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 policy 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 continuing work on this priority, the Commission is publishing this request for public comment on issues related to MDMA/Ecstasy and methylone, one of the synthetic cathinones included in the Commission's study. The issues for comment are set forth in the Supplementary Information portion of this notice.

DATES: Public comment regarding the issues for comment set forth in this notice should be received by the Commission not later than **August 7, 2017**.

ADDRESS: 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 U.S. Sentencing Comm'n, "Notice of Final Priorities," 81 FR 58004 (Aug. 24, 2016). The Commission expects that this study will be conducted over a multi-year

period, and may solicit comment several times during this period from experts and other members of the public.

On December 19, 2016, the Commission published a request for comment inviting general comment on synthetic cathinones (MDPV, methylone, and mephedrone) and synthetic cannabinoids (JWH-018 and AM-2201), as well as about the application of the factors the Commission traditionally considers when determining the marihuana equivalencies for specific controlled substances to the substances under study. See U.S. Sentencing Comm'n, "Request for Public Comment," 81 FR 92021 (Dec. 19, 2016). On April 18, 2017, the Commission held a public hearing relating to this priority. The Commission received testimony from experts on the synthetic drugs related to the study, including testimony about their chemical structure, pharmacological effects, trafficking patterns, and community impact.

As part of its continuing work on this priority, the Commission is publishing this second request for comment specifically focused on issues related to MDMA/Ecstasy and methylone, one of the synthetic cathinones included in the Commission's study. In addition to the substance-specific topics discussed below, the Commission anticipates that its work will continue to be guided by the factors the Commission traditionally considers when determining marihuana equivalencies for specific controlled substances, including their chemical structure, pharmacological effects, legislative and scheduling history, potential for addiction and abuse, the pattern of abuse and harms associated with their abuse, and the patterns of trafficking and harms associated with their trafficking.

MDMA.— MDMA (3,4-Methylenedioxy-methamphetamine) is a Schedule I controlled substance with a chemical structure similar to methamphetamine and the hallucinogen mescaline. See U.S. SENTENCING COMM'N, REPORT TO THE CONGRESS: MDMA DRUG OFFENSES: EXPLANATION OF RECENT GUIDELINE AMENDMENTS 6–7 (May 2001) ("MDMA Report"), available at http://www.ussc.gov/sites/default/files/pdf/news/congressional-testimony-and-reports/drug-topics/200105_RtC_MDMA_Drug_Offenses.pdf. MDMA, also known as "ecstasy" or "molly," was originally developed for therapeutic use, but became a drug of abuse by the late 1970s. Id. at 7. Its use results in enhanced feelings of pleasure, relaxation, and self-confidence, while accompanying physical symptoms may include increased heart rate and blood pressure and difficulty regulating body temperature. MDMA is typically marketed and consumed in pill form. Id.

MDMA is not specifically listed in the Drug Quantity Table at §2D1.1 (Unlawful Manufacturing, Importing, Exporting, or Trafficking (Including Possession with Intent to Commit These Offenses); Attempt or Conspiracy), but it is referenced in the Drug Equivalency Tables. See USSC §2D1.1, comment. (n.8(D)). Prior to 2001, the marihuana equivalency of MDMA was 1 gm of MDMA = 35 gm of marihuana. The Commission established the current marihuana equivalency and penalties for MDMA in 2001 in response to the Ecstasy Anti-Proliferation Act of 2000, Pub. L. No. 106–310 (Oct. 17, 2000). The Act directed the Commission to examine whether the then-current penalties associated with MDMA were appropriate, adopt any appropriate amendments to the Guidelines Manual, and submit a report to Congress explaining its actions. Id. at 2. The Act also instructed the Commission to consider five distinct "dangers" associated with

unlawful activity involving MDMA: (1) rapid growth in its use; (2) a recent increase in its importation; (3) the young age at which usage began; (4) the marketing of the substance to youth; and (5) the large number of doses per gram of MDMA. Id. at 3.

The Commission implemented the directive by adopting an amendment setting the marihuana equivalency for MDMA as 1 gm of MDMA = 500 gm of marihuana. See USSG App. C, amend. 609 (effective May 1, 2001). In response to the directive, the Commission also published its MDMA Report and submitted it to Congress. In the MDMA Report, the Commission explained that it had found evidence supporting all of Congress's concerns except for the fifth (the number of doses per gram). See id. at 11–16. The MDMA Report also explained that there was conflicting evidence about MDMA's potential long-term mental and physical harms and dangers relative to other controlled substances. See id. at 17–18. After considering all the evidence, the Commission chose a 500:1 ratio, which was less than an earlier 1,000:1 proposal, but would result in significant increases in the penalties for MDMA offenses. See id. at 6. The 500:1 ratio was intended to punish "local distributors" with sentences of approximately five years, and "upper and middle level distributors" with sentences of ten or more years. See id. at 18.

The marihuana equivalency of MDMA remains 1 gm of MDMA = 500 gm of marihuana. Some public comment and judicial opinions have suggested that the current marihuana equivalency for MDMA may no longer be appropriate in light of scientific and practical developments that have occurred since 2001. Other stakeholders have suggested that the current ratio remains appropriate in light of the concerns expressed by Congress in 2000.

Methylone and Other Synthetic Cathinones.—According to the National Institute on Drug Abuse, synthetic cathinones, also known as "bath salts," are human-made substances chemically related to cathinone, a stimulant found in the khat plant. See National Institute on Drug Abuse, DrugFacts: Synthetic Cathinones ("Bath Salts") (January 2016) *available at* https://www.drugabuse.gov/publications/drugfacts/synthetic-cathinones-bath-salts. Methylone (3,4-methylenedioxy-N-methylcathinone), also known as MDMC, is a synthetic cathinone that has been reported to have hallucinogenic effects broadly similar to those of MDMA. Like MDMA, methylone has been associated with use at dance parties or "raves." According to the Drug Enforcement Agency, methylone is typically imported from abroad and consumed in capsule form. DRUG ENFORCEMENT AGENCY, U.S. DEP'T OF JUSTICE, DRUGS OF ABUSE: A DEA RESOURCE GUIDE 80 (2015).

Unlike MDMA, methylone is not specifically listed in either the Drug Quantity Table or the Drug Equivalency Tables at §2D1.1. As with any drug trafficking offense that involves a controlled substance not specifically referenced in the guidelines, courts are required in cases involving methylone 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, a court must determine the most closely related controlled substance by considering, to the extent practicable, the factors set forth in Application Note 6. Once the most closely related controlled substance is determined, the next step is to determine the

appropriate quantity of marihuana equivalent, using the Drug Equivalency Tables at Application Note 8(D). The final step is to use the Drug Quantity Table at §2D1.1(c) to determine the base offense level that corresponds to that amount of marihuana.

A preliminary review of Commission data regarding cases involving synthetic cathinones indicates that, in determining the most closely related controlled substance, courts recognize distinctions among types of synthetic cathinones. For example, in cases involving methylone, Commission data indicates that courts have almost always identified MDMA as the most closely related controlled substance to methylone, and have used either MDMA's marihuana equivalency of 500:1 or a reduced equivalency.

Issues for Comment.—

1. The Commission invites general comment on whether, and if so how, the guidelines for MDMA/Ecstasy trafficking should be changed. As stated above, the marihuana equivalency of MDMA is 1 gm of MDMA = 500 gm of marihuana. Is the marihuana equivalency for MDMA appropriate? Should the Commission establish a different equivalency for MDMA? If so, what equivalency should the Commission provide and on what basis?

   The Commission further seeks comment on any relevant developments in the scientific literature on the health effects of MDMA use since the Commission published its MDMA

Report and last amended the marihuana equivalency for MDMA in 2001. The Commission also seeks comment about whether there have been changes in MDMA distribution and usage patterns, such as marketing to or prevalence of use among youth, since 2001. For example, how is MDMA typically manufactured, distributed, and marketed today? How does MDMA compare to other controlled substances referenced in §2D1.1 in terms of health effects (including addictiveness and abuse potential), marketing and trafficking patterns, and potency by dosage unit? How should the Commission assess the harms of MDMA relative to those of other controlled substances?

Finally, the Commission seeks comment on whether since 2001 there have been any developments to suggest that the Commission, in addition to or instead of establishing a different equivalency for MDMA, should revise the "typical weight per unit" measure set forth in Application Note 9 to §2D1.1, which is currently set at 250 mg for MDMA. If so, what are those developments? How should the Commission revise the "typical weight per unit" measure set forth for MDMA?

2. As noted above, courts have typically identified MDMA as the most closely related controlled substance to methylone. Under the current guidelines, including Application Note 6 to §2D1.1, is this determination appropriate? If not, is there any controlled substance referenced in §2D1.1 that is most closely related to methylone? If so, what substance?

The Commission seeks comment on whether the Commission should provide a marihuana equivalency for methylone. If so, and MDMA is determined to be the most closely related controlled substance to methylone, should the Commission specify a marihuana equivalency for methylone at the same ratio as MDMA, regardless of whether the ratio for MDMA is changed from its current 500:1 level? Should the Commission establish a marihuana equivalency for methylone at a higher or lower ratio than the current MDMA equivalency? If so, what equivalency should the Commission provide and why? To the extent methylone has different characteristics than MDMA, how do those characteristics compare with other controlled substances referenced in §2D1.1 in terms of health effects (including addictiveness and abuse potential), marketing and trafficking patterns, and potency by dosage unit?

If the Commission were to establish a marihuana equivalency for methylone, which is often marketed and consumed in capsule form, should the Commission establish a "typical weight per unit" for methylone in Application Note 9 to §2D1.1?

3. The Commission seeks general comment on whether there are synthetic cathinones, other than methylone, that are substantially similar in their effects to MDMA. If so, what are those substances? How do those substances compare to MDMA in terms of health effects (including addictiveness and abuse potential), marketing and trafficking patterns, and potency by dosage unit? If the Commission were to include any such other synthetic cathinones in the Drug Equivalency Tables at Application Note 8(D) to §2D1.1, how

should the Commission establish marihuana equivalencies for these other synthetic cathinones in relation to one another and to the other controlled substances referenced in §2D1.1?

AUTHORITY: 28 U.S.C. § 994(a), (o), (p), (x); USSC Rules of Practice and Procedure 4.4.

William H. Pryor, Jr.,

Acting Chair

INDEX TO PUBLIC COMMENT RECEIVED ON SYNTHETIC DRUGS
Issue for Comment: MDMA/Ecstacy & Methylone
August 10, 2017

Submissions

U. S. Department of Justice
Drug Enforcement Administration
Diversion Control Division

www.dea.gov

August 3, 2017

The Honorable William H. Pryor, Jr.
Acting Chair
United States Sentencing Commission
One Columbus Circle, NE
Suite 2-500, South Lobby
Washington, D.C. 20002-8002

Dear Judge Pryor:

In June of 2017, the Commission published an issue for public comment on MDMA and methylone, as well as other synthetic cathinones.[1] Please see below for the Drug Enforcement Administration's responses on these issues. Thank you in advance for considering our thoughts.

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Issue 1

"The Commission invites general comment on whether, and if so how, the guidelines for MDMA/Ecstasy trafficking should be changed. As stated above, the marihuana equivalency of MDMA is 1 gm of MDMA = 500 gm of marihuana. Is the marihuana equivalency for MDMA appropriate? Should the Commission establish a different equivalency for MDMA? If so, what equivalency should the Commission provide and on what basis?
The Commission further seeks comment on any relevant developments in the scientific literature on the health effects of MDMA use since the Commission published its MDMA Report and last amended the marihuana equivalency for MDMA in 2001. The Commission also seeks comment about whether there have been changes in MDMA distribution and usage patterns, such as marketing to or prevalence of use among youth, since 2001. For example, how is MDMA typically manufactured, distributed, and marketed today? How does MDMA compare to other controlled substances referenced in §2D1.1 in terms of health effects (including addictiveness and abuse potential), marketing and trafficking patterns, and potency by dosage unit? How should the Commission assess the harms of MDMA relative to those of other controlled substances?
Finally, the Commission seeks comment on whether since 2001 there have been any developments to suggest that the Commission, in addition to or instead of establishing a different equivalency for MDMA, should revise the "typical weight per unit" measure set forth in Application Note 9 to §2D1.1, which is currently set at 250 mg for MDMA. If so, what are those developments? How should the Commission revise the "typical weight per unit" measure set forth for MDMA?"

Drug seizure data demonstrate that MDMA (3,4-methylenedioxymethamphetamine, often

1 UNITED STATES SENTENCING COMMISSION, SENTENCING GUIDELINES FOR UNITED STATES COURTS: REQUEST FOR PUBLIC COMMENT BAC 2210-40 (2017) https://www.ussc.gov/sites/default/files/pdf/amendment-process/federal-register-notices/20170622_fr_comment.pdf.

sold as "Ecstasy"), is still a popular drug of abuse and is still being encountered regularly by law enforcement. According to National Forensic Laboratory Information System (NFLIS), MDMA reports increased from 2003 through 2009 and steadily decreased from 2009 through the second half of 2013 before leveling off from 2014 to 2016 at 2,901 drug reports representing 0.36% total drug reports from State and local laboratories in the U.S.[2] The data (NFLIS reports) demonstrates that MDMA continues to be trafficked for its psychoactive effects.

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*.[3] MDMA is a powerful recreational drug of abuse resulting in toxic outcomes to serotonin neurons within the cortex and the hippocampus, amongst other areas.[4] The desired effects of MDMA have included increased energy, euphoria, and positive social and emotional feelings. However, accompanying these effects are a host of harms that 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).[5] 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.[6]

Scientific data continue to demonstrate that MDMA is a threat to public health and safety. Acute and long-term adverse health effects are documented for MDMA, a Schedule I controlled substance that has a high potential for abuse due to its pharmacological, hallucinogenic, and stimulant effects. While users of MDMA commonly experience intense euphoria while under the influence of the drug, its chronic usage depletes the neurotransmitters that contribute to these feelings. Neurotransmitter depletion can lead to adverse mental health effects such as depression, anxiety, panic, and psychosis—conditions common to other drugs that are susceptible to abuse. In response to the drug's activity, remodeling and degeneration of brain circuitry have been observed in animal and human studies. Consequently, MDMA users experience long lasting confusion, depression, and neurocognitive impairment. Thus, MDMA has the capacity to cause lasting physical harm to the user (neurological damage) and continues to be a threat to public health and safety.[7]

Current research shows that MDMA, even when taken in low doses, is neurotoxic.[8]

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2 NFLIS, 2016 MIDYEAR REPORT (US. Dept. of Justice, DEA (2016).

3 Commonly Abused Drugs Charts, https://www.drugabuse.gov/drugs-abuse/commonly-abused-drugs-charts#mdma-ecstasy-molly (last visited July 19, 2017).

4 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*, BRAIN 133: 1779-1797 (2010).

5 J Meyer, 3,4-Methylenedioxymethamphetmine (MDMA): current perspectives. SUBSTANCE ABUSE REHABILITATION 4: 83–99 (2013).

6 UD McCann et al., *Positron Emission Tomographic Evidence of Toxic Effect of MDMA ("Ecstasy") on Brain Serotonin Neurons in Human Beings*, LANCET 352: 1433-1437 (1998); RL Cowan, *Neuroimaging Research in Human MDMA Users: a Review*, PSYCHOPHARMACOLOGY 189: 539-556 (2007).

7 AC Parrott et al., *MDMA is Certainly Damaging after 25 Years of Empirical Research: a Reply and Refutation of Doblin*, HUMAN PSYCHOPHARMACOLOGY 29: 109-119 (2014).

8 AC Parrott et al., *MDMA (3,4-methylenedioxymethamphetamine) or ecstasy: the contemporary human and animal research perspective*, J PSYCHOPHARMACOL 143, 143-6 (2006).

Moreover, repeated findings have continued to confirm that MDMA serves as a catalyst for other neurological disorders such as serotonin syndrome and depression.[9] This is concerning given that Ecstasy tablets have notably increased in overall size and the amount of MDMA per tablet. There have also been reported increases in the clandestine manufacturing and trafficking of the substance.[10]

Despite the overwhelming amount of scientific data that underscores the dangers of MDMA, there continues to be a misplaced belief among users and traffickers that the drug is safe and benign, even amidst the many reports of victims suffering from severe acute toxicity and deaths.[11] In fact, MDMA is one of the most popular drugs bought online and on the "darknet," where transactions are intentionally hidden to evade detection.[12] It is misleading and dangerous to send the message to young people that MDMA is a benign drug in response to clinical trials; many other Schedule I controlled substances such as marijuana, psilocybin, and LSD have been or continue to be investigated in humans and have not been approved therapeutic agents. The particular example with MDMA is showcased by a first-hand experience of an individual who decided to use MDMA based upon its use in psychotherapy and showed memory deficits in a neurocognitive study ten years later.[13] In fact, one study found impaired memory and clinically significant levels of depression, impulsiveness, and sleep disturbance in a group of former and current ecstasy users.[14] Still nearly half of high school students surveyed (10th and 12th graders) continue to believe that "molly" (a slang term for a variety of synthetic cathinones including MDMA) is not harmful if they try it once or twice.[15]

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;[16] (2) significantly worse performance of male MDMA users on the tasks that correlate to cognitive flexibility and on the combined executive function task;[17] (3) reduced associative memory performance using fMRI;[18] (4) a significant decrement in

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9 R de la Torre et al. *Human pharmacology of MDMA: pharmacokinetics, metabolism, and Disposition*, THER DRUG MONIT 26: 137 (2004).

10 *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.

11 P Armenian et al., *Multiple MDMA (Ecstasy) Overdoses at a Rave Event: A Case Series*. J INTENSIVE CARE MED May 28 (2012).

12 Findings per DEA investigations.

13 AC Parrott. *MDMA is certainly damaging after 25 years of empirical research: a reply and refutation of Doblin et al.* HUMAN PSYCHOPHARMACOLOGY 29: 109-119 (2014).

14 L Taurah et al. *Depression, impulsiveness, sleep, and memory in past and present polydrug users of 3,4-methylenedioxymethamphetamine (MDMA,ecstasy)*. Psychopharmacology (Berl) Feb;231(4):737-51 (2014).

15 LD Johnston et al., *Monitoring the Future national survey results on drug use, 1975-2016: Overview, key findings on adolescent drug use*. Ann Arbor: Institute for Social Research, The University of Michigan.

16 K Leslie, et al., *Preliminary Evidence of Hippocampal Dysfunction in Adolescent MDMA ("Ecstasy") Users: Possible Relationship to Neurotoxic Effects*, PSYCHOPHARMACOLOGY (Berl) 383, 38390 (2004).

17 NA von Geusau et al., *Impaired Executive Function in Male MDMA ("ecstasy") Users*, PSYCHOPHARMACOLOGY 331, 331-41 (2004).

18 G Jager et al., *Assessment of Cognitive Brain Function in Ecstasy Users and Contributions of Other Drugs of Abuse: Results from an FMRI Study*, NEUROPSYCHOPHARMACOLOGY 33: 247-258 (2008).

verbal memory in the MDMA user as compared to control subjects;[19] and (5) cortex deficiencies during a word recognition task in MDMA users.[20] Lastly, a study 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 which persisted even after they were abstinent from MDMA use for two years prior to testing.[21]

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 who presented to an emergency room with MDMA toxicity, four who suffered permanent neurological, musculoskeletal and/or renal deficits and two who died, all directly resultant from MDMA ingestion.[22] Other overdose events with MDMA have been reported, some with tragic outcomes.[23]

Studies demonstrate that MDMA dependence is associated with intensity and lifetime use.[24] MDMA-associated overdoses commonly occur with polysubstance use; other drugs are possibly used to enhance the effects of MDMA. In the absence of national data for MDMA overdose deaths, the Florida Department of Law Enforcement publishes the *Drugs in Deceased Persons Report*. From 2006 to 2012, a total of 286 MDMA-related deaths were reported.[25] This remains especially concerning given that, as noted above, the amount of MDMA present in each individual pill has increased in recent years.[26]

In its 2001 Report to Congress, the Sentencing Commission identified 6 major factors that helped guide the decision to use the 500:1 ratio. Those were as follows:

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19 G Rogers et al., *The Harmful Health Effects of Recreational Ecstasy: a Systematic Review of Observational Evidence*, HEALTH TECH. ASSESSMENT 13.6 xii, iii-iv, ix-xii (2009).

20 AP Burgess et al., *Event Related Potential (ERP) Evidence for Selective Impairment of Verbal Recollection in Abstinent Recreational Methylenedioxymethamphetamine ("Ecstasy")/Polydrug Users*, PSYCHOPHARMACOLOGY 216: 545-556 (2011).

21 MJ Morgan et al., *Ecstasy (MDMA): Are the Psychological Problems Associated With Its Use Reversed By Prolonged Abstinence?* PSYCHOPHARMACOLOGY 159: 294-303 (2002).

22 P Armenian et al., *Multiple MDMA (Ecstasy) Overdoses at a Rave Event: A Case Series*, J. INTENSIVE CARE MED. 28: 252-258 (2012).

23 MORBIDITY AND MORTALITY WEEKLY REPORT, ECSTASY OVERDOSES AT A NEW YEAR'S EVE RAVE – LOS ANGELES, CA, 2010 677-681 (Center for Disease Control June 11, 2010); MORBIDITY AND MORTALITY WEEKLY REPORT, ILLNESS AND DEATHS AMONG PERSONS ATTENDING AN ELECTRONIC DANCE MUSIC FESTIVAL – NEW YORK CITY, 2013 1195-98 (Center for Disease Control Dec. 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 242, 242-248 (2004).

24 N Bruno and 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*, DRUG AND ALCOHOL DEPENDENCE 83: 221-235 (2006).

25 After 2012, FDLE changed its reporting so that MDMA was included in a category of hallucinogenic phenethylamines/piperizes and identified as a separate category.

26 EUROPEAN MONITORING CENTRE FOR DRUGS AND DRUG ADDICTION, RECENT CHANGES IN EUROPE'S MDMA.ECSTASY MARKET (EMCCDA Rapid communication, Publication Office of the E.U., Luxembourg, April 2016).

1. The rapidly growing incidence of abuse of the controlled substances
2. The threat to public safety that such abuse poses
3. The recent increase in the illegal importation of the controlled substances
4. The young age at which children are beginning to use the controlled substances
5. The fact that the controlled substances are frequently marketed to youth
6. The large number of doses per gram of the controlled substances.[27]

These factors considered by the Commission continue to hold true and have been further strengthened by studies demonstrating the harms associated with MDMA use, the aggressive marketing to youth, and the current importation and trafficking patterns. Continuous publications utilizing updated and more precise measurements repeatedly conclude that MDMA, even when taken in low doses, is neurotoxic.

For the reasons outlined above, the equivalency of 1 gm of MDMA = 500 gm of marijuana should be maintained in response to those traffickers preying on vulnerable populations, especially given our understanding of the drug's negative outcomes on the user.

The USSC was correct in its analysis in 2001, and information gained over the past 16 years has only substantiated that MDMA is harmful, neurotoxic, and potentially lethal to users. The illicit manufacture and distribution of this neurotoxic and potentially lethal substance deserves an appropriate penalty for the harms it is causing to users and society. To be sure, nothing has made the drug less dangerous than it was in 2001.

Issue 2

As noted above, courts have typically identified MDMA as the most closely related controlled substance to methylone. Under the current guidelines, including Application Note 6 to §2D1.1, is this determination appropriate? If not, is there any controlled substance referenced in §2D1.1 that is most closely related to methylone? If so, what substance?

The Commission seeks comment on whether the Commission should provide a marihuana equivalency for methylone. If so, and MDMA is determined to be the most closely related controlled substance to methylone, should the Commission specify a marihuana equivalency for methylone at the same ratio as MDMA, regardless of whether the ratio for MDMA is changed from its current 500:1 level? Should the Commission establish a marihuana equivalency for methylone at a higher or lower ratio than the current MDMA equivalency? If so, what equivalency should the Commission provide and why? To the extent methylone has different characteristics than MDMA, how do those characteristics compare with other controlled substances referenced in §2D1.1 in terms of health effects (including addictiveness and abuse potential), marketing and trafficking patterns, and potency by dosage unit?

If the Commission were to establish a marihuana equivalency for methylone, which is often marketed and consumed in capsule form, should the Commission establish a "typical weight per unit" for methylone in Application Note 9 to §2D1.1?

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27 UNITED STATES SENTENCING COMMISSION, MDMA DRUG OFFENSES: EXPLANATION OF RECENT GUIDELINE AMENDMENTS 3 (2001), https://www.ussc.gov/sites/default/files/pdf/news/congressional-testimony-and-reports/drug-topics/200105_RtC_MDMA_Drug_Offenses.pdf.

Methylone

In law enforcement investigations, it is not uncommon for tablets marketed as "molly" to be composed of synthetic cathinones such as methylone, a drug that shares similar pharmacological effects with MDMA and other substances of abuse such as cocaine. Important health-related issues have emerged in relation to the somatic, psychiatric, and addictive consequences of methylone use. According to the DEA's 2011 report that analyzed mephedrone, methylone, and MDPV and recommended temporary scheduling of these substances under Schedule I, these drugs were "the most commonly encountered synthetic cathinone. . . represent[ing] more than 98% (1,401 of 1,429) of the synthetic cathinones that have been encountered by law enforcement."[28] The report also observed that at the time of its publishing, the abuse of these drugs was growing, with poison control centers receiving 4,137 calls in forty-seven states and the District of Columbia relating to these three specific substances.[29] According to the DEA's 2016 special report (NFLIS, October 2016) on synthetic drugs, from January 2013 through December 2015, the 20 most frequently identified synthetic cathinones accounted for 51,824 drug reports from state and local forensic laboratories.[30] Among these reports, methylone, alpha-PVP, and ethylone accounted for 91% of the 51,824 drug reports. Whereas methylone decreased from 2013 to 2015 for all U.S. census regions, ethylone increased during the same period for all regions.[36]

By way of background, research in anti-depressant and anti-Parkinson agents resulted in the development and patenting of methylone in 1996.[31] However, there is no evidence that methylone has a legitimate non-research use. According to the Department of Health and Human Services (HHS), as of July 2017, 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, improved concentration, and improved focus.[32] The number of deaths associated with the use of this substance highlights the danger to the user

MDMA is considered to be the most closely related substance to methylone; however, the substance also shares similarities with cocaine and other stimulants. Many courts have reached the opinion that methylone is most similar to MDMA in applying §2D1.1 Note 6.[33] This reaffirms our

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28 DRUG ENFORCEMENT ADMINISTRATION, BACKGROUND, DATA AND ANALYSIS OF SYNTHETIC CATHINONES: MEPHEDRONE (4-MMC), METHYLONE (MDMC) AND 3,4-METHYLENEDIOXYPYROVALERONE (MDPV) 4 (Aug. 2011), www.regulations.gov/document?=DEA-2011-0008-0002. The report also notes that "Of all the reports, (1,429) of synthetic cathinones recorded by NFLIS from January 2009 to June 2011, 55% (791) were MDPV, 23% (331) were mephedrone, and 20% (279) were methylone."

29 *Id.* at 11.

30 NFLIS, SPECIAL REPORT: SYNTHETIC CANNABINOIDS AND SYNTHETIC CATHINONES REPORTED IN NFLIS, 2013-2015 (US DOJ DEA Diversion Control Division 2016), https://www.nflis.deadiversion.usdoj.gov/DesktopModules/ReportDownloads/Reports/NFLIS-SR-SynthCannabinoidCathinone.pdf..

31 P Jacob and A Shulgin, U.S. Patent No. WO 1996039122 (filed Jun. 6, 1996).

32 L Karila et al., *Synthetic Cathinones: A New Public Health Problem,13(1)* CURRENT NEUROPHARMACOLOGY 12, 12-20 (2015); L Karila et al., *The Effects and Risks Associated to Mephedrone and Methylone in Humans: A Review of the Preliminary Evidences*, 126 BRAIN RES BULL 61, 61-67(2016).

33 See e.g. *United States v. Arroyo*, 2:14-cr-186 (D. N.J.); *United States v. Borges*, 13-cr-20239 (S.D. FL.); *United States v. Flasey*, 12-cr-29 (M.D.FL.); *United States v. Guerrero*, 12-cr-390 (D.N.J.); *United States v. Marhsall*, 1:14-cr-00232 (N.D.N.Y.); *United States v. Martinez*, 13-cr-00316 (E.D.N.Y.)(comparing to MDMA); but see e.g. *United States*

belief that methylone should have the same marijuana equivalency as MDMA.

Scientific Evidence of the Substance's Pharmacological Effect

Methylone has many similarities with MDMA and other Schedule I substances. The clinical presentation of intoxication is similar to MDMA and other substances (*e.g.*, cathinone, methcathinone, MDMA, amphetamine, methamphetamine, and cocaine) that have a stimulant effect on the central nervous system.[34] 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.[35] Furthermore, methylone, like MDMA, has been associated with serotonin syndrome, a syndrome characterized by altered mental status, hyper-reflexia, and autonomic instability and possibly leading to death in extreme cases.[36]

A comprehensive review of the scientific literature suggests that methylone is as potent as MDMA in various animal studies that have investigated methylone's abuse potential. According to these studies (e.g., drug discrimination, self-administration, conditioned place preference, and locomotor activity studies) methylone, similar to MDMA, produces pharmacological effects that are similar to those substances that cause a stimulant effect on the central nervous system. The types of animal abuse-related behavioral pharmacology that may be important in an abuse potential assessment for a central nervous system (CNS)-active drug and that have been recommended by the Department of Health and Human Services (HHS) include drug discrimination, self-administrations, and conditioned place preference studies.[37] In addition, locomotor tests may provide relevant information about the behavioral similarities of a test drug relative to known drugs of abuse.

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v. Carrillo, 13-cr-0779 (C.D. CA); *United States v. Farmer*, 13-cr-20920 (E.D.MI.); *United States v Farrington*, 13-cr-129 (D.ME); *United States v. Letasi*, 13-cr-635 (D.N.J.); *United States v. Marte*, 13-cr-20537(S.D.FL.); *United States v. McLaughlin*, 13-cr-239 (N.D.N.Y.); *United States v. Merlin*, 13-cr-96 (D.NV.); *United States v. Murdough*, 12-cr-163 (D.N.H.); *United States v. Myers*, 13-cr-117 (D.N.H.); *United States v. Orton*, 12-cr-00017 (D.ME.); *United States v. Safari*, 12-cr-249 (E.D.VA.)(believed to be compared to MDMA but applying an interpretation of the guidelines resulting in a 1:250 ratio).

34 L Karila, et al., *Synthetic Cathinones: A New Public Health Problem*, CURRENT NEUROPHARMACOLOGY 13(1)12-20 (2015); L Karila et al., *The Effects and Risks Associated to Mephedrone and Methylone in Humans: A Review of the Preliminary Evidences*, BRAIN RES BULL 126: 61-67 (2016).

35 JM Pearson et al., *Three Fatal Intoxications Due to Methylone*, J. ANALYTICAL TOXICOLOGY 36: 444-451 (2012); B. Warrick et al., *Lethal Serotonin Syndrome After Methylone and Butylone Ingestion*, J. MED. TOXICOLOGY 8: 65-68 (2012); B. Cawrse et al., *Distribution of Methylone in Four Postmortem Cases*, J. ANALYTICAL TOXICOLOGY 36: 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)*, J. MED. TOXICOLOGY 8: 69-75 (2012); K. Kesha et al., *Methylenedioxypyrovalerone ("Bath Salts"), Related Death: Case Report And Review Of The Literature*, J. FORENSIC SCI. 58: 1654-1659 (2013).

36 R de la Torre, et al., *Human pharmacology of MDMA: pharmacokinetics, metabolism, and disposition*. THER DRUG MONIT. Apr;26(2):137-44. Review (2004); Warrick BJ et al. *Lethal serotonin syndrome after methylone and butylone ingestion*. JOURNAL OF MEDICAL TOXICOLOGY: OFFICIAL JOURNAL OF THE AMERICAN COLLEGE OF MEDICAL TOXICOLOGY 8:65-68 (2012).

37 HHS, U.S. Department of Health and Human Services (HHS), *Assessment of abuse potential of drugs Guidance for industry*. January 2017 available at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

The drug discrimination study in animals is a commonly used method to assess the abuse potential of test drugs or substances. This method can be used to predict subjective effects of substances in humans.[38] This is because 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. 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.[39] Data from a separate published drug discrimination study found that methylone (ED_{50} = 2.66 mg/kg) fully substitutes for the discriminative stimulus effects produced by methamphetamine.[40] MDMA, also tested by these authors, fully substitutes for the discriminative stimulus effects produced by methamphetamine with an ED_{50} of 1.83 mg/kg.[41] In rodents trained to discriminate cocaine from saline, methylone substitutes for cocaine with ED_{50} values 1.47 and 3.09 mg/kg, respectively. This is highly relevant, the animal perceives the effects of methylone to be similar to the training drug cocaine. Drug discrimination studies are accepted as the gold standard in studying abuse-related effects of psychoactive drugs.[42] Thus, in drug discrimination studies, methylone is slightly less potent than MDMA in MDMA-trained animals, but slightly more potent than cocaine in cocaine-trained animals.

Another study used to assess the abuse potential or reinforcing effects of novel drugs is the self-administration study. In drug self-administration studies, drugs that have rewarding properties in animals will likely increase the behavioral responses of animals to obtain additional drugs.[43] Furthermore, drugs that have rewarding effects in animals are likely to produce rewarding (*i.e.*, reinforcing) effects in humans, which is indicative of abuse potential.[44] In self-administration studies, methylone, like MDMA, was self-administered by rodents.[45] The conclusion from these

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38 RL Balster and GE Bigelow. *Guidelines and methodological reviews concerning drug abuse liability assessment.* DRUG AND ALCOHOL DEPENDENCE, 70: S13-40 (2003); Panlilio LV, Goldberg SR. *Self-administration of drugs in animals and humans as a model and an investigative tool.* ADDICTION, 102: 1863-1870 (2007); Kamien JB, et al. *Drug discrimination by humans compared to nonhumans: current status and future directions.* PSYCHOPHARMACOLOGY, 111: 259-270 (1993).

39 T Dal Cason et al., *Cathinone: An investigation of several N-alkyl and methylenedioxy-substituted analogs.* PHARMACOLOGY BIOCHEMISTRY AND BEHAVIOR, 58: 1109-1116 (1997).

40 MB Gatch , CM Taylor, MJ Forster. *Locomotor stimulant and discriminative stimulus effects of 'bath salt' cathinones.* BEHAVIOURAL PHARMACOLOGY, 24: 437-447 (2013).

41 NIDA, National Institute on Drug Abuse, email communication, (2012).

42 CR Schuster and CE Johanson, *Relationship between the discriminative stimulus properties and subjective effects of drugs.* PSYCHOPHARMACOLOGY 161-175 (1988); M Solinas et al., *Using drug-discrimination techniques to study the abuse-related effects of psychoactive drugs in rats.* NATURE PROTOCOLS 1(3): 1194-1206 (2006); LP Carter and RR Griffiths. *Principles of laboratory assessment of drug abuse liability and implications for clinical development.* DRUG ALCOHOL DEPEND S14-S25 (2009).

43 RL Balster and GE Bigelow. *Guidelines and methodological reviews concerning drug abuse liability assessment.* DRUG AND ALCOHOL DEPENDENCE, 70: S13-40 (2003); LV Panlilio and SR Goldberg. *Self-administration of drugs in animals and humans as a model and an investigative tool.* ADDICTION, 102: 1863-1870 (2007).

44 HHS, Department of Health and Human Services. *Basis for the recommendation to place 3,4-methylenedioxymethcathinone (methylone) and its salts in Schedule I of the Controlled Substances Act (CSA).* Dated August 14 (2012).

45 KM Creehan et al., Intravenous self-administration of mephedrone, methylone and MDMA in female rats. Neuropharmacology, 92: 90-97 (2015); LR Watterson et al. *The Reinforcing and Rewarding Effects of Methylone, a*

studies was that methylone may possess an addiction potential similar to or greater than MDMA.

The conditioned place preference (CPP) paradigm is yet another preclinical animal behavioral model used to study the reinforcing effects (rewarding or aversive) of drugs.[46] CPP tests are able to detect addictive substances. Psychostimulants, such as amphetamine and cocaine, often produce a robust CPP. In the conditioned place preference test, mice treated with of methylone (intraperitoneal doses of 2.5 and 5.0 mg/kg) developed CPP confirming that methylone, like methamphetamine, has a rewarding effect.[47]

Stimulant effects can be assessed in locomotor activity studies (i.e., studies of enhanced physical performance). Several studies show that methylone, like methamphetamine and cocaine, is a CNS stimulant.[48] In locomotor activity studies, methylone treatment resulted in time- and dose-dependent stimulation of locomotor activity in doses from 3 to 30 mg/kg. The stimulant effects of methylone (3 and 10 mg/kg) occurred within 10 minutes following injection and lasted 60 to 120 minutes. Based on the 30-minute time period in which maximal stimulant effects occurred (0 to 30 minutes following injection), an ED_{50} of 1.5 mg/kg was calculated. The maximal stimulant effect of methylone was 87% of the maximal stimulant effect of methamphetamine and 82% that of cocaine. In comparison, treatment with methamphetamine resulted in time- and dose-dependent stimulation of locomotor activity following 0.5 to 4 mg/kg with stimulant effects occurring within 10 minutes following injection and lasting 130 to 310 minutes. The ED_{50} of methamphetamine was estimated at 0.48 mg/kg. Treatment with cocaine resulted in time- and dose- dependent stimulation of locomotor activity following 10 to 40 mg/kg with stimulant effects of 10 and 20 mg/kg occurring within 10 minutes following injection and lasting 120 to 170 minutes. The ED_{50} of cocaine was estimated at 7.2 mg/kg. In a similar study investigating the effects of methylone and other synthetic cathinones on locomotor activity, subcutaneous administration of methylone (5 – 25 mg/kg), like MDMA (5 mg/kg), dose-dependently increased locomotor activity in mice.[49] In yet another study, mice that have been given methylone by oral administration, methylone (5 - 100 mg/kg), like MDMA and methamphetamine, significantly increased locomotor activity.[50] The maximum increase in locomotor activity for methylone occurred at 50 mg/kg. In comparing the effects of the methylone, MDMA, and methylone administered to mice at equivalent doses of 0.205 mmol/kg (which is equivalent to 50 mg/kg methylone) on locomotor activity, methylone increased locomotor activity

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Synthetic Cathinone Commonly Found in "Bath Salts" ADDICTION RESEARCH & THERAPY S9:002. doi:10.4172/2155-6105.S9-002 (2012).

46 I Stolerman. Drugs of abuse: behavioral principles, methods and terms. Trends in Pharmacological Sciences, 13: 170-176 (1992); JA Prus et al., *Conditioned Place Preference*. In: Buccafusco JJ, editor. METHODS OF BEHAVIOR ANALYSIS IN NEUROSCIENCE. 2nd edition. Boca Raton (FL): CRC Press; Chapter 4. Available from: http://www.ncbi.nlm.nih.gov/books/NBK5229/ (2009).

47 M Miyazawa et al., *Behavioral and rewarding effects of methylone, an analog of MDMA in mice*. HIROSAKE MEDICAL JOURNAL, 62: 56-71 (2011).

48 MH Baumann et al., *The designer methcathinone analogs, mephedrone and methylone, are substrates for monoamine transporters in brain tissue*. NEUROPSYCHOPHARMACOLOGY. 37: 1192-1203 (2011); M Miyazawa, et al., *Behavioral and rewarding effects of methylone, an analog of MDMA in mice*. HIROSAKE MEDICAL JOURNAL, 62: 56-71 (2011); R Lopez-Arnau et al., *Comparative Neuropharmacology Of Three Psychostimulant Cathinone Derivatives: Butylone, Mephedrone and Methylone*. BRIT J PHARMACOLOGY 167: 407-420 (2012).

49 R Lopez-Arnau et al., *Comparative Neuropharmacology Of Three Psychostimulant Cathinone Derivatives: Butylone, Mephedrone and Methylone*. BRIT. J. PHARMACOLOGY 167: 407-420 (2012).

50 M Miyazawa et al. *Behavioral and rewarding effects of methylone, an analog of MDMA in mice*. HIROSAKE MEDICAL JOURNAL, 62: 56-71 (2011).

more than methamphetamine or MDMA. Thus, in locomotor activity studies, methylone, compared to MDMA, induced locomotor activity but to a greater degree.

The above mentioned data indicate that methylone produces pharmacological effects that are similar to those produced by Schedule I and II substances methamphetamine, cocaine, and MDMA. Methylone, like methamphetamine, amphetamine, and cocaine, is a CNS stimulant and produces locomotor stimulant effects in mice.[51] Methylone substitutes for MDMA, cocaine, or amphetamine in rats trained to discriminate MDMA, cocaine, or amphetamine from saline, respectively.[52] Methylone, like methamphetamine, produced rewarding effects as studied in CPP tests.[53] Based on the results of preclinical studies, HHS postulates that in humans, methylone is likely to produce pharmacological effects similar to those produced by amphetamine, methamphetamine, cocaine, and MDMA.[54] Although some animal abuse-related behavioral pharmacology studies show methylone to be less potent than MDMA, others show methylone to be as potent or more potent than MDMA. So collectively, given the variations in these animal studies, it is reasonable to conclude that in humans it is expected that methylone will be at least as potent as MDMA.

The Substance's History and Current Pattern of Abuse

The DEA's forensic laboratories have analyzed drug exhibits received from state, local, and 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 indicates that the most common methods of administering methylone are by swallowing capsules or tablets and by snorting the powder. The reported average amount of use reported for methylone ranged from 100 mg to 250 mg.[55] In contrast, the average amount of MDMA used ranged from 75 mg to 125 mg.[56] Evidence from poison centers, published case reports, and law enforcement encounters suggest that the main users of methylone are young adults.[57] 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

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51 MH Baumann et al. *The designer methcathinone analogs, mephedrone and methylone, are substrates for monoamine transporters in brain tissue*. NEUROPSYCHOPHARMACOLOGY. 37: 1192-1203 (2011); M Miyazawa, T Kojima, S Nakaji. *Behavioral and rewarding effects of methylone, an analog of MDMA in mice*. HIROSAKE MEDICAL JOURNAL 62: 56-71 (2011); R Lopez-Arnau et al., *Comparative Neuropharmacology of Three Psychostimulant Cathinone Derivatives: Butylone, Mephedrone and Methylone*. BRIT. J. PHARMACOLOGY 407:407-420 (2012).

52 T Dal Cason et al., *Cathinone: An investigation of several N-alkyl and methylenedioxy-substituted analogs*. PHARMACOLOGY BIOCHEMISTRY AND BEHAVIOR, 58: 1109-1116 (1997); Gatch MB, et al. *Locomotor stimulant and discriminative stimulus effects of 'bath salt' cathinones*. BEHAVIOURAL PHARMACOLOGY, 24: 437-447 (2013).

53 M Miyazawa et al. *Behavioral and rewarding effects of methylone, an analog of MDMA in mice*. HIROSAKE MEDICAL JOURNAL, 62: 56-71 (2011).

54 HHS 8-factor review and scheduling recommendation for methylone, available at https://www.regulations.gov/document?D=DEA-2012-0006-0002 (2014).

55 JP Kelly et al., *Cathinone Derivatives: a Review of Their Chemistry, Pharmacology, Toxicology*, DRUG TESTING AND ANALYSIS 3: 439-453 (2011).

56 J Cami et al., *Human Pharmacology of 3,4-Methylenedioxymethamphetamine ("Ecstasy"): Psychomotor, Performance and Subjective Effects*, J. CLINICAL PSYCHOPHARMACOLOGY 20: 455-466 (2000); AC Parrott, *Human Psychobiology of MDMA or 'Ecstasy': an Overview of 25 Years of Empirical research*, HUMAN PSYCHOPHARMACOLOGY 28: 289-307 (2013).

57 DRUG ENFORCEMENT ADMINISTRATION, BACKGROUND, DATA AND ANALYSIS OF SYNTHETIC CATHINONES: MEPHEDRONE (4-MMC), METHYLONE (MDMC) AND 3,4-METHYLENEDIOXYPYROVALERONE (MDPV) (Aug. 2011), www.regulations.gov/document?=DEA-2011-0008-0002.

were sold as MDMA (marketed as "Molly") were found by the DEA to contain methylone.[58]

Equivalency for Methylone: Methylone as Comparable to MDMA

Regarding the methylone equivalency, the DEA proposes that the Commission compare Methylone to MDMA. Based on the evidence that methylone has similarities with MDMA regarding its pharmacological and toxic potential.[59] the DEA recommends that the marijuana equivalency for methylone be the same as for MDMA (1:500 marijuana). If the Commission should consider an equivalency greater than 1:500 based upon the established abuse liability and similarities with additional drugs of abuse, the DEA would be in full support.

Issue 3

The Commission seeks general comment on whether there are synthetic cathinones, other than methylone, that are substantially similar in their effects to MDMA. If so, what are those substances? How do those substances compare to MDMA in terms of health effects (including addictiveness and abuse potential), marketing and trafficking patterns, and potency by dosage unit? If the Commission were to include any such other synthetic cathinones in the Drug Equivalency Tables at Application Note 8(D) to §2D1.1, how should the Commission establish marihuana equivalencies for these other synthetic cathinones in relation to one another and to the other controlled substances referenced in §2D1.1?

Last year the DEA and the Department of Justice requested the Commission to create equivalencies in the guidelines for both *Mephedrone* and *MDPV*.[60] The DEA renews that request.

Synthetic Cathinones

Methylone, mephedrone, and MDPV are synthetic cathinones that have many similarities to other Schedule I substances such as cathinone, methcathinone, and MDMA. 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.[61] 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.[62]

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58 *Id.* at 34.

59 DRUG ENFORCEMENT ADMINISTRATION, SCHEDULE OF CONTROLLED SUBSTANCE: PLACEMENT OF 3,4-METHYLENEDIOXY-N-METHYLCATHINONE (METHYLONE) INTO SCHEDULE I: BACKGROUND, DATA, AND ANALYSIS: EIGHT FACTORS DETERMINATIVE OF CONTROL AND FINDINGS PURSUANT TO 21 U.S.C. 812(B) (2012).

60 *See* JONATHAN WROBLEWSKI, DIRECTOR, OFFICE OF POLICY AND LEGISLATION, CRIMINAL DIVISION, DEP'T OF JUSTICE, ANNUAL LETTER TO PATTI B. SARIS, CHAIR, U.S. SENTENCING COMM'N.(2014), http://www.ussc.gov/sites/default/files/pdf/amendment-process/public-comment/20140729/DOJ.pdf).

61 JM Prosser and LS Nelson, *The Toxicology of Bath Salts: A Review of Synthetic Cathinones*, J. MEDICAL TOXICOLOGY 8: 33-42 (2012).

62 JM Pearson et al., *Three Fatal Intoxications Due to Methylone*, J. ANALYTICAL TOXICOLOGY 36: 444-451 (2012); B. Warrick et al., *Lethal Serotonin Syndrome After Methylone and Butylone Ingestion*, J. MED. TOXICOLOGY 8: 65-68 (2012); B. Cawrse et al., *Distribution of Methylone in Four Postmortem Cases*, J ANALYTICAL TOXICOLOGY 36 :434-439 (2012); J Wyman et al., *Postmortem Tissue Distribution of MDPV Following Lethal Intoxication by "Bath Salts,"* J ANALYTICAL TOXICOLOGY 37: 182-185 (2013); B Murray et al., *Death Following Recreational Use Of Designer Drug*

The DEA has encountered these synthetic cathinones being trafficked for their psychoactive properties with no regard for the user's safety. These substances are falsely marketed as "research chemicals," "plant food or fertilizer," "jewelry cleaner," "stain remover," "insect repellant," or "bath salts" to evade detection. 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 were promoted as "legal" alternatives to cocaine, methamphetamine, and MDMA, because at the time, detection of these substances was not included in the routine drug screen for illicit substances.

On October 21, 2011, the DEA Administrator 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 posed an imminent threat to public safety.[63] The Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144) (FDASIA) 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.

The Public Health Concerns of MDPV and Mephedrone

Adverse health effects associated with the consumption of 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.[64] Excited delirium, a condition characterized by agitation, aggression, acute distress and sudden death,[65] is also associated with MDPV.

The DEA remains concerned about these psychoactive substances because of their composition of highly dangerous substances that elicit serious and even lethal outcomes. This danger, coupled with easy access, has made them responsible for a large number of hospital emergency department admissions and Medical Examiner reports.[66]

Why Equivalencies are Necessary for These Specific Synthetics

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"Bath Salts" Containing 3,4-Methylenedioxypyrovalerone (MDPV), J MED TOXICOLOGY 8: 69-75 (2012); K Kesha et al., *Methylenedioxypyrovalerone ("Bath Salts"), Related Death: Case Report And Review Of The Literature*, J FORENSIC SCI 58: 1654-1659 (2013).

63 76 Fed. Reg. 65371 (Oct. 21, 2011).

64 JM Pearson et al., *Three Fatal Intoxications Due to Methylone*, J. ANALYTICAL TOXICOLOGY 36:444-451 (2012); B Warrick et al., *Lethal Serotonin Syndrome After Methylone And Butylone Ingestion*, J. MED. TOXICOLOGY8:65-68 (2012); B Cawtse et al., *Distribution of Methylone in Four Postmortem Cases*, J. OF ANALYTICAL TOXICOLOGY, 36:434-439 (2012); J Wyman et al., *Postmortem Tissue Distribution of MDPV Following Lethal Intoxication by "Bath Salts,"* J. OF ANALYTICAL TOXICOLOGY 37: 182-185 (2013); B. Murray et. al., *Death Following Recreational Use Of Designer Drug "Bath Salts" Containing 3,4-Methylenedioxypyrovalerone (MDPV)*, J MED. TOXICOLOGY , 8:69-75 (2012); K Kesha et al., *Methylenedioxypyrovalerone ("Bath Salts"), Related Death: Case Report And Review Of The Literature*, J OF FORENSIC SCI 58: 1654-1659 (2013).

65 A Takeuchi et al., *Excited Delirium*, WEST J EMERG. MED 12(1):77-83 (2011).

66 *Deadly Synthetic Drugs: The Need to Stay Ahead of the Poison Peddlers Before the Sen. Comm. On the Judiciary*, 114th Cong. 2 (2016) [hereinafter *Deadly Synthetic Drugs*] (testimony of Dr. Douglass Throckmorton, Deputy Director for Regulatory Programs, Center for Drug Evaluation and Research, Food and Drug Administration NY).

As described below, Mephedrone and Methylone are similar to MDMA and the Commission should use the same marijuana equivalencies for these as MDMA. As explained in Dr. Boos' statement for the March 2017 hearing before the Commission, MDPV is especially comparable to methamphetamine based on the numerous pharmacological studies published in the scientific literature. These studies use accepted methodologies and have been conducted by the leaders in the field of drug abuse research.

According to the DEA's 2011 report analyzing mephedrone, methylone, and MDPV and recommending temporary scheduling under schedule I, these drugs were "the most commonly encountered synthetic cathinone. . . represent[ing] more than 98% (1,401 of 1,429) of the synthetic cathinones that have been encountered by law enforcement."[67] The report also observed that at the time of its publishing, the abuse of these drugs was growing, with poison control centers receiving 4,137 calls in forty-seven states and the District of Columbia relating to these three specific products.[68]

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.[69] There is no evidence that 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.[70]

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. This data 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.[71] 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

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67 DRUG ENFORCEMENT ADMINISTRATION, BACKGROUND, DATA AND ANALYSIS OF SYNTHETIC CATHINONES: MEPHEDRONE (4-MMC), METHYLONE (MDMC) AND 3,4-METHYLENEDIOXYPYROVALERONE (MDPV) 4 (Aug. 2011), www.regulations.gov/document?=DEA-2011-0008-0002. The report also notes that "Of all the reports, (1,429) of synthetic cathinones recorded by NFLIS from January 2009 to June 2011, 55% (791) were MDPV, 23% (331) were mephedrone, and 20% (279) were methylone."

68 *Id.* at 11.

69 L Karila et al., *The Effects and Risks Associated to Mephedrone and Methylone in Humans: A Review of the Preliminary Evidences*, BRAIN RES BULL. 126: 61-67 (2016).

70 L Karila et al., *Synthetic Cathinones: A New Public Health Problem.,13(1)* CURRENT NEUROPHARMACOLOGY 12, 12-20 (2015).

71 College on Problems of Drug Dependence (CPDD) 77th Annual Scientific Meeting, Arizona Biltmore, Phoenix, Arizona, June 13-18, 2015.

and VESSPA questionnaire).[72] Based on the above study, mephedrone has a stimulant effect that is similar to MDMA but less potent. However, these conclusions are made with limitations since there were few participants 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.[73] 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.[74] 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.[75] In an additional study that claims MDMA-like drugs can be discerned from methamphetamine-like drugs by measuring a specific locomotor activity (voluntary wheel activity), mephedrone is more similar to MDMA than to MDPV or methamphetamine.[76]

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.[77] Data from a published drug

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72 *Id.*

73 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).

74 MH Baumann et al., *The Designer Methcathinone Analogs, Mephedrone and Methylone, are Substrates for Monoamine Transporters*, 37 NEUROPSYCHOPHARMACOLOGY 1192, 1192-1203 (2012).

75 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).

76 P-K Huang et al., *Contrasting Effects of d-Methamphetamine,3,4-Methylenedioxymethamphetamine, 3,4-Methylenedioxypyrovalerone, and 4-Methylmethcathinone on Wheel Activity in Rats*, DRUG AND ALCOHOL DEPENDENCE 126: 168-175 (2012).

77 JB Kamien et al., *Drug Discrimination by Humans Compared to Nonhumans: Current Status and Future Directions*, PSYCHOPHARMACOLOGY 11(3): 259-270 (1993); RL Balster & GE Bigelow, *Guidelines and Methodological Reviews Concerning Drug Abuse Liability Assessment*, DRUG AND ALCOHOL DEPENDENCE 70(3):S13-S40 (2003); LV Panlilio & SR Goldberg, *Self-Administration of Drugs in Animal and Humans as a Model and an Investigative Tool*, ADDICTION 102(12): 1863-1870 (2007).

discrimination study indicate that MDMA fully substitutes for the discriminative stimulus effects produced by mephedrone (ED_{50}=0.90 mg/kg) in rats.[78] 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.[79] 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.[80] It has also been reported that mephedrone is used in binges; in other words, the user has a strong desire to re-dose the drug. The desire to re-dose is similar to other reinforcing drugs of abuse. Abusers have reported that typical sessions using mephedrone last approximately 10.4 hours with some individuals administering several times throughout a session.[81] A possible reason for binging may be to prolong the duration of effects. In comparison, the average amount of MDMA used ranged from 75 mg to 125 mg (oral administration).[82] 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.[83]

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.[84] 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.[85] Participants in a survey of

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78 KJ Varner et al., *Comparison of the Behavioral and Cardiovascular Effects of Mephedrone with Other Drugs of Abuse in Rats*, PSYCHOPHARMACOLOGY 225(3):675-685 (2013).

79 JP Kelly et al., *Cathinone Derivatives: a Review of Their Chemistry, Pharmacology, Toxicology*, DRUG TESTING AND ANALYSIS 3: 439-453 (2011).

80 JP Kelly et al., *Cathinone Derivatives: a Review of Their Chemistry, Pharmacology, Toxicology*, DRUG TESTING AND ANALYSIS 3: 439-453 (2011).

81 Schifano et al., *Mephedrone (4-methylmethcathinone: 'meow meow'): chemical, pharmacological and clinical issues.* PSYCHOPHARMACOLOGY(Berl) 214(3):593-602 (2011).

82 AC Parrott, *Human Psychobiology of MDMA or 'Ecstasy': an Overview of 25 Years of Empirical Research*, HUMAN PSYCHOPHARMACOLOGY 28: 289-307 (2013).

83 DEA 3-Factor Analysis Mephedrone, Methylone, and MDPV, October 2011

84 H Uosukainen et al., *Self-reported prevalence of dependence of MDMA compared to cocaine, mephedrone and ketamine among a sample of recreational poly-drug users.* INT J DRUG POLICY 26(1):78-83(2015); M Kapitany-Foveny et al, *Is there any difference in patterns of use and psychiatric symptom status between injectors and non-injectors of mephedrone?* HUM PSYCHOPHARMACOL 30(4): 233-43(2015);

85 76 Fed. Reg. 65371 (Oct. 21, 2011).

readers of a popular UK dance music magazine reported that mephedrone gave a better high than cocaine.[86] 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.[87] 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; while, other products were found to contain mephedrone. The unsuspecting user is at the mercy of the trafficker distributing these dangerous drugs.

Methylenedioxypyrovalerone (MDPV)

Methylenedioxypyrovalerone (MDPV) is closely related in structure and pharmacological effect to the phenethylamines such as the Schedule I and II substances methamphetamine, cathinone, methcathinone, and methylenedioxymethamphetamine (MDMA).[88] MDPV is also structurally related to pyrovalerone, which is a psychoactive drug that was used to treat chronic lethargy and fatigue and at one time was an approved treatment agent.[89] In our assessment, 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.[90]

Scientific Evidence of the Drug's Pharmacological Effects

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.[91] In addition, MDPV is a powerful locomotor stimulant like methamphetamine.[92] As described in the literature, MDPV is at least 10 times more potent than

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86 A Winstock et al., *Mephedrone, new kid for the chop?* ADDICTION 106(1):154-61 (2011).

87 RL Carhart-Harris et al., *A web-based survey on mephedrone* DRUG AND ALCOHOL DEPENDENCE 118: 19-22.

88 CL German, et al., *Bath salts and synthetic cathinones: An emerging designer drug phenomenon*, LIFE SCI. 97:, 2-8 (2014); LJ De Felice, et al., *Synthetic cathinones: Chemical phylogeny, physiology, and neuropharmacology*, LIFE SCI 97: 20-6 (2014).

89 S Strano-Rossi,et al., *Toxicological determination and in vitro metabolism of the designer drug methylenedioxypyrovalerone (MDPV) by gas chromatography/mass spectrometry and liquid chromatography/quadrupole time-of-flight mass spectrometry: Rapid communications in mass spectrometry*, RCM 24: 2706-2714 (2010).

90 JM Prosser and LS Nelson, *The Toxicology of Bath Salts: A Review of Synthetic Cathinones*, J. MEDICAL TOXICOLOGY 8: 33-42 (2012).

91 P-K Huang et al., *Contrasting Effects of d-Methamphetamine,3,4-Methylenedioxymethamphetamine, 3,4-Methylenedioxypyrovalerone, and 4-Methylmethcathinone on Wheel Activity in Rats*, DRUG AND ALCOHOL DEPENDENCE 126(1): 168-175 (2012).

92 MH Baumann et al., *Powerful Cocaine-like Actions of 3,4-Methylenedioxypyrovalerone (MDPV), a Principal Constituent of Psychoactive 'Bath Salt' Products*, NEUROPSYCHOPHARMACOLOGY 38(4):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*, NEUROPSYCHOPHARMACOLOGY 38(4): 563-573

cocaine in locomotor studies.[93]

Drug discrimination studies indicate that MDPV produces pharmacological effects that are similar to those of methamphetamine and cocaine.[94] 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.[95] 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.[96] 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.[97] 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. In studies of MDPV self-administered in rats, rats were observed to self-administer a greater and greater amount of MDPV. As a result, the authors of these studies concluded that MDPV poses a substantial threat for compulsive use that is potentially greater than that for methamphetamine.[98]

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

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(2013); M Gatch et al., *Locomotor Stimulant and Discriminative Stimulus Effects of 'Bath Salt' Cathinones*, BEHAVIORAL PHARMACOLOGY 24: 437-447 (2013); JA Marusich et al., *Pharmacology of Novel Synthetic Stimulants Structurally Related to "Bath Salts" Constituents 3,4-Methylenedioxypyrovalerone (MDPV)*, NEUROPHARMACOLOGY 87:206-213 (2014).

93 M Baumann, et al., *Powerful cocaine-like actions of 3,4-methylenedioxypyrovalerone (MDPV), a principal constituent of psychoactive 'bath salts' products*. NEUROPSYCHOPHARMACOLOGY, *38*;552-562,(**2013).**

94 M Gatch et al., *Locomotor Stimulant and Discriminative Stimulus Effects of 'Bath Salt' Cathinones*, BEHAVIORAL PHARMACOLOGY 24: 437-447 (2013).

95 RI Balster and GE Bigelow, *Guidelines and Methodological Reviews Concerning Drug Abuse Liability Assessment*, DRUG AND ALCOHOL DEPENDENCE 13, 13-40 (2003); LV Panllio & SR Goldberg, *Self-Administration of Drugs in Animals and Humans as a Model and an Investigative Tool*, ADDICTION 102(12) 1863-1870 (2007).

96 M Gatch et al., *Locomotor Stimulant and Discriminative Stimulus Effects of 'Bath Salt' Cathinones*, BEHAVIORAL PHARMACOLOGY 24:437-447 (2013).

97 WE Fantegrossi et al., *In Vivo Effects of Abused 'Bath Salt' Constituent 3,4-Methylenedioxypyrovalerone (MDPV) in Mice: Drug Discrimination, Thermoregulation, and Locomotor Activity*, NEUROPSYCHOPHARMACOLOGY 38(4):563-573 (2013).

98 SM Aarde et al., *The Novel Recreational Drug 3,4-Methylenedioxypyrovalerone (MDPV) is a Potent Psychomotor Stimulant: Self-administration and Locomotor Activity in Rats*, NEUROPSYCHOPHARMACOLOGY 71: 130-140 (2013); M Gatch et al., *Locomotor Stimulant and Discriminative Stimulus Effects of 'Bath Salt' Cathinones*, BEHAVIORAL PHARMACOLOGY 24:437-447 (2013); JA Marusich et al., *Pharmacology of Novel Synthetic Stimulants Structurally Related to "Bath Salts" Constituents 3,4-Methylenedioxypyrovalerone (MDPV)*, NEUROPHARMACOLOGY 87: 206-213 (2014).

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 – 2 grams) depending on the substance, duration of intake, and method of administration.[99] 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.[100] 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, Customs and Border Protection (CBP) reports large seizures of MDPV.[101]

Risk to Public Health

MDPV has been reported to cause a number of stimulant-like adverse health effects.[102] 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.[103] 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.[104] Published case reports describing MDPV related adverse effects are summarized below.

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99 P Deluca et al., Psychonaut WebMapping Research Group. 2010. MDPV report, Institute of Psychiatry, King's College London: London, UK; IVERSON, ADVISORY COUNCIL ON THE MISUSE OF DRUGS, CONSIDERATION OF THE CATHINONES, (Mar. 31, 2010).

100 CC Cruickshank and KR Dyer, *A Review of the Clinical Pharmacology of Methamphetamine*, ADDICTION 104(7):1085-1099 (2009).

101 Communications to DEA.

102 GT Collins et al., *Discriminative Stimulus Effects of Binary Drug Mixtures: Studies with Cocaine, MDPV, and Caffeine*. J PHARMACOL EXP THER 359(1):1-10 (2016); LR Watterson et al., *Sensitization to the motor stimulant effects of 3,4-methylenedioxypyrovalerone (MDPV) and cross-sensitization to methamphetamine in rats*. J DRUG ALCOHOL RES 1-21 (2016); P-K Huang et al., *Contrasting effects of d-methamphetamine, 3,4-methylenedioxymethamphetamine, 3,4-methylenedioxypyrovalerone, and 4-methylmethcathinone on wheel activity in rats*, DRUG AND ALCOHOL DEPENDENCE 168, 168-175 (2012).

103 Glennon RA, *Bath salts, mephedrone, and methylenedioxypyrovalerone as emerging illicit drugs that will need targeted therapeutic intervention*. ADV PHARMACOL 69:581-620 (2014); LM Colon-Perez et al.,*The Psychoactive Designer Drug and Bath Salt Constituent MDPV Causes Widespread Disruption of Brain Functional Connectivity*. NEUROPSYCHOPHARMACOLOGY 41(9):2352-2365(2016).

104 Froberg et al., *Acute Methylenedioxypyrovalerone Toxicity*. J MED TOXICOL 11(2): 185-194; Ross et al., *Psychoactive "bath salts" intoxication with methylenedioxypyrovalerone*. AM J MED 125(9): 854-8.

Regarding MDPV, the DEA recommends that the Commission begin with the marijuana equivalency currently used for methcathinone which has a marijuana equivalency ratio of 1:380, but then impose a ratio for MDPV that is based upon the currently available scientific information and harms to the public, which are more similar to those of methamphetamine as explained above and in various studies.[105] Based on 1) pharmacological similarities between MDPV and methamphetamine, 2) the potency of MDPV relative to methamphetamine, and 3) the marijuana equivalencies for methamphetamine, the DEA recommends the marijuana equivalency of 1000 grams of marijuana for MDPV and for products containing MDPV; a higher equivalency could be justified based upon similarities with methamphetamine.

* * *

We appreciate the opportunity to provide the Commission with our views, comments, and suggestions, and we look forward to working with the Commission on the above projects and proposals, among other things, over the remainder of the amendment cycle. The DEA would also express its desire for a class-based approach to synthetic drugs. The current process is unwieldy and inefficient. The DEA looks forward to working with the Commission to develop a more effective process.

Sincerely,

Demetra Ashley
Acting Assistant Administrator

cc: Commissioners
Ken Cohen, Staff Director
Kathleen Grilli, General Counsel

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105 P-K Huang, et al., *Contrasting effects of d-methamphetamine, 3,4-methylenedioxymethamphetamine, 3,4-methylenedioxypyrovalerone, and 4-methylmethcathinone on wheel activity in rats*, DRUG AND ALCOHOL DEPENDENCE 126: 168-175 (2012); MH Baumann et al., *Powerful cocaine-like actions of 3,4-methylenedioxypyrovalerone (MDPV), a principal constituent of psychoactive 'bath salts' products*, NEUROPSYCHOPHARMACOLOGY 38:552-562 (2013); WE Fantagrossi et al., *In vivo effects of abused 'bath salt' constituent 3,4-methylenedioxypyrovalerone (MDPV) in mice: drug discrimination, thermoregulation, and locomotor activity*, NEUROPHARMACOLOGY 38:563- 573 (2013); MB Gatch et al., *Locomotor stimulant and discriminative stimulus effects of 'bath salt' cathinones*, BEHAVIOURAL PHARMACOLOGY 24:437-447 (2013); JA Marusich et al., *Pharmacology of novel synthetic stimulants structurally related to the "bath salts" constituent 3,4-methylenedioxypyrovalerone (MDPV)*, NEUROPHARMACOLOGY 87:206-213 (2014).

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August 7, 2017

Honorable William H. Pryor, Jr.
Acting Chair
United States Sentencing Commission
One Columbus Circle, N.E.
Suite 2-500, South Lobby
Washington, D.C. 20002-8002

Re: Public Comment on MDMA/Methylone/Synthetic Cathinones

Dear Judge Pryor:

This letter offers the comments of the Federal Defender Sentencing Guideline Committee on issues related to MDMA/Ecstasy, methylone, and synthetic cathinones. We appreciate that the Commission is revisiting the marihuana equivalency ratio for MDMA and the typical dosage weight, along with methylone and other synthetic cathinones. We incorporate by reference our March 2017 letter to the Commission, which offered many comments to the Commission on the issues the Commission is currently considering and included transcripts and declarations from experts involved in litigating these drugs.[1] The remainder of this letter offers additional comments encouraging the Commission to (1) revisit the method it uses to measures drug harms; (2) lower the ratio for MDMA; (3) set a marihuana equivalency ratio no higher than 1:100 for methylone and several other synthetic cathinones; and (4) change the typical weight per unit of MDMA, which takes into account the lowest common dosage rate.

I. The Commission's Study of Drug Offenses

As the Commission undertakes its multi-year study of MDMA/Ecstasy, synthetic cathinones, and synthetic cannabinoids, Defenders highly recommend that it apply a well-defined, consistent harm-based rationale to drug sentencing, while also addressing gaps in the research.

[1] Letter from Marjorie Meyers, Chair, Federal Defender Sentencing Guidelines Committee, to the Honorable William Pryor, Jr., U.S. Sentencing Comm'n 2-4 (Mar. 10, 2017) (*Meyers Letter Mar. 2017*).

A. The Commission's Theory Behind Drug Sentencing Should be Well Articulated and Consistently Applied.

Defenders have previously noted difficulty commenting on proposed changes to drug sentencing without an explanation from the Commission of how the guideline, and particularly the Drug Quantity Table (DQT), is intended to achieve the purposes of sentencing.[2]

We believe it is important for the Commission to adopt and consistently apply some theory of drug sentencing. Once articulated, judges can use the rationale when considering and applying the guidelines. Other stakeholders can use the rationale when evaluating and commenting upon proposed changes. And the Commission can use it to guide policy making, and to help ensure that the guidelines achieve the purposes of sentencing. Without such a theory, the guidelines are more vulnerable to piecemeal decision making by Congress and the Commission, which often creates anomalies, disproportionalities, and unjustified disparities among recommended sentences for different drugs.

B. The Commission's Analysis of Drug Types and Determining Drug Equivalency Should Focus on Direct Harms Rather than Ancillary Harms Associated with Trafficking.

The Commission has requested comment on a number of issues, including distribution and usage patterns and other matters, as well the health effects of the controlled substances under consideration and how their harms compare with those of other drugs. It also has stated that it "anticipates that its work will continue to be guided by the factors the Commission traditionally considered when determining marihuana equivalencies for specific controlled substances, including their chemical structure, pharmacological effects, legislative and scheduling history, potential for addiction and abuse, the pattern of abuse and harms associated with their abuse, and the patterns of trafficking and harms associated with their trafficking." At the same time, the Commission explicitly asks how it should assess the harms of MDMA relative to those of other controlled substances.

We noted in previous comments that a harms-based analysis might provide a workable rationale for proportionate drug sentencing. When establishing quantity thresholds in the DQT, and the drug equivalencies in Application Note 8, we encouraged the Commission to focus on direct harms caused by the drugs themselves. Comparing one drug to other controlled dangerous substances on all of the criteria the Commission has included in its request for comment will likely result in inconsistent, subjective assessments of the harms associated with a particular drug, especially since the Commission has never adopted a standard methodology for consideration of those factors. Nor should actual patterns of trafficking and harms associated with the trafficking of a particular drug be used to determine the appropriate marihuana

[2] *Id*. at 2-4.

equivalency. Such patterns and ancillary harms are already addressed in the many specific offense characteristics found in the guidelines.[3]

C. Addressing Gaps in the Research

Regardless of the theory of sentencing adopted, the available research is likely to fall short of what is ideally needed to write guidelines implementing the theory. Contemporaneous observers of the legislative history of the Anti-Drug Abuse Act of 1986 noted that Congress made serious mistakes in establishing the quantity thresholds in the penalty statutes.[4] Data may not be available; some preliminary research may turn out to be mistaken or there may be a lack of consensus in the scientific community. For example, we are not aware of data on what quantities of various drugs are reliably associated with "major" versus "serious" traffickers. And scientists have already disagreed on the effects of MDMA.[5]

Even if the Commission is dissatisfied with the research currently available on the comparative harms of the drugs currently under consideration, it needs to try to synthesize the available data. It failed to do this in 2001 when it established the marihuana equivalency for MDMA, opting to dismiss criticisms of certain studies that exaggerated the toxic effects of MDMA.[6]

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[3] *See, e.*g., USSG §2D1.1(a) (setting base offense levels when death or serious bodily injury resulted from the use of the substance; §2D1.1(b)(1) (offense level increase for possession of a dangerous weapon); §2D1.1(b)(2) (increase in offense level for using, threatening, or directing the use of violence); §2D1.1(b)(3) (increased offense level and offense level floor for certain importations and exportations); §2D1.1((b)(6) (distribution through mass-marketing by means of an interactive computer service). *See also* §2D1.2 (increased offense levels for drug offense occurring near protected locations or involving underage or pregnant individuals).

[4] *See Mandatory Minimum Sentencing Laws – The Issues: Hearing Before the Subcomm. on Crime Terrorism, and Homeland Security of the H. Comm. on the Judiciary*, 110th Cong., 1st Sess., at 166, 169-70 (June 26, 2007) (statement of Eric Sterling). Mr. Sterling has described the legislative process as "like an auction house . . . . It was this frenzied, panic atmosphere – I'll see you five years and raise your five years. It was the crassest political poker game." Michael Isikoff & Tracy Thompson, *Getting Too Tough on Drugs: Draconian Sentences Hurt Small Offenders More Than Kingpins*, Wash. Post, Nov. 4, 1990, at C1, C2.

[5] *See, e.g.*, Rick Doblin, et al., *A Reconsideration and Response to Parrott AC (2013) Human Psychobiology of MDMA or 'Ecstasy: An Overview of 25 Years of Empirical Research*, 29 Human Psychopharmacology Clinical and Experimental *105-108* (Mar. 2014) (discussing how Dr. Parrott's review of the literature on MDMA/ecstasy was inaccurate and failed "to address the central controversies in the literature").

[6] USSC, *Report to the Congress: MDMA Drug Offenses, Explanation of Recent Guideline Amendments*, at 8, n.15 (2001) (*MDMA Report*).

The solution is for the Commission to make the best use of the available research, erring on the side of lenity. This approach is consistent with the overriding statutory mandate that sentencing courts impose a sentence sufficient, but not greater than necessary. 18 U.S.C. § 3553(a). It will also avoid guideline amendments that call for an unwarranted deprivation of liberty, particularly given the strong data showing that severe sentences will not promote deterrence[7] and that less severe sentences will help satisfy the Commission's obligation to assure that the guidelines meet the purposes of sentencing[8] and control the prison population.[9]

D. Addressing Unavoidable Imprecision in the Guidelines

Even with adequate research, vagaries in the real world—in matters such as the purity of different batches of drugs and the amounts that constitute typical doses—will ensure that no set of guidelines will lead to the right recommendation in every possible case. This is why it is so important for the Commission to articulate the assumptions underlying its decisions and the rationale for the guidelines, i.e. how they are *intended* to achieve the purposes of sentencing. Armed with that kind of understanding—for example, why the Commission expected the typical weight of a dose of MDMA to be 250 mg—judges and advocates can recognize when those expectations are not met in a particular case and weigh and adjust the guidelines' recommendation accordingly.

Vagaries such as these are already recognized in the guidelines, but in a limited and unbalanced way. We have previously noted how the inclusion of the weight of "any mixture or substance containing a detectable amount" of a drug in determining the base offense level in the DQT inevitably introduces arbitrariness into drug sentencing.[10] Defendants trafficking in similar

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[7] National Institute of Justice, *Five Things About Deterrence* (Sept. 2014) ("certainty of being caught is a vastly more powerful deterrent than the punishment"; " prisons may have opposite effect of deterring crime"); Daniel Nagin, *Deterrence in the Twenty-First Century*, 42 Crime & Just. 199, 201 (2013) ("lengthy prison sentences cannot be justified on a deterrence-based, crime prevention basis"); Brennan Center for Justice, *What Caused the Crime Decline*? 26 (Feb. 2015) ("The National Academy of Sciences (NAS) concluded that 'insufficient evidence exists to justify predicating policy choices on the general assumption that harsher punishments yield measurable deterrent effects.'"); National Institute of Corrections, *Myths and Facts: Why Incarceration is Not the Best Way to Keep Communities Safe* 2 (2016) ("[r]esearch suggests that incarceration does little to change a person's behavior"); Patricia Clark, Office of Justice Programs, National Institute of Justice, *Preventing Future Crime with Cognitive Behavioral Therapy*, 265 Nat'l Instit. of Just. J 22 (2010) ("Cognitive behavioral skill-building is more effective in reducing future criminal behavior than punishment even among persons at high-risk of reoffending.").

[8] 28 U.S.C. § 991(b)(1)(A).

[9] 28 U.S.C. § 994(g) ("sentencing guidelines prescribed under this chapter shall be formulated to minimize the likelihood that the Federal prison population will exceed the capacity of the Federal prisons").

[10] *Meyer Letter March 2017*, at 8.

amounts of the actual controlled substance, and thus causing similar harms, may be sentenced very differently if the mixtures for which they are held accountable vary in purity.

USSG §2D1.1, Application Note 27, recognizes that the weight of a mixture may *mis*represent the relative seriousness of a drug crime, for example, if the mixture is of "unusually high purity". In such a case, a given amount of the drug represents many more doses than is ordinarily the case, and may indicate something about a defendant's role or position in the chain of distribution. Application Note 27 authorizes an upward departure in these circumstances. But the complementary problem—mixtures that are especially diluted, and thus represent *fewer* doses, *lesser* harms, and *less* culpability—is not addressed in the guidelines. We encourage the Commission to avoid and address instances like this, where the guidelines show greater concern for excessive leniency than for excessive severity.

We share the Commission's concern with limitations on the research and believe the problem should be acknowledged explicitly. If the Commission were to conclude, for example, that the available research is insufficient to make finely tuned distinctions among the harmfulness of different drugs, the Commission should say so. It would not be appropriate to suggest that the guidelines' detailed recommendations about the punishment deserved by different drug crimes are the product of research and expertise if they are not.[11] Only by a good faith effort to explain the rationale and evidence for a guideline, including limitations in that evidence, can the Commission provide judges with the appropriate guidance to sentence the individual before them.

E. Addressing Relative Harmfulness

In previous comments, we discussed how the Commission's harmfulness comparisons have appeared to be *ad hoc*. Relevant factors such as dosage weights and prevalence of use have been ignored or considered inconsistently. Indirect harms not fairly attributable to defendants have been mixed with the direct harms relevant to fair sentencing. Judges are directed to consider matters such as a drug's chemical structure, despite its highly technical nature and unclear relationship to harms. We have instead encouraged focus on data bearing on direct harms, such as a drug's role in emergency room visits, overdose deaths, addiction and treatment seeking, and similar medical harms. News reports and other anecdotes (such as the supposed methylone"zombies"), isolated case studies, or even toxicology studies investigating the *potential* harms caused by drugs if taken in concentrations far greater than typical use are of limited value in assessing the relative harmfulness of different drugs as actually used.

[11] *See Kimbrough v. United States*, 552 U.S. 85, 109 (2007) (discussing how Commission did not take into account "empirical data and national experience" when formulating guideline ranges for crack cocaine offenses).

Even statistical data, for example, on the frequency of a drug leading to an emergency room admission, or to overdose death, are of little value unless considered in the context of the overall number of users of the drug. For example, the Substance Abuse and Mental Health Services Administration (SAMSHA) reported that "bath salts" were mentioned in nearly 23,000 emergency room admissions in 2011 (out of a total of nearly 2.5 million ER admissions that involved substance misuse and abuse).[12] However, without data on the number of users of bath salts in that year, it is difficult to put the data on emergency room admission in context in order to compare the harm of bath salts with other drugs. Unfortunately, the best source of data on the number of lifetime, past month, and past year users, is the National Survey on Drug Abuse and Mental Health (NSDAMH), and it does not estimate the number of specific methylone users.

II. Guidelines for MDMA/Ecstasy

The Commission requests comment on whether the marihuana ratio for MDMA is appropriate. As discussed in our March 2017 letter to the Commission,[13] the marihuana equivalency for MDMA unquestionably needs to be revised. And contrary to the dangers Congress believed were associated with MDMA when it passed the Ecstasy Anti-Proliferation Act of 2000, Public Law 106-310,[14] the DEA's recent National Drug Threat Assessment concluded that "[u]se of these drugs remains a low threat."[15] As discussed below, the available data shows that MDMA is one of the least harmful of the major controlled substances and many of the reasons the Commission gave in 2001 for increasing the ratio from 1:35 to 1:500 gm of marihuana are not supported by current data and research.

A. Public Health Data Shows that MDMA Presents a Relatively Low Risk of an Emergency Room Visit.

For MDMA, relatively complete data regarding harmfulness are available, and they lead to one conclusion: by all available measures, ecstasy is much less harmful than most other major controlled substances. The NSDAMH has estimated the prevalence of past month, past year, and lifetime ecstasy use for nearly two decades. The Drug Abuse Warning Network (DAWN) collected data on emergency room admissions involving various drug for many of those years, until being discontinued in 2011 pending development of a new emergency department surveillance system. The most recent year in which both datasets are available is 2011.

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[12] SAMHSA, *The DAWN Report* (Sept. 17, 2013), https://www.samhsa.gov/data/sites/default/files/spot117-bath-salts-2013/spot117-bath-salts-2013.pdf.

[13] *Meyers Letter Mar. 2017.*

[14] *See MDMA Report*, at 3.

[15] U.S. Dep't of Justice, *Drug Enforcement Administration: 2016 National Drug Threat Assessment Summary*, 132 (Nov. 2016).

Importantly, both of these data sources also report findings on other major drugs of abuse, including heroin, cocaine, LSD, PCP, methamphetamine, and marihuana. With these data, it is possible to compare the drugs in terms of the likelihood of an emergency room admission involving the drug, given the overall number of recent users of that drug.[16] The ratio of the number of emergency room admissions involving the drug to the total number of recent users of that drug provides an estimate of the risk of an emergency room visit among recent users of the drug.

Chart1, which is a Table taken from a longer paper that explains the reasoning behind the data, shows these "risk ratios" for nine major drugs of abuse for the two most recent years in which both datasets are available.[17] While showing some fluctuation between the years, the ordering remains the same, and is largely consistent with other measures of the relative harms of different drugs, as discussed below. MDMA is among the *least* harmful drugs in terms of emergency room admission risk, having a risk similar to marihuana, and just a small fraction of the risk of other major drugs of abuse.

Chart 1

Table 6: Emergency Room Risk Ratios 2010, 2011

Drug	Emergency Room Mentions 2011	Risk Ratio 2011	Risk Ratio 2010
PCP	75,538	2.9	1.5
Heroin	258,224	.92	.94
Oxycodone/Oxycontin	151,218	.39	.26
Cocaine	505,224	.37	.33
Methamphetamine	102,961	.23	.27
All Stimulants	70,831	.23	.12
MDMA/Ecstasy	22,498	.04	.03
Marijuana	455,668	.03	.03
LSD	4,819	.03	.02

Emergency room episodes provide the best data on the relative harmfulness of MDMA, both because MDMA mentions are counted separately and because of the availability of national data

[16] *See* Paul J Hofer, *Ranking Drug Harm for Sentencing Policy* 15 (2015), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2612654.

[17] *Id.*

on the number of recent MDMA users. Data on admissions to addiction treatment facilities, or on overdose deaths, can be developed for other major drugs of abuse, but are not available for MDMA to the best of our knowledge. There are, however, other types of evidence on the relative harmfulness of ecstasy, and all indicate that MDMA is among the least harmful controlled substances.

B. Drug Harm Rankings Show that MDMA Is Less Harmful Than Many Other Drugs.

Although less than ideal for the purposes of sentencing policy making, drug harm rankings using a variety of methods have been developed by the United Nations,[18] and by researchers in Australia,[19] New Zealand,[20] Canada,[21] Scotland,[22] the Netherlands, and the United Kingdom.[23] Only some of these have compared MDMA to other drugs, but those that do have consistently found MDMA to be less harmful to individuals and to society than other major drugs of abuse.[24]

Van Amsterdam and colleagues provided experts with scientific research on medical harms from chronic drug use, and had them rank the drugs in terms of toxicity and somatic disease

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[18] United Nations Office on Drugs and Crime, *2005 World Drug Report* 165-174 (vol. I (2005)).

[19] Michael McFadden, *The Australian Federal Police Drug Harm Index: A New Methodology for Quantifying Success in Combating Drug Use*, Australian J. of Pub.Admin. *65*, 68–81 (Dec. 2006); Tim Moore, *Drug Policy Modelling Program, Working Estimates of the Social Costs Per Gram and Per User For Cannabis, Cocaine, Opiates and Amphetamines* (2007), https://ndarc.med.unsw.edu.au/sites/default/files/ndarc/resources/14%20Working%20estimates%20of%20the%20social%20costs.pdf.

[20] Adrian Slack et al., Business and Economic Research Limited, *New Zealand Drug Harm Index* (2008), https://fyi.org.nz/request/1213/response/4866/attach/4/BERL%202008%20New%20Zealand%20Drug%20Harm%20Index%20final%20report.pdf.

[21] Wayne Hall et al., Addiction Research Foundation, Toronto Canada, *Comparing the Health and Psychological Risks of Alcohol, Cannabis, Nicotine, and Opiate Use*, in The Health Effects of Cannabis (Kalant et al., eds.) (1999).

[22] Mark Taylor et al., *Quantifying the RR of Harm to Self and Others from Substance Misuse: Results from a Survey of Clinical Experts Across Scotlandd*, BMJ Open (Aug. 2017), http://bmjopen.bmj.com/content/bmjopen/2/4/e000774.full.pdf.

[23] Jan GC 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).

[24] *Id*. *See also* David Nutt, et al., *Drug Harms in the UK: A Multicriteria Decision Analysis*, 376 The Lancet 1558-65 (2010).

(psychiatric harms were excluded).[25] As shown in the reverse harm ranking in Chart 2,[26] among illegal drugs, crack cocaine received the highest scores, followed by heroin and methamphetamine; mushrooms and LSD were ranked the least physically harmful; ecstasy, steroids, and marihuana were in the middle.

Chart 2

Table 1: Physical Harms (Amsterdam et al 2013)

Drug	Toxicity	Individual disease burden
Magic mushrooms	0.47	0.50
LSD	0.82	0.75
Methylphenidate	0.73	0.71
Khat	0.98	1.12
Benzodiazepines	0.73	0.94
Buprenorphine	1.11	0.91
Ketamine	1.15	1.23
Ecstacy	1.13	0.88
Anabolic steroids	1.13	1.36
Cannabis	1.04	1.19
Methadon	1.34	1.46
GHB	1.64	1.33
Amphetamine	1.68	1.65
Cocaine	1.75	1.81
Methamphetamine	1.95	2.14
Heroin	1.97	2.31
Tobacco	1.54	2.19
Alcohol	2.02	1.88
Crack cocaine	2.28	2.54

Another type of direct harm is the risk that a drug will cause death by overdose. Robert Gabel reviewed the English-language research on the toxicity of twenty commonly abused substances, using a combination of animal studies, clinical reports, and experimental research. The goal was to create standardized comparisons that would focus on direct pharmacological effects and not be affected by usage prevalence rates.[27] Lethality depends on factors such as a user's body weight, habituation, and mode of administration. However, by making reasonable estimates about typical dosage size and user attributes, it was determined that "[d]espite residual uncertainties, the substantial difference in safety ratios suggests that abused substances can be rank-ordered on the basis of their potential acute lethality." [28]

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[25] Van Amsterdam, *supra* note 23.

[26] Hofer, *supra* note 16, at 11.

[27] Robert S. Gable, *The Toxicity of Recreational Drugs*, 94 Scientific American 206-208 (2006).

[28] Robert S. Gable, *Comparison of Acute Lethal Toxicity of Commonly Abused Psychoactive Substances*, 99 Addiction 686 (2004).

Chart 3 displays the rankings of drugs in terms of their "safety ratio," i.e., the difference between a typical non-medical dose amount and a lethal dose (for a person of normal weight, without tolerance or residue from previous use, and without interactions with other drugs).[29] For example, the equivalent of two shots of vodka is a typical dose of alcohol, while 20 shots taken quickly on an empty stomach can be fatal. This yields a safety ratio for alcohol of 10. Heroin and GHB/GBL have the lowest safety ratios, and thus the highest potential lethality. MDMA had a ratio of 16, better than every major controlled substance except "roofies," marihuana, and LSD, the latter two of which have not been found to have lethal doses.

Chart 3

Table 2: Rank Order of Safety Ratios for Commonly Abused Drugs (Gabel, 2004)

- 6 Heroin
- 8 Gamma-hydroxybutyrate (GHB/GBL)
- 10 Methamphetamine
- 10 Alcohol
- 15 Cocaine
- 16 MDMA (Ecstasy)
- 30 Rohypnol ("Roofies")
- > 1000 Marihuana, LSD

Another aspect of direct harm is addictiveness. Drugs have been compared on this dimension through the measurement of "capture ratios," i.e., the portion of users who go on to develop a physical or psychological dependence on the drug. Gabel reported that "[h]eroin and methamphetamine are the most addictive by this measure. Cocaine, pentobarbital (a fast-acting sedative), nicotine and alcohol are next, followed by marihuana and possibly caffeine. Some hallucinogens – notably LSD, mescaline and psilocybin – have little or no potential for creating dependence."[30] A government witness, Dr. Parrot, has testified that cocaine is "far more addictive than MDMA" and the problems associated with MDMA "won't be as severe as many of the problems of cocaine."[31] Dr. Glen Hanson – a pharmacologist and toxicologist – agreed

[29] Hofer, *supra* note 16, at 11.

[30] Gable, *supra* note 27, at 206-208.

[31] Transcript of Proceedings, *United States v. McCarthy*, No. 1:09-cr-01136, at 46 (S.D.N.Y. Dec. 6, 2010), ECF No. 39 (attached as Appendix A to *Meyers Letter Mar. 2017*) (*McCarthy Transcript*). *Id.* at 291-92.

that MDMA is less addictive than cocaine and that "unlike cocaine users even heavy users generally decline in their use of MDMA."[32]

Other researchers have compared addictiveness by simply asking users about their experiences. Morgan et al. created an online survey, which was completed by 5791 individuals from over 40 countries.[33] Respondents rated fifteen commonly abused drugs on seven dimensions of risk, including the risks of bingeing, reliance, and craving.[34] As shown in Chart 4, among drugs illegal in the U. S., opiates were ranked highest on reliance and craving, while cocaine was first on bingeing.[35] Amphetamines also were rated relatively high-risk, while ecstasy, hallucinogens, and cannabis were near the bottom.

Chart 4

Table 3. **Mean harm ratings of drugs on each of the seven risk factors.**

	Short-term	Long-term physical risk	Risk of injecting	Risk to society	Risk of bingeing	Risk of reliance	Risk of craving
Opiates	**1.3**	**2.1**	**2.4**	**1.8**	**2.3**	**2.5**	**2.7**
Prescription analgesics	**1.1**	**2.0**	**1.6**	**1.5**	**2.3**	**2.4**	**2.5**
Cocaine	**1.1**	**2.2**	**1.4**	**1.8**	**2.5**	**1.6**	**2.5**
Alcohol	**1.0**	**2.1**	**0.2**	**2.3**	**2.6**	**1.8**	**2.0**
Amphetamines	**1.0**	**1.9**	**1.2**	**1.5**	**2.2**	**1.7**	**2.1**
Tobacco	**0.9**	**2.4**	**0.1**	**1.1**	**2.0**	**2.3**	**2.6**
Benzodiazepine	**0.9**	**1.9**	**0.7**	**1.1**	**2.1**	**2.2**	**2.1**
Ketamine	**0.9**	**1.5**	**1.4**	**0.8**	**1.6**	**0.8**	**1.5**
Mild stimulants	**0.5**	**1.1**	**0.5**	**0.5**	**1.3**	**1.4**	**1.6**
Ecstasy	**0.8**	**1.4**	**0.4**	**0.6**	**1.7**	**0.6**	**1.2**
Nitrous oxide	**0.7**	**1.1**	**0.1**	**0.4**	**1.5**	**0.4**	**1.2**
Hallucinogens	**1.0**	**1.2**	**0.5**	**0.7**	**1.1**	**0.3**	**0.6**
Viagra/ Cialis	**0.3**	**0.6**	**0.3**	**0.3**	**0.9**	**0.6**	**0.4**
Skunk cannabis	**0.3**	**0.7**	**0.1**	**0.3**	**0.6**	**0.3**	**1.1**
Herbal cannabis	**0.3**	**0.7**	**0.1**	**0.3**	**0.6**	**0.3**	**1.0**

[32] *Id*. at 337, 340, 369.

[33] CJ Morgan, *Harms and Benefits Associated with Psychoactive Drugs: Findings of an International Survey of Active Drug Users*, 27 J. of Psychopharmocology 497 (2013).

[34] *Id*. at 499 (other ratings included topics such as risks of short- or long-term physical harms, on which better data are available than user ratings).

[35] *Id*. at 502.

C. Experts In Substance Abuse Have Agreed that MDMA is Less Harmful Than Cocaine and Many Other Drugs.

Dr. Valerie Curran – a psychopharmacologist with extensive knowledge of the research involving MDMA – testified in *United States v. McCarthy*, that MDMA "is less harmful than either ketamine or marihuana."[36] And while not in complete agreement with Dr. Curran, research on the comparative risks of MDMA compared to alcohol, tobacco, cannabis, and other illicit drugs using the "margin of exposure" approach shows that ecstasy (MDMA), cocaine, amphetamine-type stimulants, opiates, and bondeodiazepines fall into a lower risk category than alcohol and cigarettes and a higher risk category than cannabis.[37] Another expert, Dr. Charles Grob—a psychiatrist specializing in hallucinogens—has testified that "MDMA causes significantly less risk of injury to users than cocaine."[38]

D. MDMA is Punished Far Too Severely.

To evaluate the proportionality of sentencing under the current guideline, the relative harmfulness of different drugs must be compared with the relative severity of punishment. At the April hearing, Dr. Rick Doblin noted that MDMA was punished *more* severely than drugs like methamphetamine that are more harmful. When asked to respond, Dr. Boos assumed that MDMA is sentenced more leniently because it was lower marijuana equivalency.[39] But his assumption is flawed because it ignores differences in typical dosage amounts. Under Dr. Boos' reasoning, sentences for LSD (where one gram equates to 100,000 grams of marihuana) is by far the most severely sentenced drug. But the Commission has determined that the typical dosage weight of one dose of LSD is just .0004 gms, while the typical dose of methamphetamine

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[36] *McCarthy Transcript*, at 46.

[37] *See* Dirk Lachenmeier & Jurge Rehm, *Comparative Risk Assessment of Alcohol, Tobacco, Cannabis and Other Illicit Drugs Using the Margin of Exposure Approach*, *Scientific Reports* 5 (Jan. 30, 2015) ("margin of exposure" approach is "defined as ratio between toxicological threshold (benchmark dose) and estimated human intake"), https://www.nature.com/articles/srep08126. *See also* David Nutt, et al., *Drug Harms in the UK: A Multicriteria Decision Analysis*, 376 The Lancet 1558-65 (2010) (ranking ecstasy in the bottom quarter of 20 drugs).

[38] Declaration of Charles Grob, *United States v. Chin Chong*, No 13-CR-570 (E.D.N.Y. Aug. 22, 2014) (attached as Appendix D to *Meyers Letter Mar. 2017*).

[39] Transcript of Public Hearing Before the U.S. Sentencing Comm'n, Washington, D.C., at 224 (Apr. 18, 2017). *See USSG* §2D1.1, comment. (n.8.D).

mixture is about 40 times that.[40] On a per dosage basis, methamphetamine mixture is punished roughly similarly to LSD, but less severely than MDMA.

One method to compare the severity of punishment is to use data on typical dosage weights of various drugs to determine how many doses would receive a five-year statutory minimum or base offense level under the DQT.[41] As Chart 5 shows, the results are striking.[42] When taking a range of typical dosage amounts into account (low, middle, high), the guidelines treat MDMA more severely than pure PCP, meth mixture, heroin, or powder cocaine. Only meth actual and crack cocaine are treated more severely.

Chart 5

Table 8: Numbers of Doses Resulting in Similar Penalties

Drug	Low Estimate	Middle Estimate	High Estimate
Meth Actual	125	208	312
Crack cocaine	140	186	280
MDMA	320	430	667
Pure PCP	1,000	1,333	2,000
LSD		2,500	
Meth Mix	2,000	3,333	5,000
Heroin	1,000	3,333	6,667
Powder cocaine	3,571	4,166	8,333
Marijuana	500,000	666,666	1,000,000

A striking feature of the punishments recommended for different drugs is that they do not appear to closely track the rankings of drug harms reviewed earlier. Marihuana, the least severely punished drug on a per-dose basis, did indeed rank at or near the bottom of several types of direct harm. But MDMA/Ecstasy, which also ranked low, is among the most severely punished drugs.

[40] USSG §2D1.1(c), comment. (n.G & n.B).

[41] The minimum quantities at level 24 of the DQT were used for the table in Chart 5. For drugs with mandatory minimums, these quantities correspond to the five year mandatory minimum thresholds in the statutes.

[42] Hofer, *supra* note 16, at 24, Tbl. 9.

E. Scientific Analysis on Health Effects of MDMA Call into Question Conclusions from the Commission's 2001 Report.

When the Commission increased the ratio for MDMA in 2001, it relied heavily upon research from George Ricaurte, M.D., and his colleagues,[43] which concluded that the use of MDMA had a long lasting effect on serotonin cells, negatively affecting memory and other brain functions.[44] In 2003, Ricaurte retracted his MDMA studies after it was discovered that the studies had not used ecstasy, but methamphetamine.[45] The Commission also relied upon research from Una McCann,[46] which modern brain imaging technology has since proven inaccurate.[47] Other studies the Commission depended on also have been shown to be flawed, as discussed in Dr. Rick Doblin's testimony at the Commission's April 2017 hearing.[48]

Research provided to the Commission by Dr. Doblin shows that MDMA can have positive effects on mental health.[49] And studies since 2001 have shown that MDMA's impact on cognitive functioning is not nearly what the Commission concluded when it adopted the 1:500 ratio. For example, a 2011 study assessing the cognitive function of ecstasy users "found little evidence of decreased cognitive performance in ecstasy users,"[50] while acknowledging that "the

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[43] *MDMA Report*, at 8, n. 15 (discussing research of George Ricaurte and how appearance of the articles in peer-reviewed journals "lends credence to this work"). *See also id*. at 9 (discussing that the Ricaurte study showed "actual loss of serotonin nerve endings").

[44] *MDMA Report*, at 8, 11.

[45] *See* Donald McNeil, Jr., *Research on Ecstasy if Clouded by Errors*, NY Times (Dec. 2, 2003), http://www.nytimes.com/2003/12/02/science/research-on-ecstasy-is-clouded-by-errors.html. *See also* Multidisciplinary Association for Psychedelic Studies, *Ricarute MDMA Research Controversy* http://www.maps.org/research-archive/mdma/studyresponse.html.

[46] *MDMA Report*, at 9, n.18 (citing an article from the National Institute of Drug Abuse, which relied upon McCann studies).

[47] Stephen Kish et al., *Decreased Cerebral Cortical Serotonin Transporters Binding in Ecstasy Users: A Positron Emission Tomography/[11C]DSAB and Structural Brain Imaging Study*, 133 Brain 1779, 1791 (2010) (study of ecstasy users "did not find a global, massive reduction of brain [serotonin transporter] bindings as reported in the first [serotonin transporter] imaging study of ecstasy users [in 1998]").

[48] Statement of Rick Doblin, Ph.D, Before the U.S. Sentencing Comm'n, Washington, D.C., at 5-11 (Apr. 18, 2017). *See also* Motion for Determination of Appropriate Marihuana-to-MDMA Ratio Pursuant to *Kimbrough v. United States*, *United States v. Kamper*, No. 1:11-CR-3 (E.D. Tenn. Dec. 29, 2011), ECF No. 162 (discussing research on MDMA and why the Commission's 2001 report is inaccurate).

[49] Dr. Doblin Statement, *supra* note 48, at 12-17.

[50] J.H. Halpern, et al., *Residual Neurocognitive Features of Long-Term Ecstasy Users with Minimal Exposure to Other Drugs*, 4 Addiction 777 (2011). *See also* Daniel Wagner, et al., *Learning, Memory and Executive Function in New MDMA Users: A 2-Year Follow-Up Study*, 9 Frontiers in Neuroscience 8, 1 (Dec. 2015) (findings on tests of executive functioning were consistent with the Halpern study; finding no

neurotoxicity of human ecstasy use remains incompletely resolved."[51] Another study discussed the methodological limitations of the earlier reports that linked the use of MDMA with lowered cognitive function and assessed cognitive functions of ecstasy polydrug users compared to other drug users.[52] Acknowledging that the "longer-term effects of ecstasy use remain unknown," the study did not find support for the "hypothesis that ecstasy users would display lower cognition that non-users" and concluded that "[a]lthough the results suggest that heavy use of ecstasy is associated with some lowering of higher-level cognitive functions, they do not indicate a clinical picture of substantial cognitive dysfunction."[53] Yet another study found that "use of Ecstasy/MDMA does not lead to clinically deficient memory performance in the long term."[54]

Any research suggesting the opposite, upon which the DEA relies,[55] must be carefully scrutinized. As several experts pointed out in 2009, some studies of heavy ecstasy users concluding that the effect of ecstasy on memory is substantial do not always account for other factors that can impact memory, such as "age, gender, IQ, and other substance abuse," as well as the prevalence of childhood abuse and neglect among ecstasy users, which is associated with "decreased verbal memory in adulthood."[56]

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significant difference in neuropsychological tests, other than visual paired associates learning, over a two-year follow-up period and noting how the study groups differed in their use of illicit drugs such that "performance differences between the groups cannot [be] completely ascribed to the use of MDMA").

[51] Halpern, *supra* note 50, at 785.

[52] Gillinder Bedi & Jennifer Redman, *Ecstasy Use and Higher-level Cognitive Functions: Weak Effects of Ecstasy After Control for Potential Confounds*, 38 Psychological Medicine 1319 (Feb. 2008), https://www.researchgate.net/publication/5626135_Ecstasy_use_and_higher-level_cognitive_functions_Weak_effects_of_ecstasy_after_control_for_potential_confounds.

[53] *Id*. at 1327, 1319.

[54] Kim P.C. Kuypers, et al., *Verbal Memory Impairment in Polydrug Ecstasy Users: A Clinical Perspective*, 11 PLoS One 1 (2016).

[55] Statement of Terry Boos and Shontal Linder, DEA, Before the U.S. Sentencing Comm'n, Washington, D.C., at 24-26 (Apr. 18, 2017).

[56] T.S. Krebs et al., *Letter to the Editor: Importance of Psychiatric Confounding in Non-Randomized Studies of Heavy Ecstasy Users*, 39 Psychological Medicine 876-878 (Feb. 2009), https://www.cambridge.org/core/journals/psychological-medicine/article/letter-to-the-editor-importance-of-psychiatric-confounding-in-nonrandomized-studies-of-heavy-ecstasy-users/92C189AE12C46514326B6F8A309312D0. *See also* Laura Moreno-Lopez et al., *Neural Correlates of the Severity of Cocaine, Heroin, Alcohol, MDMA, and Cannabis Use in Polysubstance Abusers: A Resting-PET Brain Metabolism Study*, PLoS One (discussing limitations of a study involving poly drug users and why the study could not "yield conclusions about cause-effect relationships between the use of drug and resting BM" and how other findings "could be due to premorbid brain alterations or the results

Lastly, one of the issues the Commission should consider in looking at data on the potential harms associated with MDMA is that MDMA is often mixed with other substances or taken with other drugs (e.g., marijuana, alcohol)[57] so the information on hospitalization and other information on risk associated with the drug cannot be tied exclusively to MDMA.

F. Distribution and Usage Patterns of MDMA Have Changed Significantly Since 2001.

As noted above, we encourage the Commission to focus on direct harms from MDMA rather than consider tangential issues such as distribution and usage patterns. Marihuana equivalencies should not be affected by the popularity of a drug with specific populations, particularly when sale to or involvement of minors in a drug offense are treated elsewhere in the guidelines.[58] The frequency of use also is not relevant to the purpose of sentencing an individual defendant. Increasing the marihuana equivalency of a particular drug because of its popularity undermines the just desert rationale and seems to buy into the myth that more serious sentences deter drug trafficking.[59] The more relevant factor in measuring a drug's harm is to consider the rates of overall use in the context of medical and public health data, which would help compare the direct harms of drugs.

In response to the Commission's specific questions, however, about changes in distribution and usage patterns in deciding whether to amend the ratio for MDMA, we note that the evidence shows that the rate of MDMA use has dropped significantly. Data presented to the Commission from Dr. Eric Wish, Director of the University of Maryland Center for Substance Abuse Research, CESAR, showed that ecstasy use peaked in 2001 (9.2%) and decreased in 2016 (2.7%).[60]

The Monitoring the Future Survey shows significant declines in use of Ecstasy (MDMA) and Ecstasy/Molly for Grades 8, 10, and 12 (Combined):

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of the interaction between the premorbid alternations and the neurotoxic effects of drug use"), http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0039830.

[57] U.S. Dep't of Justice, *Drug Enforcement Administration: 2015 National Drug Threat Assessment Summary*, 88 (Oct. 2015).

[58] *See* USSG §2D1.1(b)(15)(B); §2D1.2 (Drug Offenses Occurring Near Protected Locations or Involving Underage or Pregnant Individuals); 21 U.S.C. § 859 (Distribution to persons under age twenty-one).

[59] *See, e.g.*, National Institute of Justice, *Five Things About Deterrence* (Sept. 2014) ("certainty of being caught is a vastly more powerful deterrent than the punishment").

[60] Statement of Dr. Eric Wish Before the U.S. Sentencing Comm'n, Washington, D.C., at 2, Fig. 4 (Apr. 18, 2017).

- 30 day use of Ecstasy dropped from 2.4% in 2001 to .8% in 2014 and use of Ecstasy /Molly dropped from 1.1% in 2014 to .6% in 2016;[61]

- annual use of Ecstasy dropped from 6% in 2001 to 2.2% in 2014 and use of Ecstasy/Molly dropped from 3.4% in 2014 to 1.8% in 2016;[62]

- lifetime use of Ecstasy dropped from 8% in 2001 to 3.5% in 2014 and use of Ecstasy/Molly dropped from 5% in 2014 to 3.1% in 2016.[63]

G. MDMA Should not be Characterized as Hallucinogenic.

One of the reasons the Commission gave in 2001 for choosing to treat MDMA more harshly than cocaine was that "MDMA acts as both a stimulant and a hallucinogen."[64] That conclusion is not supported by expert testimony. Dr. Halpern, a psychiatrist with expertise in hallucinogens, explained that MDMA does not produce the same hallucinogenic effects as drugs like LSD or mescaline.[65] A government expert, Dr. Parrott, agreed with Dr. Halpern that MDMA's hallucinogenic effects "are really quite mild" and testified that MDMA should be characterized as a "stimulant and engergetic stressor rather than hallucinogen."[66]

H. The Typical Weight Per Unit Measurement of MDMA Should Be Revised.

The guidelines currently set the typical weight per unit dose of MDMA as 250mg. Evidence indicates that is too high and needs to be revised down. The DEA recently stated that "MDMA use mainly involves swallowing tablets (50-150mg)."[67] Evidence from Erowid- an organization that collects information on psychoactive chemicals reports a common dosage range of 75-125mg.[68] Another study found that the "[u]sual recreational doses are 30-150mg/pill, although

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[61] Univ. of Michigan, *Teen Use of Any Illicit Drug Other than Marijuana At New Low, Same True for Alcohol* (Press Release), Table 7 (Dec. 13, 2016), http://www.monitoringthefuture.org/pressreleases/16drugpr_complete.pdf. *See also* Lloyd Johnston et al., Univ. of Michigan Institute for Social Research, *Monitoring the Future National Survey Results on Drug Use: 2016 Overview, Key Findings on Adolescent Drug Use* 36 (2017) (data shows a decline in use and availability of MDMA), http://www.monitoringthefuture.org//pubs/monographs/mtf-overview2016.pdf.

[62] *Teen Use*, *supra* note 61, at Table 6.

[63] *Id*. at Table 5

[64] *MDMA Report*, at 5.

[65] *McCarthy Transcript*, at 164.

[66] *McCarthy Transcript*, at 93.

[67] Drug Enforcement Administration, *Drugs of Abuse: A DEA Resource Guide* 66 (2017).

[68] Erowid, *MDMA Dosage*, https://erowid.org/chemicals/mdma/mdma_dose.shtml.

purity of the street drug is notoriously poor."[69] Accordingly, the typical weight per unit measurement of MDMA should be no greater than 150mg.

III. The Equivalency Ratio for Methylone Should Be Lower than That for MDMA.

The Commission seeks a variety of comments on methylone, which are aimed at determining whether the Commission should establish a marihuana equivalency and a "typical weight per unit" for methylone. Defenders agree with Dr. Dudley that the Commission should set a ratio for methylone and it should be 1:100.[70]And given the availability of information on the typical dosage weight as discussed below, it would be appropriate to establish a typical weight per unit of methylone.

While research on methylone is limited, what is available shows that methyhlone does not deplete serotonin like MDMA.[71] Research also shows that methylone is half as potent as MDMA– a fact that some prosecutors, government experts, and the DEA have acknowledged.[72] Dr. Dudley has explained that "methylone is more similar in chemical structure to cathinone than it is to MDMA."[73] After an extensive review of available research, another expert, Dr. Anthony DeCaprio reported that "[t]he bulk of pharmacological evidence . . . supports a conclusion that

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[69] Erin A. Kolbrich, et al., *Physiological and Subjective Response to Controlled Oral MDMA Administration,* 28 J. of Clinical Pyschopharmacology 432 (p.2 on pdf version) (2008), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2587205/pdf/nihms50281.pdf.

[70] Statement of Gregory B. Dudley, Ph.D, Before the U.S. Sentencing Comm'n, Washington, D.C., at 1 (Mar. 8, 2017) (*Dudley Statement*)

[71] University of Wisconsin School of Public Health, News and Events: *Study Suggests Possible Therapeutic Use for "Bath Salt" Designer Drugs*, (describing Baumann et al., *The Designer Methcathinone Analogs, Mephedrone and Methylone, are Substrates for Monoamine Transporters in Brain Tissue*, 37 Neuropsychopharmacology 1192 (2012), http://www.med.wisc.edu/news-events/study-suggests-possible-use-for-bath-salt-designer-drugs/36980.

[72] *See, e.g., United States v. Marte*, 586 F. App'x 574, 575 (11th Cir. 2014) (relying on DEA pharmacologist's testimony that "methylone is half as potent as MDMA," the district court properly used a 1:250 ratio); *United States. v. Chin Chong*, 2014 WL 4773978 (E.D.N.Y. Sept. 22, 2014) (1:200 ratio for methylone); Drug Enforcement Administration, Office of Diversion Control, 3,4-Methylenexdioxymethcathinone (Methylone) 1 (Oct. 2013) (noting that methylone was half as potent as MDMA in animal studies).

[73] Declaration of Dr. Gregory Dudley, (Tallahassee, Florida, July 24, 2014) (attached as Appendix F in *Meyers Letter Mar. 2017*). *See also* European Monitoring Centre for Drugs and Drug Addiction, *Synthetic Cathinones Drug Profile* ("[s]ynthetic cathinones are related to the parent compound cathinone"), http://www.emcdda.europa.eu/publications/drug-profiles/synthetic-cathinones.

methylone is, on average, 5-fold less potent than MDMA for a variety of endpoints relevant to the psychoactive effects of this class of drugs of abuse."[74]

Accordingly, even if the Commission were to conclude that MDMA is the most closely related substance to methylone, the marihuana equivalency ratio should account for the lesser potency.

The other information the Commission seeks about how methylone compares to other drugs is not readily available. Methylone is not readily available in the United States.[75] Significantly, the research does not focus exclusively on methylone because it is often ingested with other drugs, such as MDMA.[76] And research on methylone and mephedrone concluded that the "actual prevalence rates of their use remains difficult to estimate" and [t]he potential chronic health effects of their prolong use remain to date unknown."[77] Without information on prevalence, it is difficult to assess relative harm. For example, any clinical examples of serious negative outcomes lack context, such as their frequency among users.

In response to the Commission's question about marketing patterns, as we have previously discussed, the method of marketing should not be a factor in determining the marihuana equivalency because the guidelines already account for trafficking patterns – including "mass marketing by means of an interactive computer service."[78] If the Commission, however, deems marketing a relevant factor, the available evidence shows that methylone and other designed drugs are commonly bought online.[79]

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[74] Declaration of Dr. Anthony Decaprio, at 9, *Chin Chong* (July 24, 2014) (attached as Appendix G in *Meyers Letter Mar. 2017*).

[75] *2016 National Drug Threat Assessment*, *supra* note 15, at Fig. A9. *See also* Drug Enforcement Administration, Diversion Control Division, *Special Report: Synthetic Cannabinoids and Synthetic Cathinones Reported in NFLIS*, 2013-2015, at 1 (from Jan. 2013 through Dec. 2015 forensic lab reports for methylone decreased for all regions).

[76] *See, e.g.*, Nicholas B. Miner, et al., *The Combined Effects of 3,4-Methylenedioxymethamphetamine (MDMA) and Selected Substituted Methcathinones on Measures of Neurotoxicity*, 61 Neurotoxicology & Teratology 74 (2017); Jane Prosser & Lewis Nelson, *The Toxicology of Bath Salts: A Review of Synthetic Cathinones*, 8 J. of Med. Toxicol. 33 (2012) (reported effects associated with the use of synthetic cathinones may not all be "related to cathinone use as many users take these substances simultaneously with other drugs and ethanol").

[77] Laurent Karila et al., *The Effects of Risks Associated to Mephedrone and Methylone in Humans: A Review of the Preliminary Evidences*, 126 Brain Research Bull. 61 (2016).

[78] USSG §2D1.1(b)(7).

[79] J. Broséus et al. *Studying Illicit Drug Trafficking on Darknet Markets: Structure and Organisation from a Canadian Perspective*, 264 Forensic Science Int'l 7-14 (2016).

Finally, responding to the Commission's question about whether to establish a "typical dosage weight per unit," the available evidence from the two most well-known user report websites converge on common dosage ranges of 100-250mg,[80] or 150-225mg.[81]

IV. Synthetic Cathinones (aka "Bath Salts")

The Commission seeks comment on whether there are "synthetic cathinones, other than methylone, that are substantially similar in their effects to MDMA" and if, and how, it should include marihuana equivalencies for these substances. Given the current limits on the research regarding synthetic cathinones and their effects,[82] as well as how these drugs change over time,[83] Defenders agree with Dr. Dudley's recommendation that the Commission set a 1:40 ratio for MDPV and 1:100 ratio for other synthetic cathinones.[84]

A set ratio for synthetic cathinones would simplify application of the guidelines and promote uniform application of the drug quantity table while acknowledging the lack of information on the specific harms of the multiple kinds of synthetic cathinones. Without a reasonably set ratio for synthetic cathinones, litigation about the "most closely related substance" is inevitable.[85]

We encourage the Commission to avoid reliance on animal drug discrimination studies to assess the "magnitude of the problems that a drug might cause."[86] While such studies have some preliminary value in assessing the potential for abuse, they cannot "account for the social, cultural, and economic factors that influence drug abuse." The fact that synthetic cathinones are

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[80] Erowid, *Methylone Dosage*, https://erowid.org/chemicals/methylone/methylone_dose.shtml.

[81] Psychonautwiki, *Methylone/Summary*, https://psychonautwiki.org/wiki/Methylone/Summary.

[82] The Congressional Research Service has noted that "synthetic drugs do not fit neatly into one class of drugs for several reasons, including that their precise chemical makeups are often unknown, and their chemical effects on individuals can be both unpredictable and replicative of more than one class of drugs." Congressional Research Service, *Synthetic Drugs: Overview and Issues for Congress* 6 (May 3, 2016).*See also* Karila, *supra* note 77 (noting that "potential chronic health effects of [] prolonged use [of synthetic cathinones] remain to date unknown").

[83] *Synthetic Cabbaninoids and Synthetic Cathinones Reported in NFLIS, 2013-2015*, *supra* note 75, at 1, Tbls. 2 & 5 (in 2015, 35 different synthetic cathinones were reported to NFLIS; ethylone was the most frequently reported).

[84] *Dudley Statement,* at 1; Transcript of Public Hearing Before the U.S. Sentencing Comm'n, Washington, D.C., at 189 (Apr. 18, 2017).

[85] *See, e.g.*, *United States v. Ketchen*, 2015 WL 3649486 (D. Me. 2015) (litigation over whether Methylenedioxypyrovalerone (MDPV) is most closely related to methcathinone or pyrovalerone);

[86] Lawrence Carter & Roland Griffiths, *Principles of Laboratory Assessment of Drug Abuse Liability and Implications for Clinical Development*, Author Manuscript, Drug & Alcohol Dependence 17 (2009), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2763984/pdf/nihms111668.pdf .

not highly available or used as often as other drugs also mitigates the need for the Commission to focus its resources on trying to determine a specific marihuana equivalency for each synthetic cathinone.[87]

Very truly yours,
/s/ *Marjorie Meyers*
Marjorie Meyers
Federal Public Defender
Chair, Federal Defender Sentencing
Guidelines Committee

cc : Rachel E. Barkow, Commissioner
Hon. Charles R. Breyer, Commissioner
Hon. Danny C. Reeves, Commissioner
J. Patricia Wilson Smoot, Commissioner *Ex Officio*
Zachary Bolitho, Commissioner *Ex Officio*
Kenneth Cohen, Staff Director
Kathleen Cooper Grilli, General Counsel

[87] *See 2016 National Drug Threat Assessment Summary*, *supra* note 15, at 158, Fig. A9, A 10, (synthetic cathinones, along with MDMA, are the least available drugs). The Monitoring the Future Survey has a single category of "Bath salts (synthetic stimulants)." That data shows that 8th, 10th, and 12th graders used Bath salts far less frequently (.8) in 2016 than many other drugs (e.g. alcohol (36.7), marijuana/hashish (22.6%), adderall (3.9), hallucinogens (2.8%), oxycontin (2.1%), cocaine (1.4)). *Teen Use of Any Illicit Drug Other than Marijuana At New Low, Same True for Alcohol*, *supra* note 61, at Tbl. 6.

PROBATION OFFICERS ADVISORY GROUP

An Advisory Group of the United States Sentencing Commission

August 7, 2017

The Honorable William H. Pryor, Jr., Acting Chair
United States Sentencing Commission
Thurgood Marshall Building
One Columbus Circle, N.E.
Suite 2-500, South Lobby
Washington, D.C. 20002-8002

Dear Judge Pryor,

The Probation Officers Advisory Group (POAG) met in Washington, D.C., on July 25 and 26, 2017, to discuss and formulate recommendations to the United States Sentencing Commission regarding the Commission's Notice of Proposed Priorities and ongoing POAG concerns. POAG comments on the selected Proposed Priorities and proposes additional issues for consideration.

Priority 2: Continuation of its multi-year study of offenses involving MDMA/Ecstasy, tetrahydrocannabinol (THC), 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. As part of this examination, the Commission more generally intends to study possible approaches to simplify the determination of the most closely related substance under Application Note 6 of the Commentary to USSG §2D1.1.

POAG reviewed and discussed the Commission's request for public comment and the public hearing material from April 18, 2017. POAG supports ongoing research and the collection of information about the chemical compounds and effects of synthetic controlled substances to establish marijuana equivalencies and base offense levels under the guidelines. Broader categories of these substances may help capture the many compounds and their effects, as well as the ever-changing chemical structure of synthetics. A simplified approach, based on scientific information, will ease guideline application, reduce lengthy court hearings regarding conversion ratios, and provide uniformity in sentencing for similar substances across the nation. POAG offers the following comments about specific synthetics:

MDMA/Ecstasy and Methylone

POAG supports the Commission's efforts to find an appropriate marijuana equivalency for MDMA/Ecstasy and Methylone. These cases appeared to have increased over the years, thus creating the need for additional guidance on how to account for these substances in a fair and consistent manner. POAG notes that some judges have held hearings on the appropriate marijuana equivalency for both MDMA and Methylone. POAG members have heard of instances where courts have found a 1:400 MDMA-to-Marijuana equivalency, a 1:200 Methylone-to-Marijuana equivalency, and a 1:250 Methylone-to-Marijuana equivalency. POAG recognizes that the Commission is in a better position to collect testimony and pharmacological evidence in order to set a science-based marijuana equivalency on these substances. Whatever ratio the Commission establishes after the study, POAG recommends the Commission provide the data supporting the ratio to the public so that the judges may have the empirical justification as added support for the adoption of the Commission's established ratios.

POAG agrees with the testimony that a synthetic cathinones category may help alleviate the problems associated with the criminal evolution of molecular changes to substances. POAG recommends that the Commission also look at Ethylone and its similarity to MDEA (with acknowledgement that Ethylone is less prevalent a problem then either MDMA or Methylone).

Synthetic Cannabinoids (JWH-018, AM-2201, XLR-11, UR-144, THJ-2201, AB-FUBINACA, ...)

POAG supports the Commission's efforts to find an appropriate set of ratios for capturing the criminal impact of synthetic cannabinoids in pure form and synthetic cannabinoids that have been infused into inert plant material (synthetic smokable cannabinoids). Under the current guidelines, courts are obligated to calculate pure synthetic cannabinoids in the same fashion as synthetic smokable cannabinoids despite the fact that the pure synthetic cannabinoids mass is smaller because it has yet to be coated over inert plant material.

POAG members discussed the testimony in which a pure form of synthetic cannabinoids could be used to make 14 times the amount of synthetic smokable cannabinoids. This 1:14 difference between the two is an excellent beginning. However, POAG members observed that the testimony the Commission heard on synthetic smokable cannabinoids appeared to presume a natural parity between marijuana and smokable synthetic cannabinoids because the amounts of THC were comparable. POAG respectfully recommends that the Commission investigate whether marijuana and synthetic smokable cannabinoids are in fact equal to each other. Marijuana is a constellation of chemicals, some of which reportedly have a mitigating impact on the more severe aspects of THC; whereas synthetic smokable cannabinoids do not have the other naturally occurring compounds that may mitigate the neurological intensity of the synthetic smokable cannabinoids.

POAG recommends the Commission make an inquiry into whether which synthetic smokable cannabinoids are more serious or damaging than marijuana and whether any degree of seriousness should be factored into the new ratios in the following fashion:

> x = the numeric value representing the degree to which synthetic smokable cannabinoids are more serious than marijuana.
> 1:x = the ratio of marijuana to JWH-018/AM-2201/XLR-11 coated plant material.
> 1:14x = the ratio of marijuana to JWH-018/AM-2201/XLR-11 in its pure powder form.

POAG does not have an opinion on what *x* should be or the resources available to determine *x*. We suggest this thought process in order to keep the ratios between the coated plant material and the pure form remain connected by the degree of seriousness the Commission attributes to synthetic smokable cannabinoids. If *x* is 1, meaning that marijuana and synthetic smokable cannabinoids are the same for all intents and purposes, then JWH-018/AM-2201/XLR-11 coated plant material is 1:1 and the pure form is 1:14. However, if the Commission determines that *x* is 10, meaning that synthetic smokable cannabinoids are ten times as dangerous/harmful as marijuana, than the ratios become 1:10 and 1:140 respectively.

POAG agrees with the testimony that a synthetic cannabinoids category may help alleviate the problems associated with the criminal evolution of molecular changes to analogous substances.

Fentanyl and Fentanyl Analogues

POAG received feedback from the field on application issues with furanyl fentanyl, which was a fentanyl analogue until November 29, 2016, at which point it was temporarily placed into Schedule I. The existing sentencing guidelines produce disparate results when furanyl fentanyl is treated as a stand-alone substance compared to when it is combined with other substances. Consider a calculation involving solely 6.4 grams of furanyl fentanyl compared to a case involving 6.4 grams of furanyl fentanyl and 100 grams of powder cocaine.

Handled as a stand-alone substance, furanyl fentanyl would be treated as a fentanyl analogue in the Drug Quantity Table and 6.4 grams of a fentanyl analogue would set a base offense level of 20. USSG §2D1.1(c)(10). The conversion ratio implicit in the drug quantity table is 1 gram fentanyl analogue is equivalent to 10 kilograms marijuana.

Adding 100 grams of powder cocaine to the 6.4 grams of furanyl fentanyl produces a different result. In the case example obtained from the field, fentanyl was determined to be the most closely related substance to furanyl fentanyl per DEA testimony and the three-part test in USSG §2D1.1, comment. (n.6).

Controlled Substance	**Conversion**	**Marijuana Equivalency**
6.4 Grams Furanyl Fentanyl	1 Gram Fentanyl = 2.5 Kilograms Marijuana	16 Kilograms Marijuana
100 Grams Cocaine	1 Gram Cocaine = 200 Grams Marijuana	20 Kilograms Marijuana
	Total:	*36 Kilograms Marijuana Equivalency (BOL: 16)*

The combination of converted furanyl fentanyl and cocaine thus results in a base offense level of 16, which is less than furanyl fentanyl as a stand-alone substance. POAG recommends that the Commission remedy this by including fentanyl analogue in the Drug Equivalency Tables at USSG §2D1.1, comment. (n.8(D)) utilizing the same ratio applied in the Drug Quantity Table found in USSG §2D1.1(c). As more fentanyl variants are prosecuted within the context of the national opiate epidemic, courts across the country will have to work around this application discrepancy – and may not even realize the issue exists.

Additional Recommendations Regarding USSG §2D1.1

POAG recognizes that there is an increased influx of synthetic drugs produced abroad and purchased for distribution in the United States. In some of these cases, POAG observed that defendants have used cryptocurrencies or blockchain based commodities (i.e. Bitcoin, Ethereum, Litecoin) to pay for the synthetic drugs. The use of such cryptocurrencies or blockchain based commodities places the purchase outside of the common banking schemes, making the investigation of the trafficking activity more difficult. Additionally, the use of such means of payment shows a higher degree of sophistication than the average drug trafficking defendant. As such, POAG recommends that the Commission consider adding a specific offense characteristic under USSG §2D1.1 for the use of cryptocurrencies or blockchain based commodities to facilitate the purchase or sale of any controlled substances.

Synthetic Drug Landscape by Circuit

The First Circuit reported a Methylone/"Molly" case in which a 1:250 gram marijuana equivalency was used. The First Circuit representative further reported synthetic cannabinoid cases (AB-FUBINACA and XLR-11) where a 1:167 marijuana equivalency was utilized – regardless of form. The First Circuit further reports fentanyl prosecutions.

The Second Circuit has had cases involving "alpha-pyrrolidinopentiophenone" (alpha-PVP) in which the courts used a 1:380 gram conversion ratio from Methcathinone to marijuana equivalency. In so doing, one of the courts rejected the argument that alpha-PVP was most closely related to pyrovalerone. The court in that case held extensive hearings related to determining the similarity of alpha-PVP to Methcathinone. The Second Circuit also has a pending case in which a defendant was distributing e-cigarette cartridges filled with a liquid based cannabis solution and was exploring a per-unit drug weight for the cartridges. The Second Circuit representative is not aware of any MDMA or Methylone cases, but has verified synthetic cannabinoid cases in which the Court applied the 1:167 ratio. The Second Circuit also reports the prosecution of fentanyl and fentanyl analogues.

The Third Circuit representative reported a few MDMA prosecutions for which a 1:500 marijuana equivalency was utilized along with Methylone prosecutions that utilized a 1:250 ratio. The Third Circuit representative was aware of at least one Methylone case that involved an evidentiary hearing.

The Fourth Circuit representative is not aware of any MDMA, Methylone, synthetic cannabinoid, cathinone, or fentanyl cases within her circuit.

The Fifth Circuit has had at least one synthetic cannabinoid case. The Court heard expert testimony regarding an appropriate conversion ratio for AM-2201. The Court agreed that THC is the most closely related substance to AM-2201 and applied the 1:167 ratio. The Court agreed that 1:167 ratio appeared arbitrary but acknowledged that the ratios often seek to outline the relative harm of certain drugs. The Fifth Circuit Court of Appeals upheld the District Court's decision to use the 1:167 ratio. The Fifth Circuit representative reported that her circuit currently has a Methylone and a MDMA case pending sentencing, but is not aware of any synthetic cathinone or fentanyl cases within her circuit.

The Sixth Circuit has had cases involving MDMA and Methylone. The cases were older and the ratios used were unclear. However, in one of the cases, the defendant was traveling to a drug deal while under the influence of Methylone and inadvertently struck a church van, killing two people. The Sixth Circuit has also had a pending case involving butyryl, acrylentanyl, carfentanil, and furanyl fentanyl. The probation office in this case has recommended that all four substances be treated as fentanyl analogues. The Sixth Circuit representative is not aware of any synthetic cannabinoids or cathinone cases within her circuit.

The Seventh Circuit reported cases involving "alpha-pyrrolidinovalerophenone" (alpha-PVP) and synthetic cannabinoids (JWH-018 and AM-2201). It should be noted that the alpha-PVP cases reported from the Second and Seventh Circuits are different underlying compounds – highlighting the need for a categorical synthetic cathinone conversion. Based on evidence provided by the government, the chemical make-up of alpha-PVP was determined to be similar to methcathinone and a 1:380 ratio was used to determine marijuana equivalency. The chemical make-up of JWH-018 and AM-2201 was determined to be similar effects of THC and a 1:167 ratio was used to determine the marijuana equivalency.

The Eighth Circuit representative reported that there are cases addressing MDMA, Methylone, synthetic cannabinoid, cathinone, or fentanyl cases within her circuit, but that these types of cases continue to be infrequent. The Eighth Circuit has found that a 1:167 tehtrahydrocannabinol (THC) to marijuana conversion was appropriate for determining the offense level for synthetic cannabinoids.

The Ninth Circuit representative reports cases involving MDMA and Methylone from at least two districts.

The Tenth Circuit representative is not aware of any MDMA, Methylone, synthetic cannabinoid, cathinone, or fentanyl cases within his circuit.

The Eleventh Circuit reports synthetic cannabinoid cases, MDMA cases, Methylone cases, and fentanyl cases within the circuit. The Eleventh Circuit has had cases involving AM-2201, XLR-11, UR-144, THJ-2201, and AB-FUBINACA. In the synthetic cannabinoid cases, most judges have adopted a 1:167 ratio regardless of whether the synthetic cannabinoids were in pure powder form or coating inert plant material. The 1:167 ratio has been used in approximately a dozen cases. There are at least two cases in which an alternative ratio was used. In one of those cases, the Court used a 1:1 ratio for AM-2201 coated inert plant material. The 1:1 ratio in that case was adopted based on a plea agreement. The other alternative ratio was a 1:14 ratio on AB-FUBINACA and XLR-11 coated inert plant material (not pure powder form of AB-FUBINACA and XLR-11).

The Eleventh Circuit has also observed MDMA and Methylone cases. In the majority of MDMA cases, the Court adopted the 1:500 ratio prescribed by the Commission. In most Methylone cases, the court adopted either a 1:500 or a 1:250 equivalency. There was an alternative ratio for MDMA and Methylone in a case dealing with Methylone; the Court in one case found that an appropriate ratio for MDMA was 1:400 and that Methylone should have a ratio half that of MDMA, finding the appropriate Methylone ratio to be 1:200.

The Eleventh Circuit also reports fentanyl cases, and the courts have been inclined to adopt the fentanyl conversion ratio of 1gm to 2.5 kg.

The DC Circuit representative is not aware of any MDMA, Methylone, synthetic cannabinoid, cathinone, or fentanyl cases within her circuit.

In conclusion, POAG would like to sincerely thank the United States Sentencing Commission for the opportunity to provide feedback on the proposed priorities. POAG supports the Commission's work on synthetic drugs will continue to solicit feedback from the field in the event this priority takes shape in a formal amendment to the guidelines.

Respectfully,

Probation Officers Advisory Group
August 2017

July 17, 2017

To: United States Sentencing Commission.

From: Enrique Enriquez

Legislators, policymakers and regulators struggle today against a broken criminal justice. Corrections facility is crowded and budget overspent, but costs keep growing, while recidivism rate are among the highest in the world.

Federal and Sates authorities have made incarceration a primary weapon in the war on crime and drugs, resulting in skyrocketing imprisonment rated rising 700 % since the 1970s.

There are 2.2 million men and woman doing time behind bars in a dangerous and inefficient U.S. incarceration system, enduring unjust limits on civil rights, with a very low percent of good chances for a head start on a better life.

The harm done to the families of the incarcerated especially children is a severe consequence of the criminal justice system. There are 1.1 million incarcerated fathers and 120,000 imprisoned mothers in the U.S. report the Pew Charitable Trusts. As a consequence more than 2.7 million U.S. children have incarcerated parents and 10 millions have experience parental incarceration in their young lives. The harms to youth, communities and the nation are incalculable. Parental Incarceration is the "greatest threat to child well- being in the U.S.

It is little known outside the families and the people involved in any way in the prison system that our records are very shameful as a nation. U.S. is the leader in mass incarceration; there is 25 % of the world inmate's population in our prisons, this is the highest incarceration rate anywhere – higher than China, Russia and Iran, U.S. is leading all this countries, some known to be the greatest human right violators in the world. U.S population is less than 5 % of the world population, our rate is the higher. Over 7 million people are doing time, on probation or parole within a dysfunctional U.S. correctional system that has corrected very little, but still costs taxpayers 210 billion yearly.

The criminal system is broken, the problems are huge, very costly and unfair, but not unsolvable. Repairing our criminal justice system is good for America.

Solutions.

The system should look at some important statistic mentioned above and others mention in the following paragraph, it is imperative a different and better approach.

Mass Incarceration is a result of severe sentences and higher recidivism rate.

Severe sentences

Since the 1980s with the tile of "War against Drug". severe and unfair sentences were imposed.

Did these severe sentences reduce drug consumption in significant numbers and deter people to commit crimes related to drugs?

The answer is NO; look at the drug epidemic affecting our society today. Severe sentences are a costly and inefficient answer that only keep increasing our incarcerated population and keep increasing costs. Studies show that crime is not reduced by lengthy imprisonment. Longer mandatory sentences did not reduce recidivism.

There are thousands of offenders that deserve a second chance, inmates with criminal category 1 to 2, also showing excellent conduct and attending course and training provide by the F.B.O.P.

Category I are 31.7 % of the inmates population, and category II are 10.4 % for a total 41.1 %, this inmates has limited, little or no prior criminal history. The safety valve should be more inclusive, not so exclusive. Inmates with fire arms are 24.4% if the fire arm was present but not used and there are not fatal consequences a more lenient approach should be considered too.

The high percent of recidivism is because ex-offenders face job and housing biases, are denied basic government services, the rudimentary rehabilitation programs is not enough, they need minimal assistance programs for society reentry. If ex- offenders become productive citizens, responsible citizens, then population inmates will be reduced, the costs will decrease and society can benefit.

The Drug Conversion drugs to marihuana is very severe, a more lenient table may be reduce the level for the amount of drugs. A more lenient approach will change the levels starting from level 6, to instead less than 1 KG should be less than 2.5 KG, level 8, 2.5 Kg to 10 Kg, level 10, 10 to 40 KG, level 12, 40 to 160 Kg, level 14, 160 to 480 KG, level 16, 480 to 900 KG, level 18, 900 to 1500 KG, level 20, 1500 to 2500 KG, level 22, 2500 to 3500 KG, level 24, 3500 to 5000 KG., level 26 5000 to 7500 KG, level 28 7500 to 15,000 KG, level 30, 15,000 to 30,000 KG, level 32 30,000 to 60,000 KG, level 34 60,000 to 120,000 KG, and level 36 > 120,000 Kg. This is one of the ways to reduce sentencing with a more lenient and more compassion level, making it retroactive, the inmate must show good behavior and discipline, good behavior and good discipline are good elements for a new life outside prison cells. Probation must be stricter and in full enforcement, for those with children they will have the opportunity to enhance their children life. The existing table is very severe with small drug dealers; it has some levels with a large amount in the same level like 1,000 to 3,000, and 3,000 to 10,000, 10,000 to 30,000 and so many others. With a very large range in the same level, it should be more lenient.

A more inclusive Safety Valve, a more lenient level for the Drug Conversion Table, a more realistic drug comparison and not the unfair used now, will help reduce our record of been the "incarcerator in chief"

Severe sentences, excessive sentences and lengthy sentences had been proving a very wrong society answer to our drugs and crimes problems and a very costly one.

Synthetic Drugs

Your commitment to review and make corrections to this matter is another way to reduce mass incarceration. The synthetic drugs had been wrongly evaluated, wrongly compare to more powerful drugs, the best example is Ethylone, a drug not in the table, but compare to MDMA a substance evaluated 1:500 in schedule 1, MAPS clearly and with irrefutable scientific data is in full disagreement with the evaluation of 1: 500 for MDMA.

If MDMA is wrongly evaluated, it was 1:35 before 2001, but using the wrong approach to deter consumption was exponential increase to 1:500 in 2001, and since 2001 no more updates in the table. The idea of severe and lengthy sentences will solve the problem is totally wrong. The idea of increasing from 1:35 to 1:500 with the purpose of imposes lengthy sentences in courts, obviously has the wrong result, its increase mass incarceration, instead other expected results. The overreacted and hysterical increase of 2001 with the purpose to deter consumption accomplished a significant criminal drug related cases reductions? The answer is no: more powerful synthetic drugs are in our streets than before, the synthetic heroin is producing more overdoses, more medical emergencies and unfortunately more deaths than before, last year more than 19,000 of our sons and daughters , just for synthetic heroin, but the overdoses total amount of deaths was more than 48,000.

Is this terrible? Yes it is, Does the government is doing the right thing with excessive sentences to prevent drugs overdoses? The answer is not at all.

Drug Ethylone

Ethylone is a synthetic drug like Buthylone, there are cathhinones.

The effect of MDMA, methylone and ethylone are not identical. In comparison to Methylone, it has approximately over 3x lower affinity for the serotonin transporter (which itself has 3x lower affinity than MDMA) The results of these differences in Pharmacology relative to methylone is that ethylone is less potent in terms of dose, and MDMA is more powerful than Methylone. Recently Dr. Dudley stated that Ethylone should 1:100, instead 1:500, Maps stated that some synthetic drugs are wrongly compared to MDMA 1:500, MAPS stated that MDMA is wrongly exaggerated. Dr. Halpern in US vs Holmes testified that cocaine produce more medical emergencies, more violence, more addiction and is it more dangerous than Ethylone and cocaine is 1:200, he testified with laboratory animals experiment, the expert DEA witness DR. Prioleau testified she has no opinion about Ethylone Potency.

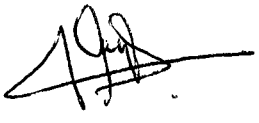
The scientific community is testifying that ethylone is less potent than methylone and methylone is less potent than MDMA. In a recent Federal court case in Tampa Florida the court evaluate Ethylone as 1:200, the defendant produce an expert witness with sufficient scientific data, however some courts go with 1:500 the wrong comparison to MDMA. If the defendant can bring an expert, the chances are much higher than a defendant without experts witness, not everyone can afford financially a professional pharmacology Dr. Ph. D expert witness.

Basically there is several ways to reduce mass incarceration, sentencing disparity and others factors increasing prison population.

The process of starting the study of synthetic drugs is very positive; there are families and inmates waiting for your final result. A lot of hope for peoples, who need it badly, it is very important to thousand of peoples your dedication and your prompt solution to this unfair comparison of synthetic drug specially ethylone and buthylone.

Make retroactive all sentencing corrections.

Respectfylly



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