p. 294-7.
450. Suarez, R.V. and R. Riemersma, *"Ecstasy" and sudden cardiac death.* Am J Forensic Med Pathol, 1988. **9**(4): p. 339-41.
451. Lora-Tamayo, C., T. Tena, and A. Rodriguez, *Amphetamine derivative related deaths.* Forensic Sci Int, 1997. **85**(2): p. 149-57.
452. Bingham, C., et al., *Necrotizing renal vasculopathy resulting in chronic renal failure after ingestion of methamphetamine and 3,4-methylenedioxymethamphetamine ('ecstasy').* Nephrol Dial Transplant, 1998. **13**(10): p. 2654-5.
453. Ghatol, A. and A. Kazory, *Ecstasy-associated acute severe hyponatremia and cerebral edema: a role for osmotic diuresis?* J Emerg Med, 2012. **42**(6): p. e137-40.
454. Beuerle, J.R. and F. Barrueto, Jr., *Neurogenic bladder and chronic urinary retention associated with MDMA abuse.* J Med Toxicol, 2008. **4**(2): p. 106-8.
455. Bryden, A.A., P.J. Rothwell, and P.H. O'Reilly, *Urinary retention with misuse of "ecstasy".* Bmj, 1995. **310**(6978): p. 504.
456. Delgado, J.H., et al., *Acute, transient urinary retention from combined ecstasy and methamphetamine use.* J Emerg Med, 2004. **26**(2): p. 173-5.
457. Holden, R. and M.A. Jackson, *Near-fatal hyponatraemic coma due to vasopressin over-secretion after "ecstasy" (3,4-MDMA).* Lancet, 1996. **347**(9007): p. 1052.
458. Henry, J.A., et al., *Low-dose MDMA ("ecstasy") induces vasopressin secretion.* Lancet, 1998. **351**(9118): p. 1784.
459. Gomez-Balaguer, M., et al., *Syndrome of inappropriate antidiuretic hormone secretion and "designer drugs" (ecstasy).* J Pediatr Endocrinol Metab, 2000. **13**(4): p. 437-8.

460. Hegadoren, K.M., G.B. Baker, and M. Bourin, *3,4-Methylenedioxy analogues of amphetamine: defining the risks to humans.* Neurosci Biobehav Rev, 1999. **23**(4): p. 539-53.
461. Woodrow, G., P. Harnden, and J.H. Turney, *Acute renal failure due to accelerated hypertension following ingestion of 3,4-methylenedioxymethamphetamine ('ecstasy').* Nephrol Dial Transplant, 1995. **10**(3): p. 399-400.
462. Cadier, M.A. and J.A. Clarke, *Ecstasy and Whizz at a rave resulting in a major burn plus complications.* Burns, 1993. **19**(3): p. 239-40.
463. Fahal, I.H., et al., *Acute renal failure after ecstasy.* Bmj, 1992. **305**(6844): p. 29.
464. Maxwell, D.L., M.I. Polkey, and J.A. Henry, *Hyponatraemia and catatonic stupor after taking "ecstasy".* Bmj, 1993. **307**(6916): p. 1399.
465. Satchell, S.C. and M. Connaughton, *Inappropriate antidiuretic hormone secretion and extreme rises in serum creatinine kinase following MDMA ingestion.* Br J Hosp Med, 1994. **51**(9): p. 495.
466. Claffey, C., *A 26-year-old woman with sudden onset cerebral edema.* J Emerg Nurs, 2011. **37**(1): p. 55-6.
467. Gritti, P., et al., *Are we aware of ecstasy effects?* Intern Emerg Med, 2009. **4**(2): p. 175-7.
468. Parr, M.J., H.M. Low, and P. Botterill, *Hyponatraemia and death after "ecstasy" ingestion.* Med J Aust, 1997. **166**(3): p. 136-7.
469. O'Connor, A., et al., *Death from hyponatraemia-induced cerebral oedema associated with MDMA ("Ecstasy") use.* N Z Med J, 1999. **112**(1091): p. 255-6.
470. Dar, K.J. and M.E. McBrien, *MDMA induced hyperthermia: report of a fatality and review of current therapy.* Intensive Care Med, 1996. **22**(9): p. 995-6.
471. Mikula, T., J. Kozlowska, and A. Wiercinska-Drapalo, *Alcohol and ecstasy (MDMA-3,4-methylenedioxymethamphetamine) overdose as a reason for acute hepatitis with gall bladder inflammation.* Drug Alcohol Rev, 2009. **28**(6): p. 685.
472. Payance, A., et al., *Severe chronic hepatitis secondary to prolonged use of ecstasy and cocaine.* Clin Res Hepatol Gastroenterol, 2013. **37**(5): p. e109-13.
473. Colak, Y., et al., *Ecstasy induced fatal hepatic failure.* J Gastrointestin Liver Dis, 2011. **20**(2): p. 215-6.
474. Chadwick, I.S., et al., *Ecstasy, 3-4 methylenedioxymethamphetamine (MDMA), a fatality associated with coagulopathy and hyperthermia.* J R Soc Med, 1991. **84**(6): p. 371.
475. Campkin, N.J. and U.M. Davies, *Treatment of 'ecstasy' overdose with dantrolene.* Anaesthesia, 1993. **48**(1): p. 82-3.
476. Fineschi, V. and A. Masti, *Fatal poisoning by MDMA (ecstasy) and MDEA: a case report.* Int J Legal Med, 1996. **108**(5): p. 272-5.
477. Wollner, K., et al., *[Death after the intake of amphetamine/ecstasy: two case reports].* Arch Kriminol, 2015. **235**(1-2): p. 53-61.
478. Clark, A.D. and N. Butt, *Ecstasy-induced very severe aplastic anaemia complicated by invasive pulmonary mucormycosis treated with allogeneic peripheral blood progenitor cell transplant.* Clin Lab Haematol, 1997. **19**(4): p. 279-81.
479. Marsh, J.C., et al., *Aplastic anaemia following exposure to 3,4-methylenedioxymethamphetamine ('Ecstasy').* Br J Haematol, 1994. **88**(2): p. 281-5.
480. Richman, J. and A. Ferber, *Severe aplastic anemia with hot pockets following daily Ecstasy ingestion.* Am J Hematol, 2008. **83**(4): p. 321-2.
481. Gomez-Fernandez, C., et al., *Facial eruption related to snorting Ecstasy.* Eur J Dermatol, 2010. **20**(6): p. 853-4.
482. Sauvageau, A., *Death from a possible anaphylactic reaction to ecstasy.* Clin Toxicol (Phila), 2008. **46**(2): p. 156.
483. Kahn, D.E., N. Ferraro, and R.J. Benveniste, *3 cases of primary intracranial hemorrhage associated with "Molly", a purified form of 3,4-methylenedioxymethamphetamine (MDMA).* J Neurol Sci, 2012. **323**(1-2): p. 257-60.

484. De Smet, K., et al., *Bilateral globus pallidus infarcts in ecstasy use.* JBR-BTR, 2011. **94**(2): p. 93.
485. Gardner, H., et al., *Acute hippocampal sclerosis following ecstasy ingestion.* Neurology, 2009. **73**(7): p. 567-9.
486. Nifosi, F., et al., *Hippocampal remodelling after MDMA neurotoxicity: a single case study.* World J Biol Psychiatry, 2009. **10**(4 Pt 3): p. 961-8.
487. Ruis, C., et al., *Cognitive disorders after sporadic ecstasy use? A case report.* Neurocase, 2014.
488. Bruggemann, N., et al., *Acute amnestic syndrome due to MDMA exposure.* J Neurol, 2016.
489. Spatt, J., B. Glawar, and B. Mamoli, *A pure amnestic syndrome after MDMA ("ecstasy") ingestion.* J Neurol Neurosurg Psychiatry, 1997. **62**(4): p. 418-9.
490. Squier, M.V., et al., *Death after ecstasy ingestion: neuropathological findings.* J Neurol Neurosurg Psychiatry, 1995. **58**(6): p. 756.
491. Brand, H.S., S.N. Dun, and A.V. Nieuw Amerongen, *Ecstasy (MDMA) and oral health.* Br Dent J, 2008. **204**(2): p. 77-81.
492. Duxbury, A.J., *Ecstasy--dental implications.* Br Dent J, 1993. **175**(1): p. 38.
493. Nixon, P.J., C.C. Youngson, and A. Beese, *Tooth surface loss: does recreational drug use contribute?* Clin Oral Investig, 2002. **6**(2): p. 128-30.
494. Marchesi, C., M. Tonna, and C. Maggini, *Obsessive-compulsive disorder followed by psychotic episode in long-term ecstasy misuse.* World J Biol Psychiatry, 2009. **10**(4 Pt 2): p. 599-602.
495. Potash, M.N., K.A. Gordon, and K.L. Conrad, *Persistent Psychosis and Medical Complications After a Single Ingestion of MDMA "Ecstasy": A Case Report and Review of the Literature.* Psychiatry (Edgmont), 2009. **6**(7): p. 40-4.
496. Tabatabaei, S.A., M. Soleimani, and A. Khodabandeh, *A case of autoenucleation associated with a contralateral field defect.* Orbit, 2011. **30**(3): p. 165-8.
497. Mutlu, H., et al., *'Ecstasy'(MDMA)-induced pneumomediastinum and epidural pneumatosis.* Diagn Interv Radiol, 2005. **11**(3): p. 150-1.
498. Onwudike, M., *Ecstasy induced retropharyngeal emphysema.* J Accid Emerg Med, 1996. **13**(5): p. 359-61.
499. Pittman, J.A. and J.C. Pounsford, *Spontaneous pneumomediastinum and Ecstasy abuse.* J Accid Emerg Med, 1997. **14**(5): p. 335-6.
500. Quin, G.I., G.M. McCarthy, and D.K. Harries, *Spontaneous pneumomediastinum and ecstasy abuse.* J Accid Emerg Med, 1999. **16**(5): p. 382.
501. Gungadeen, A. and J. Moor, *Extensive subcutaneous emphysema and pneumomediastinum after ecstasy ingestion.* Case Rep Otolaryngol, 2013. **2013**: p. 795867.
502. Clause, A.L., et al., *Spontaneous pneumomediastinum and epidural pneumatosis after oral ecstasy consumption.* Acta Clin Belg, 2014. **69**(2): p. 146-8.
503. Peters, N.F., R. Gosselin, and K.L. Verstraete, *A rare case of diffuse alveolar hemorrhage following oral amphetamine intake.* JBR-BTR, 2014. **97**(1): p. 42-3.
504. Barrett, P.J., *'Ecstasy' misuse--overdose or normal dose?* Anaesthesia, 1993. **48**(1): p. 83.
505. O'Neill, D. and J.K. Dart, *Methylenedioxyamphetamine ('Ecstasy') associated keratopathy.* Eye, 1993. **7**(Pt 6): p. 805-6.
506. Schroeder, B. and S. Brieden, *Bilateral sixth nerve palsy associated with MDMA ("ecstasy") abuse.* Am J Ophthalmol, 2000. **129**(3): p. 408-9.
507. Schifano, F., et al., *Death rates from ecstasy (MDMA, MDA) and polydrug use in England and Wales 1996-2002.* Hum Psychopharmacol, 2003. **18**(7): p. 519-24.
508. Abad, S., et al., *MDMA enhances hippocampal-dependent learning and memory under restrictive conditions, and modifies hippocampal spine density.* Psychopharmacology (Berl), 2014. **231**(5): p. 863-74.

509. Fantegrossi, W.E., et al., *Behavioral and neurochemical consequences of long-term intravenous self-administration of MDMA and its enantiomers by rhesus monkeys.* Neuropsychopharmacology, 2004. **29**(7): p. 1270-81.
510. Schenk, S., et al., *Development, maintenance and temporal pattern of self-administration maintained by ecstasy (MDMA) in rats.* Psychopharmacology (Berl), 2003. **169**(1): p. 21-7.
511. Trigo, J.M., et al., *A reliable model of intravenous MDMA self-administration in naive mice.* Psychopharmacology (Berl), 2006. **184**(2): p. 212-20.
512. Lile, J.A., J.T. Ross, and M.A. Nader, *A comparison of the reinforcing efficacy of 3,4-methylenedioxymethamphetamine (MDMA, "ecstasy") with cocaine in rhesus monkeys.* Drug Alcohol Depend, 2005. **78**(2): p. 135-40.
513. Wang, Z. and W.L. Woolverton, *Estimating the relative reinforcing strength of (+/-)-3,4-methylenedioxymethamphetamine (MDMA) and its isomers in rhesus monkeys: comparison to (+)-methamphetamine.* Psychopharmacology (Berl), 2007. **189**(4): p. 483-8.
514. Robledo, P., et al., *Study of the behavioural responses related to the potential addictive properties of MDMA in mice.* Naunyn Schmiedebergs Arch Pharmacol, 2004. **369**(3): p. 338-49.
515. Verheyden, S.L., J.A. Henry, and H.V. Curran, *Acute, sub-acute and long-term subjective consequences of 'ecstasy' (MDMA) consumption in 430 regular users.* Hum Psychopharmacol, 2003. **18**(7): p. 507-17.
516. Cottler, L.B., K.S. Leung, and A.B. Abdallah, *Test-re-test reliability of DSM-IV adopted criteria for 3,4-methylenedioxymethamphetamine (MDMA) abuse and dependence: a cross-national study.* Addiction, 2009. **104**(10): p. 1679-90.
517. Meyer, J.S., *3,4-methylenedioxymethamphetamine (MDMA): current perspectives.* Subst Abuse Rehabil, 2013. **4**: p. 83-99.
518. Topp L.J., H. W.D.., and H. J., *Is there a dependance syndrome for ecstasy?* 1997, Randwick, NSW: National Drug & Alcohol Research Centre.
519. Cottler, L.B., et al., *Ecstasy abuse and dependence among adolescents and young adults: applicability and reliability of DSM-IV criteria.* Hum Psychopharmacol, 2001. **16**(8): p. 599-606.
520. von Sydow, K., et al., *Use, abuse and dependence of ecstasy and related drugs in adolescents and young adults-a transient phenomenon? Results from a longitudinal community study.* Drug Alcohol Depend, 2002. **66**(2): p. 147-59.
521. Degenhardt, L., R. Bruno, and L. Topp, *Is ecstasy a drug of dependence?* Drug Alcohol Depend, 2010. **107**(1): p. 1-10.
522. Topp, L., et al., *Ecstasy use in Australia: patterns of use and associated harm.* Drug Alcohol Depend, 1999. **55**(1-2): p. 105-15.
523. Davis, A.K. and H. Rosenberg, *The prevalence, intensity, and assessment of craving for MDMA/ecstasy in recreational users.* J Psychoactive Drugs, 2014. **46**(2): p. 154-61.
524. De La Garza, R., 2nd, K.R. Fabrizio, and A. Gupta, *Relevance of rodent models of intravenous MDMA self-administration to human MDMA consumption patterns.* Psychopharmacology (Berl), 2007. **189**(4): p. 425-434.
525. Stolaroff, M., *The Secret Chief Revealed: Conversations with a pioneer of the underground therapy movement.* 2004, Sarasota FL: Multidisciplinary Association for Psychedelic Studies.
526. Grob, C., *MDMA research: preliminary investigations with human subjects.* Int J Drug Policy, 1998. **9**(2): p. 119-124.
527. Bouso, J.C., et al., *MDMA-assisted psychotherapy using low doses in a small sample of women with chronic posttraumatic stress disorder.* J Psychoactive Drugs, 2008. **40**(3): p. 225-36.

528. de la Torre, R., et al., *Pharmacology of MDMA in humans.* Ann N Y Acad Sci, 2000. **914**: p. 225-37.
529. Dumont, G.J. and R.J. Verkes, *A review of acute effects of 3,4-methylenedioxymethamphetamine in healthy volunteers.* J Psychopharmacol, 2006. **20**(2): p. 176-87.
530. Hysek, C.M., et al., *Pharmacokinetic and pharmacodynamic effects of methylphenidate and MDMA administered alone or in combination.* Int J Neuropsychopharmacol, 2014. **17**(3): p. 371-81.
531. Pizarro, N., et al., *Stereochemical analysis of 3,4-methylenedioxymethamphetamine and its main metabolites in human samples including the catechol-type metabolite (3,4-dihydroxymethamphetamine).* Drug Metab Dispos, 2004. **32**(9): p. 1001-7.
532. de la Torre, R., et al., *Clinical pharmacokinetics of amfetamine and related substances: monitoring in conventional and non-conventional matrices.* Clin Pharmacokinet, 2004. **43**(3): p. 157-85.
533. de Boer, D., et al., *Gas chromatographic/mass spectrometric assay for profiling the enantiomers of 3,4-methylenedioxymethamphetamine and its chiral metabolites using positive chemical ionization ion trap mass spectrometry.* J Mass Spectrom, 1997. **32**(11): p. 1236-46.
534. Helmlin, H.J., et al., *Analysis of 3,4-methylenedioxymethamphetamine (MDMA) and its metabolites in plasma and urine by HPLC-DAD and GC-MS.* J Anal Toxicol, 1996. **20**(6): p. 432-40.
535. Lanz, M., R. Brenneisen, and W. Thormann, *Enantioselective determination of 3,4-methylene-dioxymethamphetamine and two of its metabolites in human urine by cyclodextrin-modified capillary zone electrophoresis.* Electrophoresis, 1997. **18**(6): p. 1035-43.
536. Ortuno, J., et al., *Quantification of 3,4-methylenedioxymetamphetamine and its metabolites in plasma and urine by gas chromatography with nitrogen-phosphorus detection.* J Chromatogr B Biomed Sci Appl, 1999. **723**(1-2): p. 221-32.
537. Helmlin, H.J. and R. Brenneisen, *Determination of psychotropic phenylalkylamine derivatives in biological matrices by high-performance liquid chromatography with photodiode-array detection.* J Chromatogr, 1992. **593**(1-2): p. 87-94.
538. Pizarro, N., et al., *Stereochemical analysis of 3,4-methylenedioxymethamphetamine and its main metabolites by gas chromatography/mass spectrometry.* Rapid Commun Mass Spectrom, 2003. **17**(4): p. 330-6.
539. Pizarro, N., et al., *Determination of MDMA and its metabolites in blood and urine by gas chromatography-mass spectrometry and analysis of enantiomers by capillary electrophoresis.* J Anal Toxicol, 2002. **26**(3): p. 157-65.
540. Segura, M., et al., *3,4-Dihydroxymethamphetamine (HHMA). A Major in Vivo 3,4-methylenedioxymethamphetamine (MDMA) Metabolite in Humans.* Chem Res Toxicol, 2001. **14**(9): p. 1203-1208.
541. Desrosiers, N.A., et al., *Oral fluid and plasma 3,4-methylenedioxymethamphetamine (MDMA) and metabolite correlation after controlled oral MDMA administration.* Anal Bioanal Chem, 2013. **405**(12): p. 4067-76.
542. de la Torre, R., et al., *Human pharmacology of MDMA: pharmacokinetics, metabolism, and disposition.* Ther Drug Monit, 2004. **26**(2): p. 137-44.
543. Abraham, T.T., et al., *Urinary MDMA, MDA, HMMA, and HMA excretion following controlled MDMA administration to humans.* J Anal Toxicol, 2009. **33**(8): p. 439-46.
544. Fallon, J.K., et al., *Stereospecific analysis and enantiomeric disposition of 3, 4-methylenedioxymethamphetamine (Ecstasy) in humans [published erratum appears in Clin Chem 1999 Sep;45(9):1585].* Clin Chem, 1999. **45**(7): p. 1058-69.
545. Schwaninger, A.E., et al., *Urinary excretion kinetics of 3,4-methylenedioxymethamphetamine (MDMA, ecstasy) and its phase I and phase II*

metabolites in humans following controlled MDMA administration. Clin Chem, 2011. **57**(12): p. 1748-56.
546. Farre, M., et al., *Human pharmacology of 3,4-methylenedioxymethamphetamine (MDMA, ecstasy) after repeated doses taken 4h apart Human pharmacology of MDMA after repeated doses taken 4h apart.* Eur Neuropsychopharmacol, 2015.
547. Ramamoorthy, S. and R.D. Blakely, *Phosphorylation and sequestration of serotonin transporters differentially modulated by psychostimulants.* Science, 1999. **285**(5428): p. 763-766.
548. Yang, J., et al., *Implications of mechanism-based inhibition of CYP2D6 for the pharmacokinetics and toxicity of MDMA.* J Psychopharmacol, 2006. **20**(6): p. 842-9.
549. O'Mathuna, B., et al., *The consequences of 3,4-methylenedioxymethamphetamine induced CYP2D6 inhibition in humans.* J Clin Psychopharmacol, 2008. **28**(5): p. 523-9.
550. Yubero-Lahoz, S., et al., *Sex Differences in 3,4-Methylenedioxymethamphetamine (MDMA; Ecstasy)-Induced Cytochrome P450 2D6 Inhibition in Humans.* Clin Pharmacokinet, 2011. **50**(5): p. 319-29.
551. Yubero-Lahoz, S., et al., *Changes in CYP1A2 activity in humans after 3,4-methylenedioxymethamphetamine (MDMA, ecstasy) administration using caffeine as a probe drug.* Drug Metab Pharmacokinet, 2012. **27**(6): p. 605-13.
552. Pardo-Lozano, R., et al., *Clinical Pharmacology of 3,4-Methylenedioxymethamphetamine (MDMA, "Ecstasy"): The Influence of Gender and Genetics (CYP2D6, COMT, 5-HTT).* PLoS One, 2012. **7**(10): p. e47599.
553. Gouzoulis-Mayfrank, E., et al., *Psychopathological, neuroendocrine and autonomic effects of 3,4-methylenedioxyethylamphetamine (MDE), psilocybin and d-methamphetamine in healthy volunteers. Results of an experimental double-blind placebo-controlled study.* Psychopharmacology (Berl), 1999. **142**(1): p. 41-50.
554. Davison, D. and A.C. Parrott, *Ecstasy (MDMA) in recreational users: Self-reported psychological and physiological effects.* Human Psychopharmacology Clinical & Experimental, 1997. **12**(3): p. 221-226.
555. Liechti, M.E., et al., *Acute psychological effects of 3,4-methylenedioxymethamphetamine (MDMA, "Ecstasy") are attenuated by the serotonin uptake inhibitor citalopram.* Neuropsychopharmacology, 2000. **22**(5): p. 513-21.
556. Liechti, M.E. and F.X. Vollenweider, *The serotonin uptake inhibitor citalopram reduces acute cardiovascular and vegetative effects of 3,4-methylenedioxymethamphetamine ('Ecstasy') in healthy volunteers.* J Psychopharmacol, 2000. **14**(3): p. 269-74.
557. Pacifici, R., et al., *Paroxetine inhibits acute effects of 3,4-methylenedioxymethamphetamine on the immune system in humans.* J Pharmacol Exp Ther, 2004. **309**(1): p. 285-92.
558. Tancer, M. and C.E. Johanson, *The effects of fluoxetine on the subjective and physiological effects of 3,4-methylenedioxymethamphetamine (MDMA) in humans.* Psychopharmacology (Berl), 2007. **189**(4): p. 565-73.
559. Liechti, M.E., et al., *Psychological and physiological effects of MDMA ("Ecstasy") after pretreatment with the 5-HT(2) antagonist ketanserin in healthy humans.* Neuropsychopharmacology, 2000. **23**(4): p. 396-404.
560. Hysek, C.M., et al., *The norepinephrine transporter inhibitor reboxetine reduces stimulant effects of MDMA ("ecstasy") in humans.* Clin Pharmacol Ther, 2011. **90**(2): p. 246-55.
561. Simmler, L.D., C.M. Hysek, and M.E. Liechti, *Sex differences in the effects of MDMA (ecstasy) on plasma copeptin in healthy subjects.* J Clin Endocrinol Metab, 2011. **96**(9): p. 2844-50.
562. Moron, J.A., et al., *Dopamine uptake through the norepinephrine transporter in brain regions with low levels of the dopamine transporter: evidence from knock-out mouse lines.* J Neurosci, 2002. **22**(2): p. 389-95.

563. Liechti, M.E. and F.X. Vollenweider, *Acute psychological and physiological effects of MDMA ("Ecstasy") after haloperidol pretreatment in healthy humans.* Eur Neuropsychopharmacol, 2000. **10**(4): p. 289-95.
564. Schmid, Y., et al., *Interactions between Bupropion and 3,4-Methylenedioxymethamphetamine in Healthy Subjects.* J Pharmacol Exp Ther, 2015. **353**(1): p. 102-11.
565. Domes, G., et al., *Oxytocin Attenuates Amygdala Responses to Emotional Faces Regardless of Valence.* Biol Psychiatry, 2007.
566. Kirsch, P., et al., *Oxytocin modulates neural circuitry for social cognition and fear in humans.* J Neurosci, 2005. **25**(49): p. 11489-93.
567. Bartz, J.A. and E. Hollander, *The neuroscience of affiliation: forging links between basic and clinical research on neuropeptides and social behavior.* Horm Behav, 2006. **50**(4): p. 518-28.
568. Wirth, M.M. and O.C. Schultheiss, *Effects of affiliation arousal (hope of closeness) and affiliation stress (fear of rejection) on progesterone and cortisol.* Horm Behav, 2006. **50**(5): p. 786-95.
569. Kuypers, K.P., et al., *No Evidence that MDMA-Induced Enhancement of Emotional Empathy Is Related to Peripheral Oxytocin Levels or 5-HT1a Receptor Activation.* PLoS One, 2014. **9**(6): p. e100719.
570. Leng, G. and M. Ludwig, *Intranasal Oxytocin: Myths and Delusions.* Biol Psychiatry, 2016. **79**(3): p. 243-50.
571. Grob, C., *Unpublished data on human study of psychological and physiological effects of MDMA*. 2001.
572. Kuypers, K.P., et al., *Inhibition of MDMA-induced increase in cortisol does not prevent acute impairment of verbal memory.* Br J Pharmacol, 2013. **168**(3): p. 607-17.
573. Hysek, C.M., et al., *MDMA enhances emotional empathy and prosocial behavior.* Soc Cogn Affect Neurosci, 2013.
574. Seibert, J., et al., *Acute effects of 3,4-methylenedioxymethamphetamine and methylphenidate on circulating steroid levels in healthy subjects.* Neuroendocrinology, 2014. **100**(1): p. 17-25.
575. Pacifici, R., et al., *Cell-mediated immune response in MDMA users after repeated dose administration: studies in controlled versus noncontrolled settings.* Ann N Y Acad Sci, 2002. **965**: p. 421-33.
576. Ramaekers, J.G., et al., *Involvement of inferior parietal lobules in prospective memory impairment during acute MDMA (ecstasy) intoxication: an event-related fMRI study.* Neuropsychopharmacology, 2009. **34**(7): p. 1641-8.
577. de Sousa Fernandes Perna, E.B., et al., *Memory and mood during MDMA intoxication, with and without memantine pretreatment.* Neuropharmacology, 2014. **87**: p. 198-205.
578. Pacifici, R., et al., *Immunomodulating activity of MDMA.* Ann N Y Acad Sci, 2000. **914**: p. 215-24.
579. Pacifici, R., et al., *Immunomodulating properties of MDMA alone and in combination with alcohol: a pilot study.* Life Sci, 1999. **65**(26): p. L309-16.
580. Pacifici, R., et al., *Effects of repeated doses of MDMA ("ecstasy") on cell-mediated immune response in humans.* Life Sci, 2001. **69**(24): p. 2931-41.
581. Liechti, M.E., *Effects of MDMA on body temperature in humans.* Temperature, 2014. **1**(3): p. 192-200.
582. Dao, C.K., S.M. Nowinski, and E.M. Mills, *The heat is on: Molecular mechanisms of drug-induced hyperthermia.* Temperature, 2014. **1**(3): p. 183-191.
583. Parrott, A.C. and L. Young, *Saturday night fever in ecstasy/MDMA dance clubbers: Heightened body temperature and associated psychobiological changes.* Temperature, 2014. **1**(3): p. 214-219.

584. Irvine, R.J., et al., *Plasma drug concentrations and physiological measures in 'dance party' participants.* Neuropsychopharmacology, 2006. **31**(2): p. 424-30.
585. Cole, J.C., et al., *Preliminary evidence of the cardiovascular effects of polysubstance misuse in nightclubs.* J Psychopharmacol, 2005. **19**(1): p. 67-70.
586. Parrott, A.C., et al., *Dance clubbing on MDMA and during abstinence from Ecstasy/MDMA: prospective neuroendocrine and psychobiological changes.* Neuropsychobiology, 2008. **57**(4): p. 165-80.
587. Clark, C.M., et al., *Acute effects of MDMA on autonomic cardiac activity and their relation to subjective prosocial and stimulant effects.* Psychophysiology, 2015. **52**(3): p. 429-35.
588. Baggott, M.J., et al., *3,4-Methylenedioxymethamphetamine (MDMA, 'Ecstasy') and Prazosin Interactions in Humans.*, in *70th Annual Meeting of the College on Problems of Drug Dependence*. 2008: San Juan, Puerto Rico.
589. Kirkpatrick, M.G., et al., *MDMA effects consistent across laboratories.* Psychopharmacology (Berl), 2014. **231**(19): p. 3899-905.
590. Mithoefer, M.C., et al., *Safety, Efficacy and Durability of MDMA-Assisted Psychotherapy in Subjects with Chronic, Treatment-Resistant Posttraumatic Stress Disorder: Completed and Ongoing Randomized, Controlled, Triple-blind Phase 2 Pilot Studies*, in *Military medical research across the continuum of care*. 2012: Fort Lauderdale, FL.
591. Phelps, E.A., et al., *Activation of the left amygdala to a cognitive representation of fear.* Nat Neurosci, 2001. **4**(4): p. 437-41.
592. Kuypers, K.P., et al., *MDMA intoxication and verbal memory performance: a placebo-controlled pharmaco-MRI study.* J Psychopharmacol, 2011. **25**(8): p. 1053-61.
593. Chang, L., et al., *Effect of ecstasy [3,4-methylenedioxymethamphetamine (MDMA)] on cerebral blood flow: a co-registered SPECT and MRI study.* Psychiatry Res, 2000. **98**(1): p. 15-28.
594. Frei, E., et al., *Localization of MDMA-induced brain activity in healthy volunteers using low resolution brain electromagnetic tomography (LORETA).* Hum Brain Mapp, 2001. **14**(3): p. 152-65.
595. Lamers, C.T., et al., *Dissociable effects of a single dose of ecstasy (MDMA) on psychomotor skills and attentional performance.* J Psychopharmacol, 2003. **17**(4): p. 379-87.
596. Tancer, M.E. and C.E. Johanson, *The subjective effects of MDMA and mCPP in moderate MDMA users.* Drug Alcohol Depend, 2001. **65**(1): p. 97-101.
597. Huxster, J.K., A. Pirona, and M.J. Morgan, *The sub-acute effects of recreational ecstasy (MDMA) use: a controlled study in humans.* J Psychopharmacol, 2006. **20**(2): p. 281-90.
598. Neff, K., *The Development and validation of a scale to measure self-compassion.* Self and Identity, 2003. **2**: p. 223-250.
599. Kuypers, K.P. and J.G. Ramaekers, *Transient memory impairment after acute dose of 75mg 3.4-Methylene-dioxymethamphetamine.* J Psychopharmacol, 2005. **19**(6): p. 633-9.
600. Ramaekers, J.G. and K.P. Kuypers, *Acute effects of 3,4-methylenedioxymethamphetamine (MDMA) on behavioral measures of impulsivity: alone and in combination with alcohol.* Neuropsychopharmacology, 2006. **31**(5): p. 1048-55.
601. Kuypers, K.P., N. Samyn, and J.G. Ramaekers, *MDMA and alcohol effects, combined and alone, on objective and subjective measures of actual driving performance and psychomotor function.* Psychopharmacology (Berl), 2006. **187**(4): p. 467-75.
602. Kuypers, K.P. and J.G. Ramaekers, *Acute dose of MDMA (75 mg) impairs spatial memory for location but leaves contextual processing of visuospatial information unaffected.* Psychopharmacology (Berl), 2007. **189**(4): p. 557-63.
603. Ramaekers, J.G., K.P. Kuypers, and N. Samyn, *Stimulant effects of 3,4-methylenedioxymethamphetamine (MDMA) 75 mg and methylphenidate 20 mg on actual driving during intoxication and withdrawal.* Addiction, 2006. **101**(11): p. 1614-21.

604. Spronk, D.B., et al., *The acute effects of MDMA and ethanol administration on electrophysiological correlates of performance monitoring in healthy volunteers.* Psychopharmacology (Berl), 2014. **231**(14): p. 2877-88.
605. Randolph, C., et al., *The Repeatable Battery for the Assessment of Neuropsychological Status (RBANS): preliminary clinical validity.* J Clin Exp Neuropsychol, 1998. **20**(3): p. 310-9.
606. Gronwall, D.M., *Paced auditory serial-addition task: a measure of recovery from concussion.* Percept Mot Skills, 1977. **44**(2): p. 367-73.
607. Roman, D.D., et al., *Extended norms for the paced auditory serial addition task.* . Clin Neuropsychol, 1991. **5**(1): p. 33-40.
608. Hoshi, R., J. Bisla, and H.V. Curran, *The acute and sub-acute effects of 'ecstasy' (MDMA) on processing of facial expressions: preliminary findings.* Drug Alcohol Depend, 2004. **76**(3): p. 297-304.
609. Frye, C.G., et al., *MDMA decreases the effects of simulated social rejection.* Pharmacol Biochem Behav, 2014. **117**: p. 1-6.
610. Kirkpatrick, M.G. and H. de Wit, *MDMA: a social drug in a social context.* Psychopharmacology (Berl), 2015. **232**(6): p. 1155-63.
611. Schmid, Y., et al., *Effects of methylphenidate and MDMA on appraisal of erotic stimuli and intimate relationships.* Eur Neuropsychopharmacol, 2015. **25**(1): p. 17-25.
612. MacDonald, E., et al., *A review of safety, side-effects and subjective reactions to intranasal oxytocin in human research.* Psychoneuroendocrinology, 2011. **36**(8): p. 1114-26.
613. Bershad, A.K., et al., *Oxytocin receptor gene variation predicts subjective responses to MDMA.* Soc Neurosci, 2016.
614. Bosker, W.M., et al., *Dose-related effects of MDMA on psychomotor function and mood before, during, and after a night of sleep loss.* Psychopharmacology (Berl), 2010. **209**(1): p. 69-76.
615. Gradus, J.L., et al., *Posttraumatic stress disorder and completed suicide.* Am J Epidemiol, 2010. **171**(6): p. 721-7.
616. Conner, K.R., et al., *Posttraumatic stress disorder and suicide in 5.9 million individuals receiving care in the veterans health administration health system.* J Affect Disord, 2014. **166**: p. 1-5.
617. US Food and Drug Administration, *Guidance for industry: suicidal ideation and behavior: prospective assessment of occurrence in clinical trials.* Silver Springs, MD: US Food and Drug Administration Available at: h ttp://www. fda. gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm315156. htm. Accessed October, 2012. **5**: p. 2012.
618. Stone, T.E., C. Swanson, and M.D. Feldman, *Venlafaxine discontinuation syndrome and suicidal ideation: a case series.* J Clin Psychopharmacol, 2007. **27**(1): p. 94-5.
619. Tint, A., P.M. Haddad, and I.M. Anderson, *The effect of rate of antidepressant tapering on the incidence of discontinuation symptoms: a randomised study.* J Psychopharmacol, 2008. **22**(3): p. 330-2.
620. Valuck, R.J., H.D. Orton, and A.M. Libby, *Antidepressant discontinuation and risk of suicide attempt: a retrospective, nested case-control study.* J Clin Psychiatry, 2009. **70**(8): p. 1069-77.
621. Nilsson, M.E., et al., *Columbia Suicide Severity Rating Scale Scoring and Data Analysis Guide*, in *CSSRS Scoring Version 2.0*. 2013: http://www.cssrs.columbia.edu/documents/ScoringandDataAnalysisGuide_Feb2013.pdf. p. 1-13.
622. Sanger, G.J., *5-hydroxytryptamine and the gastrointestinal tract: where next?* Trends Pharmacol Sci, 2008. **29**(9): p. 465-471.

623. Hexel, M. and G. Sonneck, *Somatoform symptoms, anxiety, and depression in the context of traumatic life experiences by comparing participants with and without psychiatric diagnoses.* Psychopathology, 2002. **35**(5): p. 303-12.
624. Afari, N., et al., *Psychological trauma and functional somatic syndromes: a systematic review and meta-analysis.* Psychosom Med, 2014. **76**(1): p. 2-1.
625. Pietrzak, R.H., et al., *Psychiatric comorbidity of full and partial posttraumatic stress disorder among older adults in the United States: results from wave 2 of the National Epidemiologic Survey on Alcohol and Related Conditions.* Am J Geriatr Psychiatry, 2012. **20**(5): p. 380-90.
626. Baker, D.G., et al., *Relationship between posttraumatic stress disorder and self-reported physical symptoms in Persian Gulf War veterans.* Arch Intern Med, 1997. **157**(18): p. 2076-8.
627. Hoge, C.W., et al., *Association of posttraumatic stress disorder with somatic symptoms, health care visits, and absenteeism among Iraq war veterans.* Am J Psychiatry, 2007. **164**(1): p. 150-3.
628. Blake, D.D., et al., *A clinician rating scale for assessing current and lifetime PTSD: the CAPS-1.* . Behav Ther, 1990. **13**: p. 187-188.
629. Nagy, L.M., et al., *Open prospective trial of fluoxetine for posttraumatic stress disorder.* J Clin Psychopharmacol, 1993. **13**(2): p. 107-13.
630. Weathers, F.W., *Clinician-Administered PTSD Scale (CAPS): Technical Manual*. 2004, Los Angeles, CA: Western Psychological Services.
631. UNDOC. World Drug Report. New York, NY: United Nations Office on Drugs and Crime. 2011.
632. Gable RS. Comparison of acute lethal toxicity of commonly abused psychoactive substances. Addiction (Abingdon, England). 2004. **99**(6): p. 686-96.
633. Tiangco DA, Halcomb S, Lattanzio FA, Jr., Hargave BY. 3,4-Methylenedioxymethamphetamine alters left ventricular function and activates nuclear factor-Kappa B (NF-kappaB) in a time and dose dependent manner. Int J Mol Sci. 2010. **11**(12): p. 4843-63.
634. Glennon, R.A. and R. Young, Further investigation of the discriminative stimulus properties of MDA. Pharmacol Biochem Behav, 1984. 20(4): p. 501-5.
635. Kamien, J.B., et al., The effects of (+/-)-methylenedioxymethamphetamine and (+/-)-methylenedioxyamphetamine in monkeys trained to discriminate (+)-amphetamine from saline. Drug Alcohol Depend, 1986. 18(2): p. 139-47.
636. Evans, S.M. and C.E. Johanson, Discriminative stimulus properties of (+/-)-3,4-methylenedioxymethamphetamine and (+/-)-3,4-methylenedioxyamphetamine in pigeons. Drug Alcohol Depend, 1986. 18(2): p. 159-64.
637. Oberlender, R. and D.E. Nichols, Drug discrimination studies with MDMA and amphetamine. Psychopharmacology (Berl), 1988. 95(1): p. 71-6.
638. Callahan, P.M. and J.B. Appel, Differences in the stimulus properties of 3,4-methylenedioxyamphetamine and 3,4- methylenedioxymethamphetamine in animals trained to discriminate hallucinogens from saline. J Pharmacol Exp Ther, 1988. 246(3): p.866-70
639. Glennon, R.A., et al., Discriminative stimulus properties of MDA analogs. Biol Psychiatry, 1982. 17(7): p. 807-14.
640. Goodwin, A.K. and L.E. Baker, A three-choice discrimination procedure dissociates the discriminative stimulus effects of d-amphetamine and (+/-)-MDMA in rats. Exp Clin Psychopharmacol, 2000. 8(3): p. 415-23.
641. Goodwin, A.K., D.M. Pynnonen, and L.E. Baker, Serotonergic-dopaminergic mediation of MDMA's discriminative stimulus effects in a three-choice discrimination. Pharmacol Biochem Behav, 2003. 74(4): p. 987-95.

9.0 Appendix

Table 31: Percentage of Observations of Spontaneously Reported Reactions During Experimental Sessions in Studies MP-1, MP-2, MP-4, MP-8, MP-9, MP-12, MDA-1, MAA-1, and MP1-E2 as of 01 October 2015

Dose	0 mg (N=12)	25 mg (N=7)	30 mg (N=7)	40 mg (N=6)	75 mg (N=7)	100-125 mg (N=100)	150 mg (N=3)
Sessions	24	19	15	11	14	255	4
Anxiety							
Mild	1 (4%)	---	---	2 (18%)	4 (29%)	48 (19%)	1 (25%)
Moderate	9 (38%)	---	7 (47%)	2 (18%)	1 (7%)	61 (24%)	---
Severe	4 (17%)	---	1 (7%)	---	1 (7%)	13 (5%)	---
Total	14 (58%)	0 (0%)	8 (53%)	4 (36%)	6 (43%)	122 (48%)	1 (25%)
Diarrhea							
Mild	---	---	---	---	---	5 (2%)	---
Moderate	---	---	---	---	---	---	---
Severe	---	---	---	---	---	---	---
Total	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	5 (2%)	0 (0%)
Disturbance in Attention							
Mild	---	---	3 (20%)	1 (9%)	1 (7%)	28 (11%)	---
Moderate	1 (4%)	---	---	---	---	10 (4%)	---
Severe	---	---	---	---	---	---	---
Total	1 (4%)	0 (0%)	3 (20%)	1 (9%)	1 (7%)	38 (15%)	0 (0%)
Dizziness							
Mild	1 (4%)	---	1 (7%)	1 (9%)	1 (9%)	40 (16%)	2 (50%)
Moderate	1 (4%)	---	---	---	---	19 (7%)	---
Severe	---	---	---	---	---	1 (<1%)	---
Total	2 (8%)	0 (0%)	1 (7%)	1 (9%)	1 (7%)	60 (24%)	2 (50%)
Somnolence							
Mild	---	---	2 (13%)	---	1 (7%)	11 (4%)	---
Moderate	3 (13%)	---	---	---	---	8 (3%)	---
Severe	---	---	---	---	---	---	---
Total	3 (13%)	0 (0%)	2 (13%)	0 (0%)	1 (7%)	19 (7%)	0 (0%)

Dose	0 mg (N=12)	25 mg (N=7)	30 mg (N=7)	40 mg (N=6)	75 mg (N=7)	100-125 mg (N=100)	150 mg (N=3)
Sessions	24	19	15	11	14	255	4
Dry Mouth							
Mild	---	1 (5%)	2 (13%)	1 (9%)	---	23 (9%)	1 (25%)
Moderate	---	---	1 (7%)	2 (18%)	---	19 (7%)	1 (25%)
Severe	---	---	---	---	---	---	---
Total	0 (0%)	1 (5%)	3 (20%)	3 (27%)	0 (0%)	42 (16%)	2 (50%)
Fatigue							
Mild	3 (13%)	4 (21%)	6 (40%)	---	2 (14%)	32 (13%)	---
Moderate	7 (29%)	---	2 (13%)	3 (27%)	2 (14%)	52 (20%)	---
Severe	---	---	---	---	---	3 (1%)	---
Total	10 (42%)	4 (21%)	8 (53%)	3 (27%)	4 (28%)	87 (34%)	0 (0%)
Headache							
Mild	5 (21%)	1 (5%)	6 (40%)	3 (27%)	10 (71%)	57 (22%)	1 (25%)
Moderate	7 (29%)	---	1 (7%)	1 (9%)	---	37 (15%)	---
Severe	---	---	---	---	---	1 (<1%)	---
Total	12 (50%)	1 (5%)	7 (47%)	4 (36%)	10 (71%)	95 (37%)	1 (25%)
Sensation of Heaviness							
Mild	---	---	---	---	---	5 (2%)	1 (25%)
Moderate	---	---	---	---	---	6 (2%)	---
Severe	---	---	---	---	---	---	---
Total	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	11 (4%)	1 (25%)
Disturbed Gait							
Mild	1 (4%)	3 (16%)	---	---	2 (14%)	35 (14%)	2 (50%)
Moderate	---	---	---	---	---	6 (2%)	---
Severe	---	---	---	---	---	---	---
Total	1 (4%)	3 (16%)	0 (0%)	0 (0%)	2 (14%)	41 (16%)	2 (50%)
Judgment Impaired							
Mild	---	---	---	---	---	1 (<1%)	---
Moderate	---	---	---	---	---	---	---
Severe	---	---	---	---	---	---	---
Total	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (<1%)	0 (0%)

Dose	0 mg (N=12)	25 mg (N=7)	30 mg (N=7)	40 mg (N=6)	75 mg (N=7)	100-125 mg (N=100)	150 mg (N=3)
Sessions	24	19	15	11	14	255	4
Irritability							
Mild	---	---	1 (7%)	---	---	3 (1%)	---
Moderate	3 (13%)	---	---	---	---	3 (1%)	---
Severe	---	---	---	---	---	---	---
Total	3 (13%)	0 (0%)	1 (7%)	0 (0%)	0 (0%)	6 (2%)	0 (0%)
Insomnia							
Mild	6 (25%)	1 (5%)	1 (7%)	---	---	21 (8%)	1 (25%)
Moderate	6 (25%)	2 (11%)	---	---	3 (21%)	31 (12%)	---
Severe	---	1 (5%)	---	---	---	6 (2%)	2 (50%)
Total	12 (50%)	4 (21%)	1 (7%)	0 (0%)	3 (21%)	58 (23%)	3 (75%)
Muscle Tightness (jaw)							
Mild	2 (8%)	1 (5%)	---	1 (9%)	4 (29%)	62 (24%)	---
Moderate	3 (13%)	---	---	2 (18%)	1 (7%)	73 (29%)	1 (25%)
Severe	---	---	---	---	---	6 (2%)	1 (25%)
Total	5 (21%)	1 (5%)	0 (0%)	3 (27%)	5 (36%)	141 (55%)	2 (50%)
Decreased Appetite							
Mild	1 (4%)	2 (11%)	3 (20%)	---	4 (29%)	63 (25%)	---
Moderate	1 (4%)	1 (5%)	---	---	---	40 (16%)	1 (25%)
Severe	---	1 (5%)	---	---	---	3 (1%)	---
Total	2 (8%)	4 (21%)	3 (20%)	0 (0%)	4 (29%)	106 (42%)	1 (25%)
Depressed Mood							
Mild	---	---	---	---	---	13 (5%)	---
Moderate	2 (8%)	1 (5%)	1 (7%)	---	1 (7%)	12 (5%)	---
Severe	---	---	---	---	---	2 (1%)	---
Total	2 (8%)	1 (5%)	1 (7%)	0 (0.0%)	1 (7%)	27 (11%)	0 (0.0%)
Muscle Tightness							
Mild	1 (4%)	---	5 (33%)	1 (9%)	1 (7%)	44 (17%)	---
Moderate	2 (8%)	---	2 (13%)	2 (18%)	2 (14%)	25 (10%)	---
Severe	---	---	---	---	---	---	---
Total	3 (13%)	0 (0%)	7 (47%)	3 (27%)	3 (21%)	69 (27%)	0 (0%)

Dose	0 mg (N=12)	25 mg (N=7)	30 mg (N=7)	40 mg (N=6)	75 mg (N=7)	100-125 mg (N=100)	150 mg (N=3)
Sessions	24	19	15	11	14	255	4
Nausea							
Mild	2 (8%)	2 (11%)	1 (7%)	---	2 (14%)	34 (13%)	1 (25%)
Moderate	1 (4%)	---	2 (13%)	---	---	28 (11%)	---
Severe	---	---	---	---	---	6	---
Total	3 (13%)	2 (11%)	3 (20%)	0 (0%)	2 (14%)	68 (27%)	1 (25%)
Hypersomnia							
Mild	2 (8%)	---	1 (7%)	---	1 (7%)	3 (1%)	1 (25%)
Moderate	1 (4%)	---	---	2 (18%)	---	7 (3%)	---
Severe	---	1 (5%)	---	---	---	---	---
Total	3 (13%)	1 (5%)	1 (7%)	2 (18%)	1 (7%)	10 (4%)	1 (25%)
Nystagmus							
Mild	---	---	---	---	1 (7%)	17 (7%)	1 (25%)
Moderate	---	---	---	---	---	7 (3%)	---
Severe	---	---	---	---	---	---	---
Total	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (7%)	24 (9%)	1 (25%)
Paresthesia							
Mild	---	---	1 (7%)	---	1 (7%)	11 (4%)	1 (25%)
Moderate	---	---	---	---	---	5 (2%)	---
Severe	---	---	---	---	---	---	---
Total	0 (0%)	0 (0%)	1 (7%)	0 (0%)	1 (7%)	16 (6%)	1 (25%)
Hyperhidrosis							
Mild	---	---	2 (13%)	---	3 (21%)	44 (17%)	1 (25%)
Moderate	1 (4%)	---	---	---	---	19 (7%)	---
Severe	---	---	---	---	---	---	---
Total	1 (4%)	0 (0%)	2 (13%)	0 (0%)	3 (21%)	63 (25%)	1 (25%)
Restlessness							
Mild	---	1 (5%)	5 (33%)	---	3 (21%)	40 (16%)	---
Moderate	2 (8%)	---	1 (7%)	---	2 (4%)	22 (9%)	1 (25%)
Severe	---	---	---	---	---	1 (<1%)	---
Total	2 (8%)	1 (5%)	6 (40%)	0 (0%)	5 (36%)	63 (25%)	1 (25%)

Dose	0 mg (N=12)	25 mg (N=7)	30 mg (N=7)	40 mg (N=6)	75 mg (N=7)	100-125 mg (N=100)	150 mg (N=3)
Sessions	24	19	15	11	14	255	4
Obsessive Rumination							
Mild	---	1 (5%)	---	---	---	10 (4%)	---
Moderate	1 (4%)	---	2 (13%)	---	---	6 (2%)	---
Severe	---	---	---	---	---	---	---
Total	1 (4%)	1 (5%)	2 (13%)	0 (0%)	0 (0%)	16 (6%)	0 (0%)
Feeling Cold							
Mild	2 (8%)	1 (5%)	7 (47%)	---	4 (29%)	47 (18%)	---
Moderate	1 (4%)	---	1 (7%)	---	2 (14%)	20 (8%)	---
Severe	---	---	---	---	---	1 (<1%)	---
Total	3 (13%)	1 (5%)	8 (53%)	0 (0%)	6 (43%)	68 (27%)	0 (0%)
Thirst							
Mild	1 (4%)	---	1 (7%)	---	---	29 (11%)	1 (25%)
Moderate	---	---	---	1 (9%)	---	14 (5%)	1 (25%)
Severe	---	---	---	---	---	---	---
Total	1 (4%)	0 (0%)	1 (7%)	1 (9%)	0 (0%)	43 (17%)	2 (50%)
Asthenia							
Mild	1 (4%)	---	---	---	---	7 (3%)	1 (25%)
Moderate	---	---	---	---	---	6 (2%)	---
Severe	---	---	---	---	---	---	---
Total	1 (4%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	13 (5%)	1 (25%)

Table 32: Spontaneously Reported Reactions on Day 1-7 After All Experimental Sessions in Studies MP-1, MP-2, MP-4, MP-8, MP-9, MP-12, MDA-1, MAA-1, and MP1-E2 as of 01 October 2015

Dose	0 mg (N=12)	25 mg (N=7)	30 mg (N=7)	40 mg (N=6)	75 mg (N=7)	100-125 mg (N=100)	150 mg (N=3)
Observations	168	133	105	77	98	1785	21
	Counts (%)	Counts (%)	Counts (%)	Counts (%)	Counts (%)	Counts (%)	Counts (%)
Anxiety							
Mild	26 (15%)	4 (3%)	25 (24%)	8 (10%)	5 (5%)	239 (13%)	---
Moderate	35 (21%)	---	10 (10%)	3 (4%)	1 (1%)	172 (10%)	---
Severe	2 (1%)	---	---	---	---	24 (1%)	---
Total	63 (38%)	4 (3%)	35 (33%)	11 (14%)	6 (6%)	435 (24%)	0 (0%)
Diarrhea							
Mild	1 (1%)	---	4 (4%)	---	1 (1%)	15 (1%)	---
Moderate	---	---	---	---	---	4 (0%)	---
Severe	---	---	---	---	---	2 (0%)	---
Total	1 (1%)	0 (0%)	4 (4%)	0 (0%)	1 (1%)	21 (1%)	0 (0%)
Disturbance in Attention							
Mild	11 (7%)	---	2 (2%)	2 (3%)	---	141 (8%)	---
Moderate	11 (7%)	---	2 (2%)	2 (3%)	---	38 (2%)	---
Severe	---	---	---	---	---	3 (<1%)	---
Total	22 (13%)	0 (0%)	4 (4%)	4 (5%)	0 (0%)	182 (10%)	0 (0%)
Dizziness							
Mild	5 (3%)	6 (5%)	---	---	1 (1%)	122 (7%)	---
Moderate	---	1 (1%)	---	---	---	19 (1%)	---
Severe	---	---	---	---	---	2 (<1%)	---
Total	5 (3%)	7 (5%)	0 (0%)	0 (0%)	1 (1%)	143 (8%)	0 (0%)
Somnolence							
Mild	2 (1%)	3 (2%)	1 (1%)	---	---	2 (<1%)	---
Moderate	5 (3%)	---	---	---	---	---	---
Severe	---	---	---	---	---	---	---
Total	7 (4%)	3 (2%)	1 (1%)	0 (0%)	0 (0%)	2 (<1%)	0 (0%)
Dry Mouth							
Mild	---	---	---	1 (1%)	---	23 (1%)	1 (5%)
Moderate	---	---	---	---	---	1 (<1%)	---
Severe	---	---	---	---	---	---	---
Total	0 (0%)	0 (0%)	0 (0%)	1 (1%)	0 (0%)	24 (1%)	1 (5%)

Dose	0 mg (N=12)	25 mg (N=7)	30 mg (N=7)	40 mg (N=6)	75 mg (N=7)	100-125 mg (N=100)	150 mg (N=3)
Observations	168	133	105	77	98	1785	21
	Counts (%)	Counts (%)	Counts (%)	Counts (%)	Counts (%)	Counts (%)	Counts (%)
Fatigue							
Mild	23 (14%)	16 (12%)	20 (19%)	3 (4%)	27 (28%)	245 (14%)	2 (10%)
Moderate	27 (16%)	8 (6%)	8 (8%)	4 (5%)	1 (1%)	163 (9%)	14 (67%)
Severe	1 (1%)	1 (1%)	---	---	---	13 (1%)	2 (10%)
Total	51 (30%)	25 (19%)	28 (27%)	7 (9%)	28 (29%)	421 (24%)	18 (86%)
Headache							
Mild	9 (5%)	13 (10%)	1 (1%)	3 (4%)	4 (4%)	76 (4%)	---
Moderate	5 (3%)	13 (10%)	---	3 (4%)	---	33 (2%)	---
Severe	---	---	---	---	---	3 (<1%)	---
Total	14 (8%)	26 (20%)	1 (1%)	6 (8%)	4 (4%)	112 (6%)	0 (0%)
Sensation of Heaviness							
Mild	---	1 (1%)	---	---	---	3 (<1%)	---
Moderate	---	---	---	---	---	3 (<1%)	---
Severe	---	---	---	---	---	---	---
Total	0 (0%)	1 (1%)	0 (0%)	0 (0%)	0 (0%)	6 (<1%)	0 (0%)
Disturbed Gait							
Mild	1 (1%)	---	---	---	---	10 (1%)	---
Moderate	---	---	---	---	---	3 (<1%)	---
Severe	---	---	---	---	---	---	---
Total	1 (1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	13 (1%)	0 (0%)
Judgment Impaired							
Mild	---	---	1 (1%)	1 (1%)	---	7 (<1%)	---
Moderate	---	---	---	1 (1%)	---	2 (<1%)	---
Severe	---	---	---	---	---	1 (<1%)	---
Total	0 (0%)	0 (0%)	1 (1%)	2 (3%)	0 (0%)	10 (1%)	0 (0%)
Irritability							
Mild	12 (7%)	3 (2%)	5 (5%)	---	4 (4%)	69 (4%)	---
Moderate	9 (5%)	---	3 (3%)	3 (4%)	---	48 (3%)	---
Severe	---	---	---	---	---	2 (<1%)	---
Total	21 (13%)	3 (2%)	8 (8%)	3 (4%)	4 (4%)	119 (7%)	0 (0%)

Dose	0 mg (N=12)	25 mg (N=7)	30 mg (N=7)	40 mg (N=6)	75 mg (N=7)	100-125 mg (N=100)	150 mg (N=3)
Observations	168	133	105	77	98	1785	21
	Counts (%)	Counts (%)	Counts (%)	Counts (%)	Counts (%)	Counts (%)	Counts (%)
Insomnia							
Mild	19 (11%)	17 (13%)	8 (8%)	5 (6%)	6 (6%)	158 (9%)	---
Moderate	29 (17%)	13 (10%)	9 (9%)	5 (6%)	2 (2%)	88 (5%)	---
Severe	1 (1%)	8 (6%)	1 (1%)	5 (6%)	---	8 (<1%)	---
Total	49 (29%)	38 (29%)	18 (17%)	15 (19%)	8 (8%)	254 (14%)	0 (0%)
Muscle Tightness (jaw)							
Mild	2 (1%)	---	---	6 (8%)	2 (2%)	90 (5%)	---
Moderate	1 (1%)	---	---	4 (5%)	---	20 (1%)	---
Severe	---	---	---	---	---	2 (<1%)	---
Total	3 (2%)	0 (0%)	0 (0%)	10 (13%)	2 (2%)	112 (6%)	0 (0%)
Decreased Appetite							
Mild	---	10 (8%)	2 (2%)	1 (1%)	2 (2%)	89 (5%)	---
Moderate	---	2 (2%)	---	1 (1%)	---	67 (4%)	---
Severe	---	3 (2%)	---	---	---	1 (<1%)	---
Total	0 (0%)	15 (11%)	2 (2%)	2 (3%)	2 (2%)	157 (9%)	0 (0%)
Depressed Mood							
Mild	13 (8%)	14 (11%)	4 (4%)	3 (4%)	---	114 (6%)	3 (14%)
Moderate	8 (5%)	11 (8%)	4 (4%)	---	---	101 (6%)	---
Severe	---	---	---	---	---	17 (1%)	---
Total	21 (13%)	25 (19%)	8 (8%)	3 (4%)	0 (0%)	232 (13%)	3 (14%)
Muscle Tightness							
Mild	3 (2%)	1 (1%)	3 (3%)	9 (12%)	6 (6%)	84 (5%)	---
Moderate	6 (4%)	---	---	7 (9%)	1 (1%)	26 (1%)	---
Severe	---	---	---	---	---	5 (<1%)	---
Total	9 (5%)	1 (1%)	3 (3%)	16 (21%)	7 (7%)	115 (6%)	0 (0%)
Nausea							
Mild	9 (5%)	5 (4%)	2 (2%)	1 (1%)	---	66 (4%)	---
Moderate	3 (2%)	2 (2%)	---	1 (1%)	---	28 (2%)	---
Severe	---	7 (5%)	---	---	---	4 (<1%)	---
Total	12 (7%)	14 (11%)	2 (2%)	2 (3%)	0 (0%)	98 (5%)	0 (0%)

Dose	0 mg (N=12)	25 mg (N=7)	30 mg (N=7)	40 mg (N=6)	75 mg (N=7)	100-125 mg (N=100)	150 mg (N=3)
Observations	168	133	105	77	98	1785	21
	Counts (%)	Counts (%)	Counts (%)	Counts (%)	Counts (%)	Counts (%)	Counts (%)
Hypersomnia							
Mild	15 (9%)	8 (6%)	9 (9%)	3 (4%)	17 (17%)	145 (8%)	2 (10%)
Moderate	9 (5%)	7 (5%)	1 (1%)	3 (4%)	---	63 (4%)	---
Severe	---	---	1 (1%)	---	---	---	---
Total	24 (14%)	15 (11%)	11 (10%)	6 (8%)	17 (17%)	208 (12%)	2 (10%)
Nystagmus							
Mild	---	---	---	---	---	1 (<1%)	---
Moderate	---	---	---	---	---	---	---
Severe	---	---	---	---	---	---	---
Total	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (<1%)	0 (0%)
Paresthesia							
Mild	---	---	---	---	---	4 (<1%)	---
Moderate	---	---	---	---	---	4 (<1%)	---
Severe	---	---	---	---	---	---	---
Total	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	8 (<1%)	0 (0%)
Hyperhidrosis							
Mild	1 (1%)	---	---	---	1 (1%)	13 (1%)	---
Moderate	---	---	---	1 (1%)	---	1 (<1%)	---
Severe	1 (1%)	---	---	---	---	---	---
Total	2 (1%)	0 (0%)	0 (0%)	1 (1%)	1 (1%)	14 (1%)	0 (0%)
Restlessness							
Mild	---	2 (2%0	1 (1%)	3 (4%)	---	24 (1%)	---
Moderate	---	---	---	2 (3%)	---	24 (1%)	---
Severe	---	---	---	---	---	5 (<1%)	---
Total	0 (0%)	2 (2%)	1 (1%)	5 (6%)	0 (0%)	53 (3%)	0 (0%)
Obsessive Rumination							
Mild	2 (1%)	6 (5%)	2 (2%)	4 (5%)	1 (1%)	37 (2%)	---
Moderate	6 (4%)	1 (1%)	---	2 (3%)	---	38 (2%)	---
Severe	---	---	---	---	---	5 (<1%)	---
Total	8 (5%)	7 (5%)	2 (2%)	6 (8%)	1 (1%)	80 (4%)	0 (0%)

Dose	0 mg (N=12)	25 mg (N=7)	30 mg (N=7)	40 mg (N=6)	75 mg (N=7)	100-125 mg (N=100)	150 mg (N=3)
Observations	168	133	105	77	98	1785	21
	Counts (%)	Counts (%)	Counts (%)	Counts (%)	Counts (%)	Counts (%)	Counts (%)
Feeling Cold							
Mild	---	2 (2%)	2 (2%)	---	---	26 (1%)	---
Moderate	---	---	---	---	---	7 (<1%)	---
Severe	---	---	---	---	---	---	---
Total	0 (0%)	2 (2%)	2 (2%)	0 (0%)	0 (0%)	33 (2%)	0 (0%)
Thirst							
Mild	---	---	---	1 (1%)	---	7 (<1%)	---
Moderate	---	---	---	---	---	1 (<1%)	---
Severe	---	---	---	---	---	---	---
Total	0 (0%)	0 (0%)	0 (0%)	1 (1%)	0 (0%)	8 (<1%)	0 (0%)
Asthenia							
Mild	---	---	1 (1%)	---	---	20 (1%)	---
Moderate	---	---	---	1 (1%)	---	11 (1%)	---
Severe	---	---	---	---	---	---	---
Total	0 (0%)	0 (0%)	1 (1%)	1 (1%)	0 (0%)	31 (2%)	0 (0%)

APPENDIX B

US v. Phan (W.D. WA 2011), Supplemental Sentencing Memorandum ("*Phan* memo")

THE HONORABLE RICARDO S. MARTINEZ

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON

UNITED STATES OF AMERICA, Plaintiff, v. TRUNG DINH PHAN, Defendant.	CR10-00027-RSM DEFENDANT PHAN'S SUPPLEMENTAL SENTENCING MEMORANDUM ADDRESSING THE APPROPRIATE GUIDELINE

TABLE OF CONTENTS

TABLE OF CONTENTS ii

TABLE OF AUTHORITIES iii

PRELIMINARY STATEMENT 1

ARGUMENT 3

I. THIS COURT HAS DISCRETION TO VARY DOWNWARD FROM THE OTHERWISE-APPLICABLE GUIDELINE RANGE WHEN THE COMMISSION HAS ABANDONED ITS TRADITIONAL ROLE BY DEVELOPING GUIDELINES THAT LACK AN EMPIRICAL BASIS. . . . 3

II. LIKE THE CRACK COCAINE GUIDELINE AT ISSUE IN *KIMBROUGH*, THE MDMA GUIDELINE LACKS AN EMPIRICAL BASIS BECAUSE IT IS BASED ON NOW-DISCREDITED SCIENCE. 8

A. Contrary To The Commission's Central Conclusion, MDMA Is Not More Harmful Than Cocaine. 11

i. Medical data 11

ii. Expert opinion 14

B. The Commission's 2001 Report Is Rife With Methodologically Suspect Or Subsequently Disproved Research 15

i. Inadequate controls 16

ii. Inappropriate dosage levels 17

iii. Non-replicable studies and dubious assumptions 18

C. Recent Studies Reveal That The Commission's Report Overstated The Actual Harms of MDMA. 20

D. The Commission's Non-Scientific Justification For The MDMA Guideline — The Fear Of Particular Harm To Youth — Has Not Been Borne Out By National Experience. 22

III. THIS COURT SHOULD SELECT A SENTENCE BASED ON THE ACTUAL HARMFULNESS OF MDMA RELATIVE TO OTHER DRUGS. 24

IV. GUIDELINE CALCULATIONS 26

CONCLUSION 28

TABLE OF AUTHORITIES

Cases and Case Transcripts

Gall v. United States, 552 U.S. 38 (2007) 2, 4, 27

Henderson v. United States, 660 F. Supp. 2d 751 (E.D. La. 2009) 28

Kimbrough v. United States, 552 U.S. 85 (2007) ..... *passim*

Rita v. United States, 551 U.S. 338 (2007) 3, 4

Skidmore v. Swift & Co., 323 U.S. 134 (1944) 5

United States v. Baird, 580 F. Supp. 2d 889 (D. Neb. 2008) 5

United States v. Beiermann, 599 F. Supp. 2d 1087 (N.D. Iowa 2009) 27

United States v. Cavera, 550 F.3d 180 (2nd Cir. 2008) 4

United States v. Dorvee, 616 F.3d 174 (2nd Cir. 2010) 5, 6

United States v. Dozier, No. S1 08 Cr. 08-02, 2009 WL 1286486 (S.D.N.Y. May 8, 2009) 28

United States v. Edwards, 693 F. Supp. 2d 575 (S.D. W. Va. 2010) 27

United States v. Goodman, 556 F. Supp. 2d 1002 (D. Neb. 2008) 4

United States v. Greer, 699 F. Supp. 2d 876 (E.D. Tex. 2010) 27

United States v. Grober, 624 F.3d 592 (3d Cir. 2010) 7

United States v. Herrera-Zuniga, 571 F.3d 568 (6th Cir. 2009) 4

United States v. Lewis, 623 F. Supp. 2d 42 (D.D.C. 2009) 27

United States v. McCarthy, No. 09 Cr. 1136 (WHP) (S.D.N.Y.) (Ex. 1) ..... *passim*

United States v. Mead Corp., 533 U.S. 218 (2001) 5

United States v. Thomas, 595 F. Supp. 2d 949 (E.D. Wis. 2009) 4

United States v. Valdez, 268 Fed. App'x 293 (5th Cir. 2008) 4

United States v. Vanvliet, 542 F.3d 259 (1st Cir. 2008) 5

United States v. Williams, No. 09-CR-30099, 2010 WL 1325229 (S.D. Ill. Mar. 30, 2010) 27

Statutes and Guideline Provisions

18 U.S.C. § 3553 ..... *passim*

MDMA Anti-Proliferation Act, Pub. L. No. 106-310 (2000) 8

U.S.S.G. § 2D1.1 ..... *passim*

Other Authorities: Scientific Studies, News, and Government Papers and Hearings (courtesy copies provided to the Court)

Ban is Advised on Top Two Pills for Pain Relief, N.Y. Times, Jul. 1, 2009 14

Baumann et al., *3,4-Methylenedioxymethamphetamine (MDMA) Neurotoxicity in Rats: A Reappraisal of Past and Present Findings*, 189 Psychopharmacology (Berl.) 407 (2007) 17

Commins et al., *Biochemical and histological evidence that methylenedioxymethamphetamine (MDMA) is toxic to neurons in the rat brain*, 241 J. of Pharm. & Experimental Therapeutics 338 (1987) 17

Fantegrossi et al., *Behavioral and Neurochemical Consequences of Long-term Intravenous Self-administration of MDMA and its Enantiomers by Rhesus Monkeys*, 29 Neuropsychopharmacology 1270 (2004) 17

Green et al., *MDMA: On the Translation from Rodent to Human Dosing*, 204 Psychopharmacology 375 (2009) 17

Guidelines Stiffened for Selling MDMA, Associated Press, Mar. 21, 2001 9

Hearing on MDMA Abuse Before the S. Comm. On Int'l Narcotics Trafficking, 107th Cong. (2001) (statement of Diana E. Murphy, Chair of the U.S. Sentencing Commission) 9

Jager et al., *Incidental Use of Ecstasy: No Evidence for Harmful Effects on Cognitive Brain Function in a Prospective fMRI Study*, 193(3) Psychopharmacology (Berl.) 403 (2007) 20

Jansen, *Ecstasy (MDMA) Dependence*, 53 Drug & Alc. Dependence 121 (1999) 16

Jerome, *(+/-)-3,4-methylenedioxymethamphetamine (MDMA, "Ecstasy") Investigator's Brochure* (2007) 21

Kish et al., *Decreased cerebral cortical serotonin transporter binding in ecstasy users: a positron emission tomography/[^{11}C]DASB and structural brain imaging study*, 133 Brain 1779 (2010) 19

Mathias, NIDA Notes, *"Ecstasy" Damages the Brain and Impairs Memory in Humans*, Pub. No. 99-3478 (Nov. 1999) 19

McCann et al., *Positron emission tomographic evidence of toxic effect of MDMA ("ecstasy") on brain serotonin neurons in human beings*, 352 The Lancet 1433 (1998) 19

McNeil, *Research on Ecstasy Is Clouded By Errors*, N.Y. Times, Dec. 2, 2003 ..... 18, 19

Morgan et al., *Consequences of Chronic Ketamine Self-Administration Upon Neurocognitive Function and Psychological Wellbeing: A 1-year Longitudinal Study*, 105 Society for the Study of Addiction 121 (2009). 26

Nutt et al*., Development of a rational scale to assess the harm of drugs of potential misuse*, 369 The Lancet 1047 (2007) 14, 25

Nutt et al*., Drug harms in the UK: a multicriteria decision analysis*, 376 The Lancet 1558 (2010) 14, 25

Ricaurte et al., *(+/-) 3,4-methylenedioxymethamphetamine ('Ecstasy')-induced neurotoxicity: studies in animals*, 42 Neuropsychobiology 5 (2000) 17

Rogers et al., *The harmful health effects of recreational ecstasy: a systematic review of observational evidence, Health Tech. Assessment*, Jan. 2009 ..... 21, 22

Rosenbaum, *Ecstasy: America's New "Reefer Madness," Journal of Psychoactive Drugs* (Apr.-Jun. 2002) 9

Schifano et al., *Overview of Amphetamine-Type Stimulant Mortality Data — UK, 1997-2007*, 61 Neuropsychobiology 122 (2010) 21, 22

Selveraj et al., *Brain serotonin transporter binding in former users of MDMA ('ecstasy')*, 194 Brit. J. of Psych. 355 (2009) 19

Shahani et al., *Ketamine-Associated Ulcerative Cystitis: A New Clinical Entity*, 69(5) Urology 810 (2007) 26

U.S. Drug Enforcement Admin., *The DEA Position on Marijuana (May 2006)* 26

U.S. Sentencing Comm'n, *Report to Congress: MDMA Drug Offenses, Explanation of Recent Guideline Amendments* (2001) ..... *passim*

U.S. Sentencing Comm'n, *Tr. of U.S. Sentencing Comm'n 2001 Public Hearing* 26 (Mar. 19, 2001) 6

van Amsterdam et al., *Ranking the Harm of Alcohol, Tobacco and Illicit Drugs for the Individual and the Population*, 16 Eur. Addiction Research 202 (2010) 15, 25

Wang et al., *Methylenedioxymethamphetamine Administration to Rats Does Not Decrease Levels of the Serotonin Transporter Protein or Alter its Distribution Between Endosomes and the Plasma Membrane*, 314 J. Pharmacol. Exp. Ther. 1002 (2005) 17

Other Authorities: Usage and Medical Data (available online or as Exhibits)

Univ. of Mich., *Monitoring the Future: A Continuing Study of American Youth* (2009), tbl. 2 at 2 ("Trends in Annual Prevalence of Use of Various Drugs in Grades 8, 10, and 12"), *available at* http://monitoringthefuture.org/data/09data/pr09t2.pdf 23

U.S. Dep't of Health & Human Servs., Substance Abuse & Mental Health Services Admin., *Drug Abuse Warning Network 2006: Nat'l Estimates of Drug-Related Emergency Department Visits (2008)*, *available at* https://dawninfo.samhsa.gov/files/ED2006/DAWN2k6ED.pdf 12, 13, 14

U.S. Dep't of Health & Human Servs., Substance Abuse & Mental Health Services Admin., *Drug Abuse Warning Network 2007*: *Nat'l Estimates of Drug-Related Emergency Department Visits* (2010), *available at* https://dawninfo.samhsa.gov/files/ED2007/DAWN2k7ED.pdf 13, 14, 23

U.S. Dep't of Health & Human Servs., Substance Abuse & Mental Health Servs. Admin., *Nat'l Survey on Drug Use and Health*, *available at* http://www.oas.samhsa.gov/nsduh.htm (Ex. 2) 12, 13, 23

PRELIMINARY STATEMENT

This Supplemental Sentencing Memorandum is respectfully submitted in advance of Defendant Trung Phan's sentencing, currently scheduled for January 21, 2011. This Memorandum is not exhaustive in that it does not address Mr. Phan's personal characteristics as they relate to 18 U.S.C. § 3553(a). Instead, it supplements the Sentencing Memorandum of co-counsel, the Federal Public Defender, by speaking to one particular issue of critical importance to Mr. Phan's sentencing: the appropriateness of adhering to the empirically-flawed U.S. Sentencing Guideline for MDMA (hereinafter "MDMA Guideline").

The MDMA Guideline was established nearly ten years ago in response to public panic and is based on faulty science that has since been repudiated. When the Sentencing Commission created the MDMA Guideline in 2001, it crafted a penalty structure based on the conclusion that MDMA was more harmful than cocaine and in light of what the Commission viewed as the pharmacological and physiological harms of the drug. Subsequent studies have substantially undercut scientific support for the Commission's conclusion that MDMA is more harmful than cocaine, as well as the Commission's assessment of the harms of MDMA. Cocaine use is not only much more prevalent in the United States population, but according to recent government data, it is thirteen times more likely to cause a user to visit an emergency room. As for the harms of MDMA itself, recent research reveals that the harms are relatively mild and reversible rather than severe and long-lasting. Scientists have discovered that most of the research from ten years ago was flawed. For example, animal studies overestimated the harms of MDMA

to humans because they gave animals doses several times higher than the average human dose. Human studies failed to control for important variables such as the use of other drugs and propensity toward mental illness.

Under *Kimbrough v. United States*, 552 U.S. 85 (2007), this Court has discretion to vary from Guidelines that lack an empirical basis. Because the MDMA Guidelines are seriously flawed, as discussed in detail below, this Court should exercise that discretion here. Failure to do so would result in a grave injustice, adding unnecessary years onto a sentence based on long-discredited myths about the harmfulness of the offense. When the Supreme Court in *Kimbrough* recognized sentencing courts' power to depart from Guidelines that lack an empirical basis, this is precisely the type of case the Court had in mind. Like the crack cocaine Guideline at issue in *Kimbrough*, the MDMA Guideline is scientifically unsupportable and, as a result, prescribes sentencing ranges that are unfairly severe. This Court should exercise its sound discretion under *Kimbrough* to avoid blindly following a Guideline that offers no legitimate guidance. Instead, it should look beyond the faulty data that the Commission relied on in 2001, and determine an appropriate initial sentencing range for Mr. Phan that is based on consideration of the scientifically-documented properties and harms of MDMA.[1]

[1] As the Court is aware, the Court's final task, after consideration of the applicable Guideline, is to make "an individualized assessment based on the facts presented" in light of the sentencing factors Congress has set forth in 18 U.S.C. § 3553(a). *Gall v. United States*, 552 U.S. 38, 49-50 (2007). The application of these factors is addressed as part of the defense's separate memorandum filed by co-counsel from the Federal Public Defender.

ARGUMENT

I. THIS COURT HAS DISCRETION TO VARY DOWNWARD FROM THE OTHERWISE-APPLICABLE GUIDELINE RANGE WHEN THE COMMISSION HAS ABANDONED ITS TRADITIONAL ROLE BY DEVELOPING GUIDELINES THAT LACK AN EMPIRICAL BASIS.

The Supreme Court has held that where a particular Guideline is not based on empirical evidence, it is not an abuse of discretion for a district court to impose an outside-of-Guidelines sentence based solely on broad policy concerns. *Kimbrough v. United States*, 552 U.S. 85, 108-10 (2007). Thus, for example, a district court is free to impose a significant downward variance even in a mine-run case (an average case with no distinguishing circumstances or offender characteristics bearing on sentencing) involving crack cocaine, based on the district court's policy disagreement with the 100-to-1 crack-powder disparity embodied in the Guidelines. *See id.* at 110.

In *Kimbrough*, the Supreme Court noted that "Congress established the commission to formulate and *constantly refine* national sentencing standards." *Id.* at 108 (citation and internal quotation marks omitted and emphasis added). The Court has elaborated that "[t]he Commission's work is ongoing. The statutes and the Guidelines themselves foresee continuous evolution helped by the sentencing courts and courts of appeals in that process." *Rita v. United States*, 551 U.S. 338, 350 (2007). Moreover, the Court left no doubt that the district courts are at the forefront of this evolutionary process, and may take initiative on sentencing matters well before the Sentencing Commission alters the guidelines themselves:

> The sentencing courts, applying the Guidelines in individual cases may depart (either pursuant to the Guidelines or, since *Booker*, by imposing a non-guidelines sentence). The judges will set forth their reasons. The Courts of Appeals will determine the reasonableness of the resulting sentence. The Commission will collect and examine the results. In doing so, it may obtain advice from prosecutors, defenders, law enforcement groups, civil liberties associations, experts in penology, and others. And it can revise the Guidelines accordingly.

Id. As our empirical understanding about the science of MDMA evolves, and as our national experience changes, the MDMA Guideline should change with them.

Kimbrough's holding permitting judges to vary from Guideline ranges based on policy disagreements extends beyond cases involving crack cocaine and permits Guideline variances in other criminal matters involving non-empirically derived Guidelines, including those involving other drugs. Federal courts have cited *Kimbrough* as authority for policy-based departures from Guidelines for drugs other than crack. *See, e.g.*, *United States v. Valdez*, 268 Fed. App'x 293, 297 (5th Cir. 2008) (mem.) (methamphetamine); *United States v. Goodman*, 556 F. Supp. 2d 1002, 1010-11, 1016 (D. Neb. 2008) (methamphetamine); *United States v. Thomas*, 595 F. Supp. 2d 949, 952 (E.D. Wis. 2009) (powder cocaine). In fact, the Supreme Court has implied that its reasoning in *Kimbrough* could apply to *all* drug Guidelines, since "the Sentencing Commission departed from the empirical approach when setting the Guidelines range for drug offenses." *Gall v. United States*, 552 U.S. 38, 46 n.2 (2007).

Federal courts even depart from Guidelines for other types of offenses entirely. *See, e.g., United States v. Cavera*, 550 F.3d 180, 184 (2nd Cir. 2008) (en banc) (arms trafficking); *United States v. Herrera-Zuniga*, 571 F.3d 568, 583, 586 (6th Cir. 2009)

(illegal reentry); *United States v. Vanvliet*, 542 F.3d 259, 271 (1st Cir. 2008) (interstate travel with the intent to engage in an illicit sexual act); *United States v. Baird*, 580 F. Supp. 2d 889, 894-95 (D. Neb. 2008) (child pornography). In these cases — and in many more — appellate and sentencing courts have recognized that district courts have authority to depart from any Guideline that was not based on reasoned, empirical evidence.

In an illuminating recent decision holding that the imposition of a 240-month sentence for distributing child pornography, while procedurally correct under the Guidelines, was substantively unreasonable, the Second Circuit discussed appropriate considerations for determining how much credence to lend any particular Guideline:

> The Sentencing Commission is, of course, an agency like any other. . . . [In today's advisory-Guideline regime,] deference to the Guidelines is not absolute or even controlling; rather, like our review of many agency determinations, "[t]he weight of such a judgment in a particular case will depend upon the thoroughness evident in [the agency's] consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control."

United States v. Dorvee, 616 F.3d 174, 187-88 (2nd Cir. 2010) (quoting *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944)). The *Dorvee* court further instructed courts to take account of the Commission's "'*specialized experience* and broader investigations and *information available to the agency*'" when determining the weight owed to a Guideline. *See id.* at 188 (quoting *United States v. Mead Corp.*, 533 U.S. 218, 234 (2001)) (emphasis added).

Although the Commission heard statements from multiple scientists when revising the MDMA Guideline in 2001, no one on the Commission had any greater expertise in weighing that evidence than this Court does. During the 2001 public hearing on the proposed MDMA Guideline, Commissioner Michael E. O'Neill observed that:

> Part of the difficulty, I suppose, that we're having is, we've been able to read and have had a lot of different scientific evidence presented to us. And since none of us is a scientist that I'm aware of, it's sometimes difficult to digest this information.[2]

Given the lack of scientific expertise of the Commission, it is evident that it did not have the specialized experience that the *Dorvee* court indicated would add weight to its findings. Additionally, the "information available to the agency," *Dorvee*, 616 F.3d at 188, regarding MDMA in 2001 was at best incomplete and at worst rife with inaccuracy and myth. As discussed in detail in Part II below, years of additional scientific research since the formulation of the current Guideline have undermined assumptions central to the Commission's decisions in 2001 and provide this Court with access to far more reliable data than was available to the Commission when it set the MDMA guideline almost ten years ago. Accordingly, this Court should not defer to the findings of the Commission, but instead should make its own determination as to the appropriate offense level and sentence.

The published information discussed in detail below should be more than sufficient basis for this Court to conclude that the current MDMA Guideline is flawed

[2] U.S. Sentencing Comm'n, *Tr. of U.S. Sentencing Comm'n 2001 Public Hearing* 26 (Mar. 19, 2001).

and that another, lower range should be used as a baseline. However, if this Court would like to hear directly from the leading experts in the field, we encourage the Court to hold an evidentiary hearing to consider in greater detail the new scientific developments since the Commission's actions in 2001. *See, e.g., United States v. Grober*, 624 F.3d 592, 595 (3d Cir. 2010) (affirming sentencing varying from child pornography guideline after district court held extensive evidentiary hearing on the background and formulation of the relevant guideline).

Another district court considering the scientific validity of the MDMA Guideline has held just such a hearing. *See United States v. McCarthy*, No. 09 Cr. 1136 (WHP) (S.D.N.Y.). In this hearing, the sentencing court took two days' worth of testimony from expert witnesses, two from the government and two from the defense. Although that court's decision whether to vary from the MDMA Guideline remains pending, the transcript of that hearing (hereinafter referred to as the "New York hearing" and cited as "N.Y. Hrg. Tr.") may be illuminating for this Court and therefore is attached as an exhibit.[3] The hearing is notable for the extent of agreement among the experts about the actual harms of MDMA. Although the defense and government experts characterized the state of the field differently, the substance of the two sides' key conclusions reflected significant congruence. Therefore the New York transcript will be cited below where relevant. Courtesy copies of all additional scientific, journalistic or government sources cited in this memorandum and not easily accessible online will be provided to the Court.

[3] *See* Ex. 1, *United States v. McCarthy*, No. 09 Cr. 1136 (WHP) (S.D.N.Y. Dec. 6-7) (transcript of evidentiary hearing) [hereinafter Ex. 1, N.Y. Hrg. Tr.].

II. LIKE THE CRACK COCAINE GUIDELINE AT ISSUE IN *KIMBROUGH*, THE MDMA GUIDELINE LACKS AN EMPIRICAL BASIS BECAUSE IT IS BASED ON NOW-DISCREDITED SCIENCE.

New studies have discredited the decade-old science underlying the Commission's formulation of the Guideline for MDMA sentences. This Court should therefore place the MDMA Guideline in the same category as the crack cocaine Guideline — namely, instances in which the Commission was not acting in its traditional role. *Kimbrough*, 552 U.S. at 108-110. The Commission did not consider past sentencing practices when formulating the current MDMA Guideline. Rather, as with the crack cocaine Guideline that the Supreme Court considered in *Kimbrough*, the MDMA Guideline reflects the Sentencing Commission's response to a congressional directive issued in the midst of an uninformed panic about a supposed new drug scourge. With the benefit of hindsight, it is clear that the Commission's conclusions about the harmfulness of MDMA — and in particular the Commission's conclusion that MDMA is more harmful than cocaine — are simply incorrect and do not comport with empirical evidence and national experience.

There are strong parallels between the formulation of the MDMA Guideline and the development of the crack cocaine Guidelines. The Commission set the Guidelines for both substances in response to congressional directives, rather than empirical evidence about past sentencing practices. *See Kimbrough*, 552 U.S. at 96-97 (describing development of the crack cocaine Guidelines based on the notorious 100-to-1 crack-powder disparity); MDMA Anti-Proliferation Act, Pub. L. No. 106-310 (2000) (ordering increased penalties for MDMA). Just as crack cocaine in the 1980s became associated

in the national consciousness with violence, addiction and overdose, the sudden appearance of MDMA among teenagers and the development of a new "rave culture" in the late 1990s sparked a similar panic.[4] The potential harms from MDMA were so drastically forecast that Congress directed the Commission to promulgate an "emergency amendment" to the MDMA Guideline, and the Commission, in its haste to respond, "shifted resources from other important policy development areas, such as implementing other congressional directives regarding stalking and sexual offenses against children."[5]

It was in this context that the Commission amended the Drug Equivalency Tables in U.S.S.G. 2D1.1 to increase sentences for MDMA dramatically: as reflected in the Sentencing Commission's report to Congress explaining the 2001 MDMA amendment, prior to the amendment, one gram of MDMA was treated as equivalent to 35 grams of marijuana; the 2001 amendment set one gram of MDMA equal to 500 grams of marijuana.[6] As a result, the length of the average MDMA sentence more than doubled.[7]

This change was not the product of careful empirical investigation but rather reliance on sloppy studies that dramatically overstated the harms of MDMA. In 2001, little work had been done regarding MDMA's effects on humans, and there were no well-controlled studies that followed human users over time.[8] In the absence of such empirical

---

[4] *See* Rosenbaum, *Ecstasy: America's New "Reefer Madness," Journal of Psychoactive Drugs* 3 (Apr.-Jun. 2002); *Guidelines Stiffened for Selling MDMA*, Assoc. Press, Mar. 21, 2001 (quoting the acting director of the Office of National Drug Control Policy: "We never again want another 'crack epidemic' to blindside this nation.").

[5] *Hearing on MDMA Abuse Before the S. Comm. On Int'l Narcotics Trafficking*, 107th Cong. (2001) (statement of Diana E. Murphy, Chair of the U.S. Sentencing Commission), at 1.

[6] U.S. Sentencing Comm'n, *Report to Congress: MDMA Drug Offenses, Explanation of Recent Guideline Amendments* 5-6 (2001) [*hereinafter* "MDMA Report"].

[7] *See id.* at 6 (noting increase in average sentence from just under 3 years to just over 6 years).

[8] *See* Ex. 1, N.Y. Hrg. Tr. at 23 (Curran, defense expert); *id.* at 376 (Hanson, government expert) (agreeing that "the field is fairly new in terms of psychpharmacologists absolutely isolating the effects of MDMA alone").

data, the Commission formulated the current MDMA Guideline by comparing MDMA to two quite harmful drugs, heroin and cocaine, and deciding that MDMA fell in between them in terms of harmfulness.[9] As a result of the Commission's conclusion that MDMA is more harmful than cocaine, the Commission set one gram of MDMA equivalent to 2.5 grams of cocaine for purposes of sentencing.[10]

With the benefit of hindsight, we can conclude with confidence today that the Commission's comparison to cocaine was faulty on several levels. First, to the extent it is possible to compare the drugs directly in terms of their harmfulness — by looking to data about drug-related emergency room visits, and by looking to the opinions of scientific experts — MDMA emerges as far less harmful than cocaine. Second, to the extent the Commission's findings were based on, in the Commission's words, "the unique pharmacological and physiological harms of ecstasy,"[11] recent studies have undercut the scientific support for the Commission's understanding of these harms. The scientific data on MDMA ten years ago was rife with errors, such as mistranslating human doses to animal doses and failure to control for key variables, and some of the Commission's scientific sources and conclusions are questionable even on their face. More recent studies show that the harms of MDMA are far less serious than posited by the Commission. Finally, to the extent the Commission relied on fears of a dramatic rise in youth use of MDMA as compared with cocaine, the trends cited by the Commission have not been borne out in the intervening decade.

[9] MDMA Report, at 5.
[10] *See id.* (setting one gram of MDMA equivalent to 500 grams of marijuana, and noting one gram of cocaine is equivalent to 200 grams of marijuana).
[11] *Id.*

A. Contrary To The Commission's Central Conclusion, MDMA Is Not More Harmful Than Cocaine.

Whether judging by medical data or the views of scientific experts, the Commission was clearly wrong to conclude that MDMA is more harmful than cocaine.

i. Medical data

The simplest way to compare the harms of drugs is to look at how frequently each leads to serious medical consequences. Although emergency-room visits is not a perfect proxy, this is a measure that does reflect serious harm; it is a measure for which there is reliable government data; and it is a measure that the Commission itself thought relevant enough to cite in its 2001 Report on MDMA.[12] In the New York hearing, experts for both the defense and the government acknowledged the relevance of this data to an assessment of the harms of MDMA.[13]

Each year, the Substance Abuse and Mental Health Services Administration of the federal Department of Health and Human Services compiles data on drug-related emergency room visits, and breaks down each drug-related visit by which drug or drugs were involved according to medical records. The most recent years for which such data are available are 2006 and 2007. The Department of Health and Human Services also compiles data on overall national drug use rates.

From this data, two conclusions stand out starkly. First, on a yearly basis cocaine is abused by two to three times as many Americans as is MDMA. Second, even accounting for the differential rates of use in the population, cocaine far exceeds MDMA

[12] *See id.* at 11 n. 28.
[13] *See* Ex. 1, N.Y. Hrg. Tr. at 125 (Halpern, defense expert); *id.* at 291 (Parrott, government expert); *id.* at 372-74 (Hanson, government expert).

as a cause of drug-related emergency-room visits: a cocaine user is approximately 13 times more likely to require drug-related emergency services than an MDMA user.

According to data from the Department of Health and Human Services' National Survey on Drug Use and Health ("NSDUH"),[14] in 2006 and 2007 (the years covered by the latest emergency room data), fewer Americans used MDMA than cocaine. In 2006, approximately 6.1 million people reported using cocaine within the previous year; the number of people reporting using ecstasy during the same time period was approximately 2.1 million.[15] In 2007, similarly, approximately 5.7 million people reported using cocaine within the previous year; the number of people reporting using ecstasy during the same time period was once again approximately 2.1 million.[16]

However, the difference in emergency room visits for each drug far outstrips the difference in usage rates. The NSDUH statistics cited above reflect that two-and-a-half to three times as many people used cocaine as used MDMA in 2006 and 2007. By contrast, in 2006, cocaine was the cause of approximately *thirty-three* times as many emergency room visits as MDMA.[17] In 2007 (the most recent year for which data are available), cocaine accounted for *forty-two* times as many emergency room visits as

[14] Ex. 2, U.S. Dep't of Health & Human Servs., Substance Abuse & Mental Health Servs. Admin., *Nat'l Survey on Drug Use and Health* [hereinafter "Ex. 2, NSDUH"], *available at* http://www.oas.samhsa.gov/nsduh.htm. The website for this study is quite extensive and difficult to navigate, so the relevant tables are attached as Exhibit 2.
[15] *See id.*, tbl. 1.1A ("Types of Illicit Drug Use in Lifetime, Past Year, and Past Month among Persons Aged 12 or Older: Numbers in Thousands, 2006 and 2007").
[16] *See id.*
[17] *See* U.S. Dep't of Health & Human Servs., Substance Abuse & Mental Health Services Admin., *Drug Abuse Warning Network 2006: Nat'l Estimates of Drug-Related Emergency Department Visits* [hereinafter "DAWN 2006"] 20 (2008), *available at* https://dawninfo.samhsa.gov/files/ED2006/DAWN2k6ED.pdf.

MDMA.[18] Thus, the emergency room statistics show that cocaine is far more harmful than MDMA not only across the population as a whole but also among the respective populations that use each drug.

Put in rough numerical terms, out of the approximately 5.9 million individuals who used cocaine, on average, per year in 2006 and 2007, approximately 551,000 individuals, or approximately 9.3% (551,000 ÷ 5,900,000), on average, went to the emergency room in connection with the drug.[19] By contrast, out of the approximately 2.1 million individuals who used MDMA, on average, per year in 2006 and 2007, approximately 15,000 individuals, or approximately 0.7% (15,000 ÷ 2,100,000), on average, went to the emergency room in connection with the drug.[20] Therefore a cocaine user was more than 13 times (9.3 ÷ 0.7) more likely than an MDMA user to require drug-related emergency services.

Another simple way to put the two drugs in perspective is to note that cocaine, which accounts for almost 30% of all drug-related visits to the emergency room (including visits stemming from legal drugs as well as illegal drugs), is the leading cause of drug-related visits to the emergency room, whereas MDMA leads to less than 1% of

[18] *See* U.S. Dep't of Health & Human Servs., Substance Abuse and Mental Health Services Admin., *Drug Abuse Warning Network 2007: Nat'l Estimates of Drug-Related Emergency Department Visits* 22 [hereinafter "DAWN 2007"] (2010), *available at* https://dawninfo.samhsa.gov/files/ED2007/DAWN2k7ED.pdf.

[19] For the number of users, see Ex. 2, NSDUH, tbl. 1.1A. The 5.9 million figure is an approximate average of the 2006 number, 6,069,000, and the 2007 number, 5,738,000. For the number of emergency room visits, see DAWN 2006, at 20, and DAWN 2007, at 22. The 551,000 figure is an approximate average of the 2006 number, 548,608, and the 2007 number, 553,530.

[20] For the number of users, see Ex. 2, NSDUH, tbl. 1.1A. The 2.1 million figure is an approximate average of the 2006 number, 2,130,000, and the 2007 number, 2,132,000. For the number of emergency room visits, see DAWN 2006, at 20, and DAWN 2007, at 22. The 15,000 figure is an approximate average of the 2006 number, 16,749, and the 2007 number, 12,748.

drug-related visits.[21] In fact, more than twice as many people are hospitalized annually because of adverse reactions to acetaminophen (the active ingredient in Tylenol) as MDMA ingestion.[22]

ii. Expert opinion

In the New York hearing, experts for both the government and the defense agreed that cocaine was more harmful than MDMA.[23]

Three European surveys of scientific and health-policy experts also support the conclusion that MDMA is less harmful than cocaine. In two studies in the prominent British medical journal *The Lancet* (including one just last year) that assessed the relative harmfulness of twenty substances of abuse based on the harmfulness of the drug to the individual user and to society, MDMA ranked among the bottom four out of twenty in both studies, whereas cocaine ranked among the top five in both studies.[24] For two other comparison points, marijuana and ketamine (which the Guidelines treat as equivalent to marijuana for sentencing purposes[25]) also ranked as more harmful than MDMA: marijuana ranged between sixth and eighth, and ketamine ranked eleventh in both studies.[26]

---

[21] DAWN 2007, at 22.

[22] *Compare*, *Ban is Advised on Top Two Pills for Pain Relief*, N.Y. Times, Jul. 1, 2009, at A1 (42,000 hospitalized for acetaminophen annually), *with* DAWN 2007, at 22 (12,748 hospitalized for MDMA in 2007), *and* DAWN 2006, at 20 (16,749 hospitalized for MDMA in 2006).

[23] *See* Ex. 1, N.Y. Hrg. Tr. at 127 (Halpern, defense expert); *id.* at 231-32 (Parrott, government expert). The government's other expert, Glen Hanson, refused to compare the two drugs directly because they were in his view "apples and oranges." *Id.* at 343 (Hanson); *see also id.* at 338. However, he did acknowledge that, by the metric of emergency-room visits, MDMA is less harmful. *See id.* at 373-74.

[24] *See* Nutt et al., *Development of a rational scale to assess the harm of drugs of potential misuse*, 369 The Lancet 1047, 1051 (2007); Nutt et al., *Drug harms in the UK: a multicriteria decision analysis*, 376 The Lancet 1558, 1561 (2010).

[25] U.S.S.G. § 2D1.1, app. note 10(E), at 543 (2009).

[26] *See* Nutt 2007, 369 The Lancet at 1049-50; Nutt 2010, 376 The Lancet at 1561.

A 2010 study conducted by prominent Dutch researchers arrived at results similar to those published in *The Lancet*.[27] The Dutch study's aggregate harm scores for cocaine's individual and social harm were almost twice those for MDMA.[28] Powder cocaine was ranked sixth on its list of harmful drugs and MDMA was fourteenth.[29] Marijuana and ketamine were both ranked as more harmful than MDMA.[30]

In sum, whether one looks at the emergency room data documenting the actual consequences of MDMA use and cocaine user, or the consensus view among scientific experts about the relative harmfulness of each drug, it is clear that the Commission was incorrect in its central conclusion that MDMA is more harmful than cocaine. This faulty assumption should not continue to drive the sentences of MDMA offenders long after it has been disproved by medical data and abandoned by scientists.

B. The Commission's 2001 Report Is Rife With Methodologically Suspect Or Subsequently Disproved Research

The Commission's scientific evidence exhibits many of the problems endemic to the MDMA field ten years ago: inadequate controls, inappropriate doses, and non-replicable studies. Specifically, when considering the guidelines for MDMA, the Commission's "empirical data" included case studies of individuals who were heavy users of other drugs; studies in which animals were administered doses that we now know are exponentially larger relative to their size than doses human beings ingest; a website that the Commission itself noted was not scientific; and the work of a researcher who

[27] van Amsterdam et al., *Ranking the Harm of Alcohol, Tobacco and Illicit Drugs for the Individual and the Population*, 16 Eur. Addiction Research 202, 204 (2010).
[28] *Id.*
[29] *Id.*
[30] *Id.*

subsequently retracted multiple MDMA studies because he was testing the wrong chemical compound. These and other empirical shortcomings of the Commission's work should leave this Court profoundly skeptical of the resulting MDMA Guideline.

i. Inadequate controls

To document the purported fact that MDMA is "used compulsively by some" and "may produce dysphoria" (i.e., depression)[31] the Commission cited a paper documenting three case studies. This paper is emblematic of problems that plagued the field of MDMA science at that time, when many published papers failed to control for important variables.[32]

The subjects of the studies were, respectively, a heavy user of cocaine and marijuana, a heroin user with a family history of schizophrenia, and a PTSD patient who also consumed a bottle of Jack Daniels almost every night.[33] The failure to control for the important variables of simultaneous use of drugs other than MDMA, preexisting conditions, and family history, make it impossible to isolate the effects of MDMA in these case studies.[34] The Commission's reliance on this type of paper for its conclusions illustrates both the underdeveloped state of MDMA research in 2001 and the use of problematic source material by the Commission in setting the current Guideline.

[31] MDMA Report, at 18.
[32] *See* Ex. 1, N.Y. Hrg. Tr. at 118-20 (Halpern, defense expert); *id.* at 178 (Parrott, government expert); *id.* at 331 (Hanson, government expert).
[33] MDMA Report, at 18 n. 61 (citing Jansen, *Ecstasy (MDMA) Dependence*, 53 Drug & Alc. Dependence 121-24 (1999)).
[34] *See* Ex. 1, N.Y. Hrg. Tr. at 39-40 (Curran, defense expert); *id.* at 234-36, 239-41 (Parrott, government expert).

ii. Inappropriate dosage levels

Another major flaw in the MDMA research that dominated the scientific discourse a decade ago is the use of inappropriately high doses in animal studies to predict consequences for human users. Specifically, the Commission's 2001 Report relies on two papers that adhere to the view that monkeys and rats should be given multiples of a normal human dose in order to determine how a human would react to a normal human dose.[35] But the validity of this theory has been repudiated by newer studies that suggest the doses used in early animal studies were far too high.[36] For example, the Commins study cited by the Commission gave rats between 10 and 40 milligrams of MDMA per kilogram of body weight (expressed in scientific terms as "mg/kg"),[37] whereas recent research suggests an appropriate dose would be between 1 and 3 mg/kg.[38] Thus, the Commission relied on a study giving rats a dose equivalent to between *three and forty times* a normal human dose. More recent animal studies that have used more moderate dosage or self-administration have found little or no evidence of harm.[39]

In the New York hearing, experts for both the defense and the government acknowledged the importance of, and agreed with, recent scientific work calling into

[35] *See* MDMA Report, at 9 n.16 (citing Ricaurte et al., *(+/-) 3,4-methylenedioxymethamphetamine ('Ecstasy')-induced neurotoxicity: studies in animals*, 42 Neuropsychobiology 5-10 (2000), and Commins et al., *Biochemical and histological evidence that methylenedioxymethamphetamine (MDMA) is toxic to neurons in the rat brain*, 241 J. of Pharm. & Experimental Therapeutics 338-345 (1987)).

[36] *See, e.g.*, Baumann et al., *3,4-Methylenedioxymethamphetamine (MDMA) Neurotoxicity in Rats: A Reappraisal of Past and Present Findings*, 189 Psychopharmacology (Berl.) 407, 411 (2007); Green et al., *MDMA: On the Translation from Rodent to Human Dosing*, 204 Psychopharmacology 375, 375 (2009).

[37] *See* Commins et al., *Biochemical and histological evidence that methylenedioxymethamphetamine (MDMA) is toxic to neurons in the rat brain*, 241 J. of Pharm. & Experimental Therapeutics 338, 339 (1987).

[38] *See, e.g.*, Baumann, 189 Psychopharmacology (Berl.) at 411-13.

[39] *See, e.g.*, Fantegrossi et al., *Behavioral and Neurochemical Consequences of Long-term Intravenous Self-administration of MDMA and its Enantiomers by Rhesus Monkeys*, 29 Neuropsychopharmacology 1270, 1278-79 (2004); Wang et al., *Methylenedioxymethamphetamine Administration to Rats Does Not Decrease Levels of the Serotonin Transporter Protein or Alter its Distribution Between Endosomes and the Plasma Membrane*, 314 J. Pharmacol. Exp. Ther. 1002, 1011 (2005).

question the older principles of dose-conversion between species.[40] In fact, both of the government's experts acknowledged that 1-3 mg/kg represents the dose an average or recreational user would consume,[41] and that low to moderate use was "consistent with a typical recreational ecstasy user"[42] whereas heavy use was "rare."[43] Obviously, a substance that might have moderate effects at a low dose can have much more serious effects at a higher dose.[44] The Commission's reliance on old, inaccurate assumptions about dosing levels undercuts the validity of its conclusions.

iii. Non-replicable studies and dubious assumptions

The Commission also relied on several studies that were not able to be replicated, or scientists whose work was fraught with methodological problems. For instance, Dr. George Ricaurte, cited and relied upon as "[a] leading researcher in MDMA toxicity studies" in the Commission's 2001 report to Congress,[45] had to retract multiple studies after it was discovered that they had not been done with MDMA, but with mislabeled vials of methamphetamine. After this error came to light, in 2003 the journal *Science* retracted a Ricaurte study purporting to show that a single dose of MDMA could cause brain injury.[46] The mislabeled vials corrupted several of Ricaurte's other studies, as well, and he was forced to withdraw four other papers.[47] Even scientists Ricaurte named in defense of his work were quoted in the *New York Times* as saying that "some of his best-

[40] *See* Ex. 1, N.Y. Hrg. Tr. at 120 (Halpern, defense expert); *id.* at 355-57 (Hanson, government expert).
[41] *See id.* at 299-300 (Parrott, government expert); *id.* at 356 (Hanson, government expert).
[42] *See id.* at 352 (Hanson, government expert).
[43] *See id.* at 272 (Parrott, government expert).
[44] *See id.* at 265-66 (Parrott, government expert).
[45] MDMA Report, at 8.
[46] *See* McNeil, *Research on Ecstasy Is Clouded By Errors*, N.Y. Times, Dec. 2, 2003 at F1.
[47] *Id.*

known work has nonetheless been 'sloppy' or 'not as methodologically rigorous as you might want.'"[48]

In other areas, the Commission cited research that more recent studies with better technology have called into question. For example, the Commission referred to a study showing loss of serotonin transporters (an important neurotransmitter) "throughout the brain," and for this conclusion the Commission relied on a 1998 brain scan study by McCann and colleagues.[49] But a 2010 article in the journal *Brain*, Kish and colleagues, using more advanced technology developed over the past dozen years, found that loss of serotonin transporters was much less prevalent than had been thought and, in explicit contrast to the McCann study, noted that the new study "did not find a global, massive reduction of brain [serotonin transporter] binding."[50] A 2009 study suggested that what reduction in serotonin transporters does occur is reversible after users abstain from use — in other words, after users stop using, their brains return to normal.[51]

And some of the Commissions' authorities and claims are suspect on their very face. For example, at one point in its Report to Congress, the Commission cited, as an authority regarding purported MDMA harms, a website that the Commission itself noted consisted of "a mix of science, pseudo-science and lore."[52] In another instance, the Commission suggests that MDMA must be more harmful than cocaine because MDMA

---

[48] *Id.* at F2.
[49] MDMA Report, at 9 & n.18 (citing Mathias, NIDA Notes, *"Ecstasy" Damages the Brain and Impairs Memory in Humans*, Pub. No. 99-3478 (Nov. 1999), in turn citing McCann et al., *Positron emission tomographic evidence of toxic effect of MDMA ("ecstasy") on brain serotonin neurons in human beings*, 352 The Lancet 1433 (1998)).
[50] Kish et al., *Decreased cerebral cortical serotonin transporter binding in ecstasy users: a positron emission tomography/[^{11}C]DASB and structural brain imaging study*, 133 Brain 1779, 1791 (2010).
[51] Selveraj et al., *Brain serotonin transporter binding in former users of MDMA ('ecstasy')*, 194 Brit. J. of Psych. 355, 357 (2009).
[52] MDMA Report, at 7 n.9 (citing https://www.erowid.org).

is a stimulant and a hallucinogen whereas cocaine is merely a stimulant[53] — assuming that harm to humans can be gauged by summing the number of properties a drug has rather than measuring its actual effects. As experts for both the defense and the government agreed at the New York hearing, simply counting the number of properties a drug exhibits does not provide any information on its harmfulness.[54]

C. Recent Studies Reveal That The Commission's Report Overstated The Actual Harms of MDMA.

Research since 2001 refutes the Commission's conclusions regarding the harms of MDMA. The Commission attributed a variety of harms to MDMA, including memory impairment, increases in heart rate and body temperature, and even death.[55] In the years since the Commission's 2001 Report, memory effects among MDMA users have been shown to be negligible or moderate, with users testing well within normal limits.[56] Experts for both the defense and the government at the New York hearing acknowledged a particular 2009 meta-analysis by Rogers and colleagues as a helpful synthesis of MDMA study data;[57] according to this meta-analysis, which synthesized the results of hundreds of MDMA studies, the effects of MDMA on memory, though statistically significant, were nonetheless "small," with the mean scores of users falling within normal ranges.[58] Even one of the government's experts accepted the conclusions of Rogers and others that MDMA users' neurocognitive functioning, though impaired, nonetheless

---

[53] *Id.* at 5.
[54] *See* Ex. 1, N.Y. Hrg. Tr. at 98-99 (Curran, defense expert); *id.* at 387 (Hanson, government expert).
[55] MDMA Report, at 7, 9.
[56] *See, e.g.,* Jager et al., *Incidental Use of Ecstasy: No Evidence for Harmful Effects on Cognitive Brain Function in a Prospective fMRI Study*, 193(3) Psychopharmacology (Berl.) 403, 403 (2007).
[57] *See* Ex. 1, N.Y. Hrg. Tr. at 18-19 (Curran, defense expert); *id.* at 239, 263 (Parrott, government expert).
[58] Rogers et al., *The harmful health effects of recreational ecstasy: a systematic review of observational evidence, Health Tech. Assessment*, Jan. 2009, at *xi*.

remained "[w]ithin the normal range."[59] The heart rate and temperature increases associated with MDMA use are minor (unlike the cardiovascular effects of cocaine) and are usually no greater than the increases associated with moderate exercise.[60] Controlled administration of MDMA to human subjects in studies examining the therapeutic effects of MDMA have resulted in no serious adverse reactions among study participants.[61] The most significant effects of MDMA are limited to the immediate rise in heart rate and body temperature, and a short-term change in brain chemistry, but even the government's experts acknowledged that all of these effects generally wear off within a week.[62] As the 2009 Rogers meta-analysis summarizes, what deficits do exist among MDMA users are "unlikely" to "significantly impair the average ecstasy user's everyday functional or quality of life."[63] Finally, deaths from MDMA are quite rare: one British study examining deaths over a ten-year period found approximately 10 deaths per year attributable to MDMA use alone;[64] this represents, on average, approximately 2 deaths per 100,000 MDMA users from 2001-07, or two thousandths of 1%.[65] At the New York

[59] Ex. 1, N.Y. Hrg. Tr. at 264 (Parrott, government expert).
[60] Jerome, *(+/-)-3,4-methylenedioxymethamphetamine (MDMA, "Ecstasy") Investigator's Brochure* 12 (2007).
[61] *Id.* at 17-20.
[62] *See* Ex. 1, N.Y. Hrg. Tr. at 243-44, 252 (Parrott, government expert); *id.* at 354 (Hanson, government expert).
[63] Rogers et al., *The harmful health effects of recreational ecstasy: a systematic review of observational evidence*, Health Tech. Assessment, Jan. 2009, at *xii*.
[64] *See* Schifano et al., *Overview of Amphetamine-Type Stimulant Mortality Data — UK, 1997-2007*, 61 Neuropsychobiology 122, 125 tbl. 1 (2010). This table, which covers mortality data for a ten-year period, found 104 "deaths where MDMA was identified on its own" as the cause of death. *Id.* This category is to be distinguished from the number at the top of the table, 605 deaths, which includes all individuals who had MDMA in their systems at the time of death. *Compare id.* at 123 (explaining that the greater figure, "np-SAD" deaths, includes cases in which coroners found the "presence of controlled drugs at post-mortem"), *with id.* at 124 (noting there were 104 cases out of the 605 in which ecstasy was "identified on its own" as the cause of death); *see also* Ex. 1, N.Y. Hrg. Tr. at 87 (Curran, defense expert) (explaining this distinction).
[65] *See* Schifano, 61 Neuropsychobiology at 128 tbl. 6; *see also* Rogers et al., *The harmful health effects of recreational ecstasy: a systematic review of observational evidence*, Health Tech. Assessment, Jan. 2009, at *xii* ("Ecstasy . . . remains a rare cause of death when reported as the sole drug associated with death related to drug use.").

hearing, experts for both the defense and the government noted that cocaine was a more frequent cause of death than MDMA,[66] and that death from MDMA is rare.[67]

As for the Commission's concerns about the hallucinogenic properties of MDMA, experts for both the defense and the government at the New York hearing cast doubt on the notion that MDMA could even be properly classified as a hallucinogen at all.[68] Thus the Commission seems to have in some sense misunderstood the very nature of the drug.

The Commission's inaccurate conclusions about the harms of MDMA at the time it devised the MDMA Guideline should not now form the basis for severe sentences for MDMA offenders.

D. The Commission's Non-Scientific Justification For The MDMA Guideline — The Fear Of Particular Harm To Youth — Has Not Been Borne Out By National Experience.

Although the Commission's principal findings concerned the harmfulness of MDMA, both in and of itself and relative to cocaine, the Commission's major non-scientific conclusion warrants brief discussion. Specifically, the Commission listed among its justifications for the current MDMA Guideline the fact that MDMA was heavily marketed to youth and that use began at an early age.[69] In this regard, as others, the Commission compared MDMA unfavorably to cocaine: indeed, one of the Commission's reasons for concluding that MDMA is more harmful than cocaine was that "powder cocaine is not as aggressively marketed to youth in the same manner as

[66] *See* Ex. 1, N.Y. Hrg. Tr. at 11 (Curran, defense expert); *id.* at 366 (Hanson, defense expert).
[67] *See* id. at 11 (Curran, defense expert); *id.* at 293 (Parrott, defense expert).
[68] *See* id. at 164 (Halpern, defense expert); id. at 289-90 (Parrott, government expert).
[69] MDMA Report, at 5, 12-14.

MDMA."[70] But the Commission's concern about youth use and youth harm has proved unfounded and the comparison to cocaine inapt.

According to the federally-funded "Monitoring the Future" survey by the University of Michigan, the percentage of 12th graders who use MDMA fell by more than half from 2001 to 2009.[71] At the New York hearing, a government expert who had been the head of the National Institute on Drug Abuse embraced this data, hypothesizing that young people became less open to trying MDMA because of their perception of its risk (as opposed to, for instance, the federal penal structure).[72] Thus the Commission's concerns over an impending MDMA epidemic among youth have not been realized.

Additionally, the national experience with MDMA has shown that MDMA does not pose a greater threat to the nation's youth than cocaine does. For example, in 2007 the number of cocaine-related emergency room visits was over four times the number of MDMA-related visits for youths aged twelve to seventeen, and for 18- to 20-year-olds, the number of cocaine-related visits was almost *nine* times the number than MDMA-related visits[73] — even though the overall usage rate for cocaine among each population was less than twice that of MDMA.[74]

In sum, it is clear that, in formulating the current MDMA Guideline, the Commission seriously overestimated the harmfulness of MDMA at a time when little was known about the substance. Because the MDMA Guideline is not based on sound

[70] *Id.* at 5.
[71] *See* Univ. of Mich., *Monitoring the Future: A Continuing Study of American Youth* (2009), tbl. 2 at 2 ("Trends in Annual Prevalence of Use of Various Drugs in Grades 8, 10, and 12"), *available at* http://monitoringthefuture.org/data/09data/pr09t2.pdf.
[72] Ex. 1, N.Y. Hrg. Tr. at 382 (Hanson, government expert).
[73] *See* DAWN 2007, at 25.
[74] See Ex. 2, NSDUH, tbls. 1.2A, 1.3A, 1.4A & 1.5A.

empirical evidence, but is instead the product of unsubstantiated fears and flawed research, the sentences recommended by the MDMA Guideline do not approximate sentences that are tailored to achieve the sentencing objectives in 18 U.S.C. § 3553(a). National experience and scientific research in the intervening decade demonstrate that MDMA is less harmful than the Commission and Congress had predicted, and that the current MDMA Guideline sentencing ranges are unduly severe. This Court should therefore exercise its discretion under *Kimbrough v. United States*, 552 U.S. 85 (2007), to vary from the scientifically-flawed and therefore unnecessarily harsh MDMA Guideline.

III. THIS COURT SHOULD SELECT A SENTENCE BASED ON THE ACTUAL HARMFULNESS OF MDMA RELATIVE TO OTHER DRUGS.

As previously noted, the 2001 amendments to the MDMA Guideline increased MDMA sentences by raising the ratio at which MDMA is converted to marijuana for sentencing purposes from 35:1 to a staggering 500:1.[75] Since this ratio is unreasonably high and devoid of an empirical basis, this Court must use its judgment to select the proper ratio.

Two useful comparators for MDMA are the drugs marijuana and ketamine. Like MDMA, both marijuana and ketamine appear in both the Drug Equivalency Tables, were evaluated in the three above-cited studies comparing the relative harms of various drugs based on expert assessments,[76] and were the subject of expert testimony and comparative evaluation at the New York hearing. A comparison of MDMA with these two drugs suggests that this Court should treat 1 gram of MDMA as equivalent to 1 gram of

[75] *See* MDMA Report, at 5-6; U.S.S.G. § 2D1.1, app. note 10(E), at 542 (2009).
[76] *See supra* Part II.A.ii.

marijuana (which is treated the same as 1 gram of ketamine) for the purpose of sentencing. MDMA is no more harmful, and in some ways is substantially less harmful, than marijuana and ketamine, each of which is treated as equivalent to marijuana for the purpose of sentencing.

Marijuana and ketamine both appear in the Drug Equivalency Tables in U.S.S.G. 2D1.1. They are treated the same for federal sentencing purposes.[77] In the two *Lancet* studies comparing the relative harmfulness of twenty drugs, based on experts' assessments of each drug's harmfulness to the individual user and to society, MDMA was ranked as seventeenth or eighteenth out of twenty — less harmful than ketamine (sixth or eighth) or marijuana (eleventh in both studies).[78] The Dutch comparative study likewise ranked MDMA (fourteenth) less harmful than ketamine (thirteenth) and marijuana (twelfth).[79]

The experts' decision to rank MDMA as less harmful than these two other drugs is well-founded. A brief comparison of each drug with MDMA bears out the conclusion that MDMA is no more harmful (and in many ways less harmful) than ketamine or marijuana. Studies have shown that unlike MDMA, a single dose of ketamine can produce schizophrenia-like symptoms, dissociative effects, and broad ranging cognitive dysfunction.[80] Also in stark contrast to MDMA, ketamine use has been shown to cause

[77] U.S.S.G. § 2D1.1, app. note 10(E), at 543.
[78] *See* Nutt 2007, 369 The Lancet at 1049-50; Nutt 2010, 376 The Lancet at 1561.
[79] *See* van Amsterdam, 16 Eur. Addiction Research at 204.
[80] *See* Morgan et al., *Consequences of Chronic Ketamine Self-Administration Upon Neurocognitive Function and Psychological Wellbeing: A 1-year Longitudinal Study*, 105 Soc. for the Study of Addiction 121, 121 (2009).

destruction of the lower urinary tract, including ulcerative cystitis and blood in urine.[81] Smoking marijuana increases health risks associated with smoking cigarettes, including coughing, chronic bronchitis, shortness of breath, and lung damage.[82] Citing many of these same harms, plus the greater potential for addictiveness of marijuana in contrast to MDMA, a defense expert who has worked with and published on all three substances — MDMA, ketamine, and marijuana — gave unchallenged and unrefuted testimony at the New York hearing that MDMA was no more harmful than ketamine or marijuana.[83]

Since MDMA is no more harmful (and in many respects less harmful) than ketamine or marijuana, MDMA should not be sentenced more harshly than either of these drugs. Therefore, this Court should treat 1 gram of MDMA as equivalent to 1 gram of marijuana (or 1 gram of ketamine, which the Guidelines treat as 1:1 with marijuana).

In the alternative, this Court should at the very least wipe out the effect of the 2001 amendments and their crumbling scientific foundation by returning to the pre-2001 ratio of 35:1 for converting MDMA to marijuana.[84]

IV. GUIDELINE CALCULATIONS

Mr. Phan has pled guilty to conspiracy to distribute 160,000 pills of MDMA. Mr. Phan submits that this Court should, after calculating the Guideline sentence, express a policy disagreement with the MDMA Guideline and impose a sentence based on a 1:1 rather than a 500:1 conversion ratio to marijuana. The PSR uses a weight of 52 kg as the

[81] *See* Shahani et al., *Ketamine-Associated Ulcerative Cystitis: A New Clinical Entity*, 69(5) Urology 810, 811 (2007).
[82] *See* U.S. Drug Enforcement Admin., *The DEA Position on Marijuana* (May 2006).
[83] *See* Ex. 1, N.Y. Hrg. Tr. at 7-8, 41-46 (Curran, defense expert).
[84] *See* MDMA Report, at 5-6.

corresponding weight of 160,000 pills. Under U.S.S.G. § 2D1.1(c)(10), the base offense level for 52 kg of marijuana is 20. (In the alternative, if this Court expresses a policy disagreement with the Guidelines but uses the 35:1 MDMA-to-marijuana conversion ratio that governed prior to the flawed 2001 MDMA Guideline, the resulting base offense level for 52 kg of MDMA would be that for 1,820 kg of marijuana, which is level 32. *See* U.S.S.G. § 2D1.1(c)(4).

If the Court uses a marijuana-MDMA ratio of 1:1, the resulting level, starting at 20 and accounting for the adjustments advised in the PSR, is 22. Since Mr. Phan is in Criminal History Category I, the appropriate sentencing range would be 41 to 51 months.

If the Court uses a marijuana-MDMA ratio of 35:1, the resulting level, starting at 32 and accounting for the adjustments advised in the PSR, is 34. Since Mr. Phan is in Criminal History Category I, the appropriate sentencing range would be 151 to 188 months.

The Court should begin with one of the above ranges before making its "individualized assessment based on the facts presented" in light of the sentencing factors Congress has set forth in 18 U.S.C. § 3553(a). *Gall*, 552 U.S. at 49-50; *see also United States v. Lewis*, 623 F. Supp. 2d 42, 47 (D.D.C. 2009) (stating that categorical policy disagreements should be applied before individual considerations); *United States v. Beiermann*, 599 F. Supp. 2d 1087, 1107-08 (N.D. Iowa 2009) (applying categorical policy disagreement before adjusting for individual circumstances); *accord*, *United States v. Greer*, 699 F. Supp. 2d 876, 880 (E.D. Tex. 2010); *United States v. Edwards*, 693 F. Supp. 2d 575, 582-84 (S.D. W. Va. 2010); *United States v. Williams*, No. 09-CR-30099,

2010 WL 1325229, at *8 (S.D. Ill. Mar. 30, 2010); *Henderson v. United States*, 660 F. Supp. 2d 751, 753-54 (E.D. La. 2009); *United States v. Dozier*, No. S1 08 Cr. 08-02, 2009 WL 1286486, at *6-7 (S.D.N.Y. May 8, 2009).

The application of the 3553(a) factors to Mr. Phan is addressed in the separate sentencing memorandum submitted by co-counsel from the Federal Public Defender.

CONCLUSION

Because the MDMA Guideline promulgated in 2001 and still on the books today was the product of fear and sloppy science rather than empirically sound study, this Court has discretion to vary from the prescribed Guideline offense levels and should do so — either at this time, or if the Court would prefer, after an evidentiary hearing at which the Court may hear from scientific experts about the actual harmfulness of MDMA and the research that has undermined the Commission's 2001 conclusions.

Taking into account the actual harms of MDMA, in comparison to the ranges prescribed for marijuana and ketamine, this Court should begin with a sentencing range of 41 to 51 months before considering Mr. Phan's individual circumstances under 18 U.S.C. § 3553(a). Alternatively, if this Court wishes to do no more than reverse the effects of the flawed 2001 Guideline, it should begin with a sentencing range of 151-188 months. Either way, it is vital that this Court exercise its independent judgment to preserve fairness and ensure that the resulting sentence for Mr. Phan is "sufficient but not greater than necessary" to serve the goals of sentencing. 18 U.S.C. § 3553(a). Once this Court has identified a fair and realistic Guideline range, it should address Mr. Phan's

individualized circumstances as discussed in the sentencing memorandum from co-counsel and as required under § 3553(a).

DATED this 4th day of January, 2011.

Respectfully submitted,

/s/ Jay Rorty, Cal. Bar No. 135097*
/s/ Scott Michelman, Cal. Bar No. 236574*
American Civil Liberties Union Foundation
Co-counsel for Defendant PHAN
1101 Pacific Avenue, Suite 333
Santa Cruz, CA 95060
(831) 471-9000
(831) 471-9676 (fax)
jrorty@aclu.org
smichelman@aclu.org

*Admitted pro hac vice

CERTIFICATE OF SERVICE

I hereby certify that on January 4, 2011, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to Assistant United States Attorney Susan M. Roe.

I further certify that I have emailed the above document to non CM/ECF participant United States Probation Officer Lisa L. Combs.

s/ Charlotte Ponikvar
Assistant Paralegal
Federal Public Defender's Office
1601 Fifth Avenue, Suite 700
Seattle, WA 98101
206/553-1100 voice
206/553-0120 facsimile
charlotte_ponikvar@fd.org

APPENDIX C

US v. McCarthy (S.D. NY 2011), Memorandum and Order ("*McCarthy* order")

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

----------X

UNITED STATES OF AMERICA, :

-against- : 09 Cr. 1136 (WHP)

SEAN MCCARTHY, : MEMORANDUM & ORDER

Defendant. :

----------X

WILLIAM H. PAULEY III, United States District Judge:

On February 19, 2010, Defendant Sean McCarthy pled guilty to conspiracy to distribute and possess with the intent to distribute 37,120 grams of MDMA, commonly known as "Ecstasy," in violation of 21 U.S.C. § 841. McCarthy argues that this Court should depart from the United States Sentencing Commission's (the "Commission") MDMA Sentencing Guidelines (the "Guidelines") asserting that the Commission's analysis was flawed and has been undermined by intervening scientific developments. On December 6 and 7, 2010, this Court held an evidentiary hearing on these issues.[1] For the following reasons, this Court finds that a 500:1 MDMA-to-marijuana equivalency would give rise to a sentence that is greater than necessary to serve the objectives of sentencing. Accordingly, this Court adopts a marijuana equivalency of 200 grams for MDMA.

BACKGROUND

Prior to 2001, the Guidelines held that one gram of MDMA was equivalent to 35 grams of marijuana. United States Sentencing Commission, Report to Congress: MDMA Drug

[1] This Court heard testimony from four expert witnesses: Drs. Helen Curran and John Halpern for the Defendant, and Drs. Andrew Parrott and Glen Hanson for the Government.

Offenses, Explanation of Recent Guideline Amendments ("Ecstasy Report") 6 (2001). In 2000, however, Congress passed the Ecstasy Anti-Proliferation Act, which directed the Commission to review and increase penalties for any offense relating to the manufacture and trafficking of MDMA, and required the Commission to submit a report on the resulting amendments to Congress. Pub. L. No. 106-310, 114 Stat. 1101, 1241-45.

The Ecstasy Report determined that penalties for MDMA offenses should be more severe than for powder cocaine, which has a 200:1 marijuana equivalency, but less severe than for heroin, which has a 1000:1 marijuana equivalency. Ecstasy Report 5. The Commission decided on less severe sentences for MDMA offenses than for heroin because:

> (1) there are many more heroin cases in the federal system than MDMA cases, (2) heroin is more addictive than MDMA, (3) heroin has many more emergency room visits and deaths associated with its use than MDMA because, unlike MDMA which generally is taken orally, heroin is injected, (4) heroin has more violence associated with both its users and distribution system than MDMA, in part because MDMA users typically do not resort to violence to support their drug use, and (5) heroin causes greater secondary health effects, such as the spread of HIV and hepatitis, because it is injected.

Ecstasy Report 5. The Commission offered three reasons for imposing higher sentences for MDMA offenses than for powder cocaine: "(1) unlike MDMA, powder cocaine is not neurotoxic, (2) powder cocaine is not aggressively marketed to youth in the same manner as MDMA, and (3) powder cocaine is only a stimulant, but MDMA acts as both a stimulant and a hallucinogen." Ecstasy Report 5. Ultimately, the Commission established an MDMA-to-marijuana equivalency of 500 grams. Ecstasy Report 5.

DISCUSSION

I. Applicable Law

The Sentencing Guidelines are "advisory." United States v. Booker, 543 U.S. 220, 244-45 (2005); see also United States v. Dorvee, 616 F.3d 174, 183 (2d Cir. 2010). Accordingly, "a district court may vary from the Guidelines range based solely on a policy disagreement with the Guidelines, even where that disagreement applies to a wide class of offenders or offenses." Dorvee, 550 F.3d at 191; see also Kimbrough v. United States, 552 U.S. 85, 91 (2007) (district court did not abuse its discretion in issuing a non-Guidelines sentence for a crack cocaine offense, based on lack of empirical basis for 100:1 sentencing disparity between crack cocaine and powder cocaine sentences). A court is free to determine that the "Guidelines are not based on empirical data and national experience, and hence 'do not exemplify the Commission's exercise of its characteristic institutional role.'" United States v. Cavera, 550 F.3d 180, 192 (2d Cir. 2008) (quoting Kimbrough, 552 U.S. at 109). This determination may be based on a finding that the Guidelines "rest[] on assumptions about . . . relative harmfulness . . . that more recent research and data no longer support." Kimbrough, 552 U.S. at 98.

II. Empirical Basis of MDMA Guidelines

A. Continuing Validity of the Commission's Findings

McCarthy challenges the MDMA Guidelines on the grounds that recent research undercuts the Commission's finding that MDMA is neurotoxic. The Ecstasy Report noted that a 1998 "brain scan comparison of MDMA users with non-users indicated the users had significantly reduced number of serotonin transporters throughout the brain." Ecstasy Report 9 (citing U.D. McCann et al., Positron Emission Tomographic Evidence of Toxic Effect of

MDMA ("Ecstasy") on Brain Serotonin Neurons in Human Beings (the "McCann Study"), 352 Lancet 1433 (1998)). Both parties' experts agreed that the best and most recent study of MDMA's effects on serotonin transporters found a reduction in serotonin transporters, but only in the cerebral cortex and hippocampus. See S.J. Kisch et al., Decreased Cerebral Cortical Serotonin Transporter Binding in Ecstasy Users: A Positron Emission Tomography/[(11)C] DASB and Structural Brain Imaging Study (the "Kisch Study"), 133 Brain 1779 (2010). Importantly, the Kisch Study expressly noted that it "did not find a global, massive reduction of brain [serotonin transporter] binding as reported in the [McCann study]." Kisch at 1791; (see also Tr. 257-58 (Parrott) (discussing the differences between the McCann and Kisch studies).)

While both parties rely on the Kisch Study, its import is equivocal: the Kisch Study found less depletion in serotonin transporters than the McCann Study, but nevertheless confirmed that depletion occurs. The variation in findings between the two studies may be explained by differences in the level of MDMA use among the test subjects. (Tr. 257-58 (Parrott).) Recent studies on the effect of MDMA on cognitive functioning have also found that MDMA use can cause statistically significant (although relatively minor) impairment in memory, providing further support for the Commission's findings. (See Tr. 197 (Parrott), 263 (Parrott).) Moreover, while early MDMA studies have been criticized because they failed to consider confounding variables like polydrug use (Tr. 119 (Halpern)), the Kisch Study took those variables into account (Tr. 180 (Parrott)). And in any case, the overwhelming majority of MDMA users are polydrug users. (Tr. 331 (Hanson).) Thus, the effects of MDMA in conjunction with other drugs remains a highly relevant—and arguably more practical—consideration when determining the harm caused by MDMA. (Tr. 331-32 (Hanson).)

Accordingly, this Court cannot conclude that the Commission's findings on MDMA's neurotoxicity have been so compromised by subsequent research that they are no longer true.

Nor can this Court discount the Commission's finding that MDMA is uniquely marketed to—and prevalent within—the younger population. Prevalence of a drug among the nation's youth, a particularly vulnerable segment of the population, provides strong support for higher sentences. This Court was not presented with any evidence contradicting this finding. Although McCarthy correctly notes that MDMA use has declined since its apex in the late 1990s and early 2000s, it is again on the rise. See National Institute of Health, Monitoring the Future: National Results on Adolescent Drug Use, Overview of Key Findings 46 (2008).

However, the Commission's statement that cocaine is only a stimulant, while MDMA is both a stimulant and a hallucinogen, is without factual support and largely irrelevant. Experts for both parties testified that MDMA is not properly characterized as a "hallucinogen." (Tr. 98 (Curran), 149 (Halpern), 289-90 (Parrott).) And in any case, comparing pharmacological properties using broad descriptors like "stimulant" and "hallucinogen" says little—if anything—about the relative harm posed by a drug. (See Tr. 128-29 (Halpern) ("[The Ecstasy Report] almost read[s] like this was supposed to be some sort of arithmetic; cocaine gets a score of one [because] it's a stimulant and then MDMA gets a score of two because it's a stimulant and a hallucinogen. . . . [T]hat's not using good science."))

B. Strength of the Commission's Analysis

There is no question that MDMA use has several significant negative impacts. Yet the Commission's analysis of these impacts—particularly as compared to cocaine—was selective and incomplete. Rather than comparing the full range of health effects of MDMA and cocaine, for example, the Commission focused only on a single health effect: neurotoxicity. In

doing so, the Commission ignored several effects of cocaine that render it significantly more harmful than MDMA.

For example, cocaine is responsible for far more emergency room visits per year than MDMA. (See Def.'s Third Supp. Sentencing Mem. Ex. 2: U.S. Department of Health and Human Services, Drug Abuse Warning Network 2007: National Estimates of Drug-Related Emergency Department Visits ("DAWN") 22 (2010) (finding that cocaine abuse was responsible for 553,530 emergency room visits, or 29.4% of drug- or alcohol-related emergency room visits in 2007, while MDMA was responsible for 12,748 visits, or 0.7%); (see also Tr. 125-26 (Halpern), 373-74 (Hanson).) Even controlling for the fact that cocaine is more commonly used than MDMA, cocaine is still approximately 16 times more likely to lead to hospitalization. (Compare DAWN 22, with Def.'s Third Supp. Sentencing Mem. Ex. 3: U.S. Department of Health and Human Services, Results from the 2007 National Survey on Drug Use and Health 252 (2008) (finding that 5,738,000 people over the age of 12 used cocaine in 2007, while 2,132,000 people used MDMA); (see also Tr. 126 (Halpern).) As the Government's witnesses acknowledged, MDMA fatalities are "rare." (Tr. 293 (Parrott); see also Tr. 374 (Hanson).)

Cocaine is also far more addictive than MDMA. (Tr. 230 (Parrott), 291 (Parrott), 339 (Hanson).) Indeed, MDMA is "one of the least addictive drugs." (Tr. 212 (Parrott), 232 (Parrott).) Moreover, cocaine use causes several adverse health effects not implicated by MDMA use—such as "cardiovascular effects, including disturbances in heart rhythm and heart attacks; respiratory effects, such as chest pain and respiratory failure; [and] neurological effects, including strokes [and] seizures." United States Sentencing Commission, Report to Congress: Cocaine and Federal Sentencing Policy ("Cocaine Report") 65 (2007); (see also Tr. 128 (Halpern) ("[C]ocaine users after many years of abuse and heavy use, run the risk of heart attack,

of stroke, of death from that, and many other problems. . . . We can do a standard CAT scan of the brain that can show evidence of strokes in the brain from their repeated longstanding cocaine use.").) In addition, MDMA is not associated with significant secondary health effects such as, for example, the spread of HIV through needles. Ecstasy Report 19. In this regard, MDMA and cocaine are similar.

Moreover, in contrast to MDMA, cocaine trafficking is associated with substantial violence. Ecstasy Report 19; see also Cocaine Report 86. And finally, there are far more cocaine-related cases in the federal criminal justice system than MDMA-related cases. See U.S. Department of Justice, Bureau of Justice Statistics, 2008 Statistical Tables 9 (2008), available at http://bjs.ojp.usdoj.gov/content/pub/html/fjsst/2008/fjs08st.pdf.

The foregoing illustrates that the Commission's analysis focused on the few ways in which MDMA is more harmful than cocaine, while disregarding several significant factors suggesting that it is in fact less harmful. Such opportunistic rummaging is particularly stark when viewed against the Commission's rationale for adopting lighter sentences for MDMA than for heroin. In that context, the Commission found that five factors weighed in favor of lighter sentences for MDMA: (1) number of cases in the federal criminal justice system, (2) addiction potential, (3) emergency room visits, (4) violence associated with use and distribution, and (5) secondary health effects. As discussed above, these factors—with the exception of secondary health effects, which are similar for MDMA and cocaine—also weigh in favor of lower sentences for MDMA than for cocaine. Yet they appear to have played no role in the Commission's MDMA Guidelines determination. See Ecstasy Report 5. The Commission's selective analysis is incompatible with the goal of uniform sentencing based on empirical data.

This Court is mindful of the harm inflicted by drug abuse and trafficking. The distribution of illegal drugs is a serious crime warranting significant penalties. Yet this Court must also consider "the need to avoid unwarranted sentence disparities among defendants with similar records who have been found guilty of similar conduct." 18 U.S.C. § 3553. This fundamental principle is violated when disparate drug equivalencies are established for similar narcotics based on an incomplete analysis. See Kimbrough, 552 U.S. at 98. Ultimately, consistent with the overwhelming weight of the evidence, no witness testified that MDMA was more harmful than cocaine. (Tr. 40 (Curran), 44 (Curran), 127-28 (Halpern), 231-32 (Parrott), 343 (Hanson).)

McCarthy suggests that this Court should sentence him based on a ratio of 1:1 or, alternatively, on the pre-2001 ratio of 35:1. However, he has not presented sufficient evidence that the harm posed by MDMA is equal to that of marijuana. Nor does this Court believe that the record supports a ratio of 35:1. Although McCarthy points to several aspects in which MDMA is less harmful than cocaine, MDMA also presents its own unique dangers. This Court defers to the Commission's determination, supported by express Congressional findings, that the pre-2001 MDMA Guidelines were too low. Accordingly, this Court adopts an MDMA-to-marijuana equivalency of 200:1, equal to that of cocaine.[2] See Spears v. United States, 129 S. Ct. 840, 843 (2009) ("[T]he ability to reduce a mine-run defendant's sentence [under Kimbrough and Booker] necessarily permits adoption of a replacement ratio.").

[2] As noted, much of the evidence indicates that MDMA is less harmful than cocaine, suggesting that an even lower equivalency may be appropriate given a sufficient factual foundation in a later case.

CONCLUSION

For the foregoing reasons, this Court adopts an MDMA-to-marijuana equivalency of 200:1.

Dated: May 19, 2011
New York, New York

SO ORDERED:

WILLIAM H. PAULEY III
U.S.D.J.

Counsel of Record

Jay Rorty
American Civil Liberties Union
1101 Pacific Avenue
Suite 333
Santa Cruz, CA 95060
Counsel for the Defendant

Scott M. Michelman
American Civil Liberties Union
1101 Pacific Avenue
Suite 333
Santa Cruz, CA 95060
Counsel for the Defendant

Michael H. Sporn
Law Office of Michael H. Sporn
299 Broadway Suite 800
New York, NY 10007
Counsel for the Defendant

Daniel Park Chung
U.S. Attorney's Office, SDNY (St Andw's)
One St. Andrew's Plaza
New York, NY 10007
Counsel for the Government

APPENDIX D

MAPS/ACLU Sentencing Press Release

FOR IMMEDIATE RELEASE
July 15, 2011

CONTACT:
Brad Burge
Director of Communications
brad@maps.org
(831) 429-6362 x103

MAPS Helps ACLU Persuade Federal Judge To Use Scientific Evidence to Challenge Harsh Ecstasy Sentencing Guidelines

Santa Cruz, CA – On July 15, 2011, U.S. District Judge William Pauley III sentenced a defendant charged with selling Ecstasy to 26 months in prison, less than half the 63 to 78 months recommended by current sentencing guidelines. This watershed event took place because the American Civil Liberties Union (ACLU), which represented the defendant, presented scientific evidence challenging the sentencing guidelines as being promulgated in a time of irrational fear over the risks of MDMA, based on claims made at the time that are unsupported by current scientific evidence.*

Previously, on May 19, 2011, Judge Pauley ruled that Ecstasy-related crimes are punished far more harshly than is justified by currently available scientific evidence about the risks of the drug. This ruling is the first of its kind regarding Ecstasy, yet it mirrors similar judicial rulings that have successfully challenged the sentencing guidelines for crack cocaine as also being too harsh and unsupported by current scientific evidence.

In 2001, the US Sentencing Commission enacted a set of guidelines requiring judges to treat a single gram of Ecstasy as if it were 500 grams of marijuana for the purposes of determining the severity of a sentence for federal drug offenses involving Ecstasy. At the public hearing prior to the Sentencing Commission's determination of the Ecstasy sentencing guidelines, MAPS Executive Director Rick Doblin, Ph.D., and other experts presented testimony, but that testimony was ignored. The ACLU challenged the Sentencing Commission's standard as unfair and requested that the judge undertake a rational reconsideration of the guidelines.

Judge Pauley's ruling sharply criticizes the commission's "opportunistic rummaging" and "selective and incomplete" analysis of the scientific data that led to the creation of the guidelines, and took into account new evidence—including data from a recent National Institute on Drug Abuse (NIDA)-funded study by Harvard psychiatrist John Halpern, M.D.—showing that long-term recreational Ecstasy use did not cause clinically significant cognitive damage.

MAPS brought the idea for the Ecstasy neurocognitive study idea to Dr. Halpern and invested $15,000 in a pilot study. Dr. Halpern then used the data from the pilot study for his successful NIDA grant application for which he was awarded $1.8 million over five years. MAPS also consulted with ACLU lawyers on the case and shared its review of the entire scientific literature about Ecstasy and MDMA, including data from its international series of Phase 2 pilot studies into MDMA-assisted psychotherapy for subjects with chronic, treatment-resistant posttraumatic stress disorder (PTSD).

According to Scott Michelman, staff attorney for the ACLU Criminal Drug Law Reform Project, the ruling is a step in the right direction. He commented, "This ruling demonstrates the importance of thoroughly reviewing the empirical basis underlying each of the U.S. Sentencing Guidelines for drug offenses, to make sure the Guidelines reflect the current state of scientific knowledge."

***Note: MAPS' clinical research studies use pure MDMA manufactured in government-licensed facilities. Drugs bought and sold on the black market as "Ecstasy" may or may not contain MDMA.**

###

APPENDIX E

Media Highlights

Multiple news sources have reported on MAPS MDMA research. A brief list of media from the past year include:

- **The New York Times**: F.D.A. Agrees to New Trials for MDMA as Relief for PTSD Patients (November 30, 2016)

- **PBS Newshour**: Using Ecstasy to Treat PTSD: 'I Felt Like My Soul Snapped Back into Place' (December 1, 2016)
- **Red State**: The Cure for PTSD? How a Rave Drug Can Be a Treatment (November 16, 2016)
- **Stars and Stripes**: Ecstasy One Step Closer to Approval as PTSD Treatment (December 20, 2016)
- **Fox News**: Ecstasy Trials Approved by FDA for PTSD Patients (November 30, 2016)
- **Military.com**: Trial for PTSD Treatment with Ecstasy Ingredient to Open Soon (January 26, 2017)
- **The Guardian**: 'My Therapist Gave Me a Pill': Can MDMA Help Cure Trauma? (September 16, 2016)

A more extensive list of MAPS media coverage is also available on our website at maps.org/news/media

NATIONAL COMPARISON OF SENTENCE IMPOSED AND POSITION RELATIVE TO THE GUIDELINE RANGE[1]

Preliminary Unedited Cumulative Data (September 1, 2016, through March 1, 2017)

Date Prepared: March 7, 2017

	N	%	FY 2016 %
TOTAL CASES	**30,407**	**100.0**	**100.0**
CASES SENTENCED WITHIN GUIDELINE RANGE	**14,712**	**48.4**	**48.6**
CASES SENTENCED ABOVE GUIDELINE RANGE	**862**	**2.8**	**2.4**
DEPARTURE ABOVE GUIDELINE RANGE	**206**	**0.7**	**0.6**
Upward Departure From Guideline Range[2]	162	0.5	0.5
Upward Departure With *Booker* /18 U.S.C. § 3553[3]	44	0.1	0.2
OTHERWISE ABOVE GUIDELINE RANGE	**656**	**2.2**	**1.8**
Above Guideline Range With *Booker* /18 U.S.C. § 3553[4]	584	1.9	1.7
All Remaining Cases Above Guideline Range[5]	72	0.2	0.1
GOVERNMENT SPONSORED BELOW RANGE[6]	**8,495**	**27.9**	**28.2**
§5K1.1 Substantial Assistance Departure	3,264	10.7	11.1
§5K3.1 Early Disposition Program Departure	2,691	8.8	8.9
Other Government Sponsored Below Range	2,540	8.4	8.2
NON-GOVERNMENT SPONSORED BELOW RANGE	**6,338**	**20.8**	**20.8**
DEPARTURE BELOW GUIDELINE RANGE	**714**	**2.3**	**2.8**
Downward Departure From Guideline Range[2]	517	1.7	2.0
Downward Departure With *Booker* /18 U.S.C. § 3553[3]	197	0.6	0.8
OTHERWISE BELOW GUIDELINE RANGE	**5,624**	**18.5**	**18.0**
Below Guideline Range With *Booker* /18 U.S.C. § 3553[4]	5,375	17.7	17.4
All Remaining Cases Below Guideline Range[5]	249	0.8	0.6

[1] This table reflects the 30,673 cases sentenced on or after September 1, 2016 through March 1, 2017 with court documentation cumulatively received and coded at the U.S. Sentencing Commission by March 6, 2017. Of these, 266 cases were excluded because information was missing from the submitted documents that prevented the comparison of the sentence and the guideline range.

[2] All cases with departures in which the court did not indicate as a reason either *United States v. Booker*, 18 U.S.C. § 3553, or a factor or reason specifically prohibited in the provisions, policy statements, or commentary of the *Guidelines Manual.*

[3] All cases sentenced outside of the guideline range in which the court indicated both a departure (see footnote 2) and a reference to either *United States v. Booker*, 18 U.S.C. § 3553, or related factors as a reason for sentencing outside of the guideline system.

[4] All cases sentenced outside of the guideline range in which no departure was indicated and in which the court cited *United States v. Booker*, 18 U.S.C. § 3553, or related factors as one of the reasons for sentencing outside of the guideline system.

[5] All cases sentenced outside of the guideline range that could not be classified into any of the three previous outside of the range categories. This category includes cases in which no reason was provided for a sentence outside of the guideline range.

[6] Cases in which a reason for the sentence indicated that the prosecution initiated, proposed, or stipulated to a sentence outside of the guideline range, either pursuant to a plea agreement or as part of a non-plea negotiation with the defendant.

SOURCE: U.S. Sentencing Commission, Preliminary 2016-2017 Datafiles, USSCFY16-USSCFY17.

NATIONAL COMPARISON OF SENTENCE IMPOSED AND POSITION RELATIVE TO THE GUIDELINE RANGE FOR NON-DRUG OFFENSES[1]

Preliminary Unedited Cumulative Data (September 1, 2016, through March 1, 2017)

Date Prepared: March 7, 2017

	N	%	FY 2016 %
TOTAL CASES	**20,893**	**100.0**	**100.0**
CASES SENTENCED WITHIN GUIDELINE RANGE	**11,052**	**52.9**	**52.3**
CASES SENTENCED ABOVE GUIDELINE RANGE	**693**	**3.3**	**2.7**
DEPARTURE ABOVE GUIDELINE RANGE	**173**	**0.8**	**0.7**
Upward Departure From Guideline Range[2]	132	0.6	0.5
Upward Departure With *Booker*/18 U.S.C. § 3553[3]	41	0.2	0.2
OTHERWISE ABOVE GUIDELINE RANGE	**520**	**2.5**	**2.0**
Above Guideline Range With *Booker*/18 U.S.C. § 3553[4]	480	2.3	1.9
All Remaining Cases Above Guideline Range[5]	40	0.2	0.1
GOVERNMENT SPONSORED BELOW RANGE[6]	**4,938**	**23.6**	**24.3**
§5K1.1 Substantial Assistance Departure	1,305	6.2	6.7
§5K3.1 Early Disposition Program Departure	2,097	10.0	10.2
Other Government Sponsored Below Range	1,536	7.4	7.4
NON-GOVERNMENT SPONSORED BELOW RANGE	**4,210**	**20.2**	**20.6**
DEPARTURE BELOW GUIDELINE RANGE	**508**	**2.4**	**2.9**
Downward Departure From Guideline Range[2]	383	1.8	2.2
Downward Departure With *Booker*/18 U.S.C. § 3553[3]	125	0.6	0.8
OTHERWISE BELOW GUIDELINE RANGE	**3,702**	**17.7**	**17.7**
Below Guideline Range With *Booker*/18 U.S.C. § 3553[4]	3,507	16.8	17.1
All Remaining Cases Below Guideline Range[5]	195	0.9	0.7

[1] This table reflects the 30,673 cases sentenced on or after September 1, 2016 through March 1, 2017 with court documentation cumulatively received and coded at the U.S. Sentencing Commission by March 6, 2017. Of these, 266 cases were excluded because information was missing from the submitted documents that prevented the comparison of the sentence and the guideline range. Of the remaining cases, 20,893 were cases where the primary offense type was not drug trafficking, use of a communication facility, or simple possession.

[2] All cases with departures in which the court did not indicate as a reason either *United States v. Booker*, 18 U.S.C. § 3553, or a factor or reason specifically prohibited in the provisions, policy statements, or commentary of the *Guidelines Manual.*

[3] All cases sentenced outside of the guideline range in which the court indicated both a departure (see footnote 2) and a reference to either *United States v. Booker*, 18 U.S.C. § 3553, or related factors as a reason for sentencing outside of the guideline system.

[4] All cases sentenced outside of the guideline range in which no departure was indicated and in which the court cited *United States v. Booker*, 18 U.S.C. § 3553, or related factors as one of the reasons for sentencing outside of the guideline system.

[5] All cases sentenced outside of the guideline range that could not be classified into any of the three previous outside of the range categories. This category includes cases in which no reason was provided for a sentence outside of the guideline range.

[6] Cases in which a reason for the sentence indicated that the prosecution initiated, proposed, or stipulated to a sentence outside of the guideline range, either pursuant to a plea agreement or as part of a non-plea negotiation with the defendant.

SOURCE: U.S. Sentencing Commission, Preliminary 2016-2017 Datafiles, USSCFY16-USSCFY17.

Table 2

NATIONAL COMPARISON OF SENTENCE IMPOSED AND POSITION RELATIVE TO THE GUIDELINE RANGE FOR DRUG TRAFFICKING OFFENSES[1]
Preliminary Unedited Cumulative Data (September 1, 2016, through March 1, 2017)
Date Prepared: March 7, 2017

	N	%	FY 2016 %
TOTAL CASES	**8,893**	**100.0**	**100.0**
CASES SENTENCED WITHIN GUIDELINE RANGE	**3,152**	**35.4**	**36.0**
CASES SENTENCED ABOVE GUIDELINE RANGE	**133**	**1.5**	**1.2**
DEPARTURE ABOVE GUIDELINE RANGE	**32**	**0.4**	**0.4**
Upward Departure From Guideline Range[2]	29	0.3	0.3
Upward Departure With *Booker*/18 U.S.C. § 3553[3]	3	0.0	0.1
OTHERWISE ABOVE GUIDELINE RANGE	**101**	**1.1**	**0.8**
Above Guideline Range With *Booker*/18 U.S.C. § 3553[4]	83	0.9	0.7
All Remaining Cases Above Guideline Range[5]	18	0.2	0.1
GOVERNMENT SPONSORED BELOW RANGE[6]	**3,521**	**39.6**	**39.9**
§5K1.1 Substantial Assistance Departure	1,938	21.8	22.6
§5K3.1 Early Disposition Program Departure	594	6.7	6.7
Other Government Sponsored Below Range	989	11.1	10.6
NON-GOVERNMENT SPONSORED BELOW RANGE	**2,087**	**23.5**	**22.9**
DEPARTURE BELOW GUIDELINE RANGE	**203**	**2.3**	**2.7**
Downward Departure From Guideline Range[2]	132	1.5	1.7
Downward Departure With *Booker*/18 U.S.C. § 3553[3]	71	0.8	1.0
OTHERWISE BELOW GUIDELINE RANGE	**1,884**	**21.2**	**20.2**
Below Guideline Range With *Booker*/18 U.S.C. § 3553[4]	1,833	20.6	19.8
All Remaining Cases Below Guideline Range[5]	51	0.6	0.4

[1] This table reflects the 30,673 cases sentenced on or after September 1, 2016 through March 1, 2017 with court documentation cumulatively received and coded at the U.S. Sentencing Commission by March 6, 2017. Of these, 266 cases were excluded because information was missing from the submitted documents that prevented the comparison of the sentence and the guideline range. Of the remaining cases, 8,893 were cases where drug trafficking was the primary offense type.

[2] All cases with departures in which the court did not indicate as a reason either *United States v. Booker*, 18 U.S.C. § 3553, or a factor or reason specifically prohibited in the provisions, policy statements, or commentary of the *Guidelines Manual.*

[3] All cases sentenced outside of the guideline range in which the court indicated both a departure (see footnote 2) and a reference to either *United States v. Booker*, 18 U.S.C. § 3553, or related factors as a reason for sentencing outside of the guideline system.

[4] All cases sentenced outside of the guideline range in which no departure was indicated and in which the court cited *United States v. Booker*, 18 U.S.C. § 3553, or related factors as one of the reasons for sentencing outside of the guideline system.

[5] All cases sentenced outside of the guideline range that could not be classified into any of the three previous outside of the range categories. This category includes cases in which no reason was provided for a sentence outside of the guideline range.

[6] Cases in which a reason for the sentence indicated that the prosecution initiated, proposed, or stipulated to a sentence outside of the guideline range, either pursuant to a plea agreement or as part of a non-plea negotiation with the defendant.

SOURCE: U.S. Sentencing Commission, Preliminary 2016-2017 Datafiles, USSCFY16-USSCFY17.

NATIONAL COMPARISON OF SENTENCE IMPOSED AND POSITION RELATIVE TO THE GUIDELINE RANGE FOR IMMIGRATION OFFENSES[1]

Preliminary Unedited Cumulative Data (September 1, 2016, through March 1, 2017)

Date Prepared: March 7, 2017

	N	%	FY 2016 %
TOTAL CASES	**9,351**	**100.0**	**100.0**
CASES SENTENCED WITHIN GUIDELINE RANGE	**5,504**	**58.9**	**58.2**
CASES SENTENCED ABOVE GUIDELINE RANGE	**299**	**3.2**	**1.6**
DEPARTURE ABOVE GUIDELINE RANGE	**79**	**0.8**	**0.4**
Upward Departure From Guideline Range[2]	66	0.7	0.3
Upward Departure With *Booker*/18 U.S.C. § 3553[3]	13	0.1	0.1
OTHERWISE ABOVE GUIDELINE RANGE	**220**	**2.4**	**1.2**
Above Guideline Range With *Booker*/18 U.S.C. § 3553[4]	210	2.2	1.2
All Remaining Cases Above Guideline Range[5]	10	0.1	0.1
GOVERNMENT SPONSORED BELOW RANGE[6]	**2,399**	**25.7**	**26.5**
§5K1.1 Substantial Assistance Departure	88	0.9	1.1
§5K3.1 Early Disposition Program Departure	2,081	22.3	23.2
Other Government Sponsored Below Range	230	2.5	2.3
NON-GOVERNMENT SPONSORED BELOW RANGE	**1,149**	**12.3**	**13.7**
DEPARTURE BELOW GUIDELINE RANGE	**265**	**2.8**	**3.4**
Downward Departure From Guideline Range[2]	234	2.5	3.1
Downward Departure With *Booker*/18 U.S.C. § 3553[3]	31	0.3	0.4
OTHERWISE BELOW GUIDELINE RANGE	**884**	**9.5**	**10.3**
Below Guideline Range With *Booker*/18 U.S.C. § 3553[4]	800	8.6	9.7
All Remaining Cases Below Guideline Range[5]	84	0.9	0.6

[1] This table reflects the 30,673 cases sentenced on or after September 1, 2016 through March 1, 2017 with court documentation cumulatively received and coded at the U.S. Sentencing Commission by March 6, 2017. Of these, 266 cases were excluded because information was missing from the submitted documents that prevented the comparison of the sentence and the guideline range. Of the remaining cases, 9,351 were cases where immigration was the primary offense type.

[2] All cases with departures in which the court did not indicate as a reason either *United States v. Booker*, 18 U.S.C. § 3553, or a factor or reason specifically prohibited in the provisions, policy statements, or commentary of the *Guidelines Manual.*

[3] All cases sentenced outside of the guideline range in which the court indicated both a departure (see footnote 2) and a reference to either *United States v. Booker*, 18 U.S.C. § 3553, or related factors as a reason for sentencing outside of the guideline system.

[4] All cases sentenced outside of the guideline range in which no departure was indicated and in which the court cited *United States v. Booker*, 18 U.S.C. § 3553, or related factors as one of the reasons for sentencing outside of the guideline system.

[5] All cases sentenced outside of the guideline range that could not be classified into any of the three previous outside of the range categories. This category includes cases in which no reason was provided for a sentence outside of the guideline range.

[6] Cases in which a reason for the sentence indicated that the prosecution initiated, proposed, or stipulated to a sentence outside of the guideline range, either pursuant to a plea agreement or as part of a non-plea negotiation with the defendant.

SOURCE: U.S. Sentencing Commission, Preliminary 2016-2017 Datafiles, USSCFY16-USSCFY17.

Table 4

NATIONAL COMPARISON OF SENTENCE IMPOSED AND POSITION RELATIVE TO THE GUIDELINE RANGE FOR FRAUD OFFENSES[1]

Preliminary Unedited Cumulative Data (September 1, 2016, through March 1, 2017)

Date Prepared: March 7, 2017

	N	%	FY 2016 %
TOTAL CASES	**2,726**	**100.0**	**100.0**
CASES SENTENCED WITHIN GUIDELINE RANGE	**1,142**	**41.9**	**42.7**
CASES SENTENCED ABOVE GUIDELINE RANGE	**57**	**2.1**	**2.1**
DEPARTURE ABOVE GUIDELINE RANGE	**15**	**0.6**	**0.7**
Upward Departure From Guideline Range[2]	8	0.3	0.5
Upward Departure With *Booker*/18 U.S.C. § 3553[3]	7	0.3	0.2
OTHERWISE ABOVE GUIDELINE RANGE	**42**	**1.5**	**1.4**
Above Guideline Range With *Booker*/18 U.S.C. § 3553[4]	36	1.3	1.4
All Remaining Cases Above Guideline Range[5]	6	0.2	0.1
GOVERNMENT SPONSORED BELOW RANGE[6]	**720**	**26.4**	**26.0**
§5K1.1 Substantial Assistance Departure	465	17.1	16.8
§5K3.1 Early Disposition Program Departure	3	0.1	0.2
Other Government Sponsored Below Range	252	9.2	9.0
NON-GOVERNMENT SPONSORED BELOW RANGE	**807**	**29.6**	**29.1**
DEPARTURE BELOW GUIDELINE RANGE	**49**	**1.8**	**2.8**
Downward Departure From Guideline Range[2]	21	0.8	1.3
Downward Departure With *Booker*/18 U.S.C. § 3553[3]	28	1.0	1.5
OTHERWISE BELOW GUIDELINE RANGE	**758**	**27.8**	**26.3**
Below Guideline Range With *Booker*/18 U.S.C. § 3553[4]	722	26.5	25.3
All Remaining Cases Below Guideline Range[5]	36	1.3	1.0

[1] This table reflects the 30,673 cases sentenced on or after September 1, 2016 through March 1, 2017 with court documentation cumulatively received and coded at the U.S. Sentencing Commission by March 6, 2017. Of these, 266 cases were excluded because information was missing from the submitted documents that prevented the comparison of the sentence and the guideline range. Of the remaining cases, 2,726 were cases where fraud was the primary offense type.

[2] All cases with departures in which the court did not indicate as a reason either *United States v. Booker*, 18 U.S.C. § 3553, or a factor or reason specifically prohibited in the provisions, policy statements, or commentary of the *Guidelines Manual.*

[3] All cases sentenced outside of the guideline range in which the court indicated both a departure (see footnote 2) and a reference to either *United States v. Booker*, 18 U.S.C. § 3553, or related factors as a reason for sentencing outside of the guideline system.

[4] All cases sentenced outside of the guideline range in which no departure was indicated and in which the court cited *United States v. Booker*, 18 U.S.C. § 3553, or related factors as one of the reasons for sentencing outside of the guideline system.

[5] All cases sentenced outside of the guideline range that could not be classified into any of the three previous outside of the range categories. This category includes cases in which no reason was provided for a sentence outside of the guideline range.

[6] Cases in which a reason for the sentence indicated that the prosecution initiated, proposed, or stipulated to a sentence outside of the guideline range, either pursuant to a plea agreement or as part of a non-plea negotiation with the defendant.

SOURCE: U.S. Sentencing Commission, Preliminary 2016-2017 Datafiles, USSCFY16-USSCFY17.

NATIONAL COMPARISON OF SENTENCE IMPOSED AND POSITION RELATIVE TO THE GUIDELINE RANGE FOR FIREARM OFFENSES[1]

Preliminary Unedited Cumulative Data (September 1, 2016, through March 1, 2017)

Date Prepared: March 7, 2017

	N	%	FY 2016 %
TOTAL CASES	**3,553**	**100.0**	**100.0**
CASES SENTENCED WITHIN GUIDELINE RANGE	**1,937**	**54.5**	**52.6**
CASES SENTENCED ABOVE GUIDELINE RANGE	**157**	**4.4**	**4.7**
DEPARTURE ABOVE GUIDELINE RANGE	**37**	**1.0**	**1.1**
Upward Departure From Guideline Range[2]	26	0.7	0.7
Upward Departure With *Booker*/18 U.S.C. § 3553[3]	11	0.3	0.4
OTHERWISE ABOVE GUIDELINE RANGE	**120**	**3.4**	**3.6**
Above Guideline Range With *Booker*/18 U.S.C. § 3553[4]	112	3.2	3.5
All Remaining Cases Above Guideline Range[5]	8	0.2	0.1
GOVERNMENT SPONSORED BELOW RANGE[6]	**639**	**18.0**	**19.6**
§5K1.1 Substantial Assistance Departure	292	8.2	9.7
§5K3.1 Early Disposition Program Departure	5	0.1	0.1
Other Government Sponsored Below Range	342	9.6	9.8
NON-GOVERNMENT SPONSORED BELOW RANGE	**820**	**23.1**	**23.0**
DEPARTURE BELOW GUIDELINE RANGE	**69**	**1.9**	**2.1**
Downward Departure From Guideline Range[2]	48	1.4	1.3
Downward Departure With *Booker*/18 U.S.C. § 3553[3]	21	0.6	0.8
OTHERWISE BELOW GUIDELINE RANGE	**751**	**21.1**	**20.9**
Below Guideline Range With *Booker*/18 U.S.C. § 3553[4]	727	20.5	20.4
All Remaining Cases Below Guideline Range[5]	24	0.7	0.5

[1] This table reflects the 30,673 cases sentenced on or after September 1, 2016 through March 1, 2017 with court documentation cumulatively received and coded at the U.S. Sentencing Commission by March 6, 2017. Of these, 266 cases were excluded because information was missing from the submitted documents that prevented the comparison of the sentence and the guideline range. Of the remaining cases, 3,553 were cases where firearms was the primary offense type.

[2] All cases with departures in which the court did not indicate as a reason either *United States v. Booker*, 18 U.S.C. § 3553, or a factor or reason specifically prohibited in the provisions, policy statements, or commentary of the *Guidelines Manual.*

[3] All cases sentenced outside of the guideline range in which the court indicated both a departure (see footnote 2) and a reference to either *United States v. Booker*, 18 U.S.C. § 3553, or related factors as a reason for sentencing outside of the guideline system.

[4] All cases sentenced outside of the guideline range in which no departure was indicated and in which the court cited *United States v. Booker*, 18 U.S.C. § 3553, or related factors as one of the reasons for sentencing outside of the guideline system.

[5] All cases sentenced outside of the guideline range that could not be classified into any of the three previous outside of the range categories. This category includes cases in which no reason was provided for a sentence outside of the guideline range.

[6] Cases in which a reason for the sentence indicated that the prosecution initiated, proposed, or stipulated to a sentence outside of the guideline range, either pursuant to a plea agreement or as part of a non-plea negotiation with the defendant.

SOURCE: U.S. Sentencing Commission, Preliminary 2016-2017 Datafiles, USSCFY16-USSCFY17.

NATIONAL COMPARISON OF SENTENCE IMPOSED AND POSITION RELATIVE TO THE GUIDELINE RANGE FOR CHILD PORNOGRAPHY OFFENSES[1]
Preliminary Unedited Cumulative Data (September 1, 2016, through March 1, 2017)
Date Prepared: March 7, 2017

	N	%	FY 2016 %
TOTAL CASES	**800**	**100.0**	**100.0**
CASES SENTENCED WITHIN GUIDELINE RANGE	**211**	**26.4**	**29.1**
CASES SENTENCED ABOVE GUIDELINE RANGE	**14**	**1.8**	**2.0**
DEPARTURE ABOVE GUIDELINE RANGE	**1**	**0.1**	**0.2**
Upward Departure From Guideline Range[2]	1	0.1	0.2
Upward Departure With *Booker*/18 U.S.C. § 3553[3]	0	0.0	0.0
OTHERWISE ABOVE GUIDELINE RANGE	**13**	**1.6**	**1.9**
Above Guideline Range With *Booker*/18 U.S.C. § 3553[4]	12	1.5	1.8
All Remaining Cases Above Guideline Range[5]	1	0.1	0.1
GOVERNMENT SPONSORED BELOW RANGE[6]	**220**	**27.5**	**24.0**
§5K1.1 Substantial Assistance Departure	24	3.0	2.8
§5K3.1 Early Disposition Program Departure	0	0.0	0.0
Other Government Sponsored Below Range	196	24.5	21.2
NON-GOVERNMENT SPONSORED BELOW RANGE	**355**	**44.4**	**44.9**
DEPARTURE BELOW GUIDELINE RANGE	**16**	**2.0**	**2.9**
Downward Departure From Guideline Range[2]	11	1.4	2.1
Downward Departure With *Booker*/18 U.S.C. § 3553[3]	5	0.6	0.9
OTHERWISE BELOW GUIDELINE RANGE	**339**	**42.4**	**42.0**
Below Guideline Range With *Booker*/18 U.S.C. § 3553[4]	335	41.9	41.0
All Remaining Cases Below Guideline Range[5]	4	0.5	1.0

[1] This table reflects the 30,673 cases sentenced on or after September 1, 2016 through March 1, 2017 with court documentation cumulatively received and coded at the U.S. Sentencing Commission by March 6, 2017. Of these, 266 cases were excluded because information was missing from the submitted documents that prevented the comparison of the sentence and the guideline range. Of the remaining cases, 800 were cases where child pornography was the primary offense type.

[2] All cases with departures in which the court did not indicate as a reason either *United States v. Booker*, 18 U.S.C. § 3553, or a factor or reason specifically prohibited in the provisions, policy statements, or commentary of the *Guidelines Manual.*

[3] All cases sentenced outside of the guideline range in which the court indicated both a departure (see footnote 2) and a reference to either *United States v. Booker*, 18 U.S.C. § 3553, or related factors as a reason for sentencing outside of the guideline system.

[4] All cases sentenced outside of the guideline range in which no departure was indicated and in which the court cited *United States v. Booker*, 18 U.S.C. § 3553, or related factors as one of the reasons for sentencing outside of the guideline system.

[5] All cases sentenced outside of the guideline range that could not be classified into any of the three previous outside of the range categories. This category includes cases in which no reason was provided for a sentence outside of the guideline range.

[6] Cases in which a reason for the sentence indicated that the prosecution initiated, proposed, or stipulated to a sentence outside of the guideline range, either pursuant to a plea agreement or as part of a non-plea negotiation with the defendant.

SOURCE: U.S. Sentencing Commission, Preliminary 2016-2017 Datafiles, USSCFY16-USSCFY17.

NATIONAL COMPARISON OF SENTENCE IMPOSED AND POSITION RELATIVE TO THE GUIDELINE RANGE FOR CAREER OFFENDERS[1]
Preliminary Unedited Cumulative Data (September 1, 2016, through March 1, 2017)
Date Prepared: March 7, 2017

	N	%	FY 2016 %
TOTAL CASES	**699**	**100.0**	**100.0**
CASES SENTENCED WITHIN GUIDELINE RANGE	**156**	**22.3**	**24.7**
CASES SENTENCED ABOVE GUIDELINE RANGE	**7**	**1.0**	**1.0**
DEPARTURE ABOVE GUIDELINE RANGE	**1**	**0.1**	**0.1**
Upward Departure From Guideline Range[2]	0	0.0	0.1
Upward Departure With *Booker* /18 U.S.C. § 3553[3]	1	0.1	0.0
OTHERWISE ABOVE GUIDELINE RANGE	**6**	**0.9**	**0.9**
Above Guideline Range With *Booker* /18 U.S.C. § 3553[4]	6	0.9	0.9
All Remaining Cases Above Guideline Range[5]	0	0.0	0.1
GOVERNMENT SPONSORED BELOW RANGE[6]	**322**	**46.1**	**45.6**
§5K1.1 Substantial Assistance Departure	161	23.0	23.0
§5K3.1 Early Disposition Program Departure	6	0.9	0.7
Other Government Sponsored Below Range	155	22.2	21.9
NON-GOVERNMENT SPONSORED BELOW RANGE	**214**	**30.6**	**28.7**
DEPARTURE BELOW GUIDELINE RANGE	**23**	**3.3**	**3.0**
Downward Departure From Guideline Range[2]	11	1.6	1.5
Downward Departure With *Booker* /18 U.S.C. § 3553[3]	12	1.7	1.5
OTHERWISE BELOW GUIDELINE RANGE	**191**	**27.3**	**25.7**
Below Guideline Range With *Booker* /18 U.S.C. § 3553[4]	183	26.2	25.4
All Remaining Cases Below Guideline Range[5]	8	1.1	0.3

[1] This table reflects the 30,673 cases sentenced on or after September 1, 2016 through March 1, 2017 with court documentation cumulatively received and coded at the U.S. Sentencing Commission by March 6, 2017. Of these, 266 cases were excluded because information was missing from the submitted documents that prevented the comparison of the sentence and the guideline range. Of the remaining cases, 699 were cases where the offender received the career offender adjustment.

[2] All cases with departures in which the court did not indicate as a reason either *United States v. Booker*, 18 U.S.C. § 3553, or a factor or reason specifically prohibited in the provisions, policy statements, or commentary of the *Guidelines Manual.*

[3] All cases sentenced outside of the guideline range in which the court indicated both a departure (see footnote 2) and a reference to either *United States v. Booker*, 18 U.S.C. § 3553, or related factors as a reason for sentencing outside of the guideline system.

[4] All cases sentenced outside of the guideline range in which no departure was indicated and in which the court cited *United States v. Booker*, 18 U.S.C. § 3553, or related factors as one of the reasons for sentencing outside of the guideline system.

[5] All cases sentenced outside of the guideline range that could not be classified into any of the three previous outside of the range categories. This category includes cases in which no reason was provided for a sentence outside of the guideline range.

[6] Cases in which a reason for the sentence indicated that the prosecution initiated, proposed, or stipulated to a sentence outside of the guideline range, either pursuant to a plea agreement or as part of a non-plea negotiation with the defendant.

SOURCE: U.S. Sentencing Commission, Preliminary 2016-2017 Datafiles, USSCFY16-USSCFY17.