UNITED STATES SENTENCING COMMISSION

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PUBLIC HEARING ON SYNTHETIC CATHINONES

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WEDNESDAY
OCTOBER 4, 2017

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The Commission met in the Commission Conference Room, One Columbus Circle, NE, Washington, D.C., at 9:30 a.m., Hon. William H. Pryor, Jr., Acting Chair, presiding.

PRESENT

WILLIAM H. PRYOR, JR., Acting Chair
RACHEL BARKOW, Commissioner
CHARLES R. BREYER, Commissioner
DANNY C. REEVES, Commissioner
ZACHARY BOLITHO, Commissioner (Ex Officio)
PATRICIA WILSON SMOOT, Commissioner (Ex Officio)

ALSO PRESENT

CASSANDRA PRIOLEAU, PhD
MICHAEL GATCH, PhD
TRAVIS WORST, PhD
DR. HEALTH BOREK, MD
DR. CHRISTOPHER HOLSTEGE, MD
DR. DARRYL INABA, PharmD, CADC-DR. INABA, CATC-V
GREGORY DUDLEY, PhD
TERRENCE BOOS, PhD
NEIL DOHERTY

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P-R-O-C-E-E-D-I-N-G-S

9:32 a.m.

ACTING CHAIR PRYOR: Good morning. Welcome to the United States Sentencing Commission's public hearing on synthetic cathinones. The Commission appreciates the attendance of those joining us here, as well as those watching our live-stream broadcast on the Commission's website.

As always, we appreciate the significant public interest in the work of the Commission, particularly this year, as we tackle the important and emerging issue of synthetic drugs. I would like to start by introducing the other members of the Commission.

First, to my left is Commissioner Rachel Barkow. Commissioner Barkow is the Segal Family Professor of Regulatory Law and Policy at the NYU School of Law and serves as the Faculty Director of the Center on the Administration of Criminal Law at the law school.

To my right is Judge Charles Breyer. Judge Breyer is a Senior District Judge for the

Northern District of California and has served as a United States District Judge since 1998.

To the left of Commissioner Barkow is Judge Danny Reeves, who was appointed to the Commission this year. Judge Reeves is a District Court Judge for the Eastern District of Kentucky and has served in that position since 2001.

And to his left is Commissioner Patricia Wilson Smoot, the designated ex officio member of the Commission, representing the United States Parole Commission. Commissioner Smoot has served on the Parole Commission since 2010 and was designated as Chair in 2015.

Finally, to my far right is Zachary Bolitho, who is the ex officio Commissioner from the Department of Justice. Commissioner Bolitho serves as Counsel to the Deputy Attorney General of the United States.

Before we begin our hearing, I would like to update you briefly on some of the Commission's most recent work. Since our last public meeting on August 17, the Commission has released two publications that I think many will

find interesting.

On September 5, the Commission issued a report analyzing the almost 1,700 sentence commutations under President Obama's 2014 clemency initiative. It provides data concerning the offenders who received a sentence commutation under the initiative and the offenses for which they were incarcerated.

It also provides an analysis of the extent to which they appear to have met the announced criteria for the initiative. Finally, it compares the number of offenders incarcerated at the time the initiative was announced with the number of offenders who actually received a sentence commutation.

On September 28, the Commission issued a report that discusses the many legal and social science issues relating to the alternatives to incarceration court programs that have emerged in many Federal District Courts around the country.

As part of its consideration of alternatives to incarceration, the Commission for some time has been studying specialized court

programs for certain types of offenders, most commonly for those with substance abuse disorders.

Out of necessity, the Commission's study has been qualitative rather than quantitative, because at this junction there is a lack of robust empirical data available about them.

The Commission did, however, send staff to visit five Districts with established programs to interview program judges and staff and to observe proceedings.

On April 18, the Commission conducted a public hearing and received testimony from experts on state drug courts and other problem-solving courts, as well as from Federal District Judges who have presided over three of the more established alternative to incarceration programs.

Many questions about these programs cannot be answered at this point. Not only are they relatively new in the federal system and have graduated only a small number of

participants to date, they also have developed in a decentralized manner and differ from each other in significant respects.

Thus, they cannot yet be evaluated empirically to determine whether the problems meet their articulated goals as or more effectively than traditional federal sentencing and supervision options.

In the report, the Commission recommends that existing programs and any newly developed programs include input from social scientists, so that data may be properly collected to allow for a meaningful evaluation in the future.

Look for the Commission's upcoming publications, Mandatory Minimum Penalties for Drug Offenders in the Federal Criminal Justice System and an update of the Analysis of Demographic Differences in Sentencing that the Commission performed for its 2012 *Booker* report, within the next few months.

With regard to training, on September 6-8, approximately 500 judges, probation

officers, defense attorneys, and prosecutors attended the Commission's National Training Seminar in Denver, Colorado.

Next year's National Training Seminar will be held on May 30 through June 1, 2018 in San Antonio, Texas. We hope to see many of you there.

Finally, I'd like to remind the public that the Commission is currently accepting public comment regarding seven proposed amendments to the Guidelines.

Among the proposed amendments are proposals to provide adjustments in the Guidelines for certain first-time offenders, as well as further consideration of the availability of alternatives to incarceration for certain federal offenders.

Amendments that would respond to legislation, including implementation of the Bipartisan Budget Act, which relates to fraudulent claims under Social Security programs.

And an amendment that would address recommendations from the Commission's Tribal

Issues Advisory Group regarding how tribal convictions are treated in Chapter 4 of the Guidelines Manual and the definition of Court Protection Order in the Manual.

These are important issues, so I would urge the public to provide comment to the Commission by October 10, which is the close of the original public comment period. The Federal Register notice and instructions on how to provide public comment can be found on the Commission's website.

The Commission is also currently seeking public comment on an issue for comment pertaining to THC, synthetic cannabinoids, and synthetic cathinones, the latter of which is the subject of today's hearing.

The public comment period ends on October 27, 2017. And, again, we look forward to receiving and reviewing the public comment as we grapple with this complicated issue.

This is our second public hearing on the general issue of synthetic drugs. We held a public hearing on synthetic drugs on April 18,

which was within weeks of the Commission regaining its quorum. And the Commission is already planning a third public hearing for December, that will focus on synthetic cannabinoids and fentanyl.

The issues raised by emerging synthetic drugs are very complicated and novel in many respects, and it is essential for the Commission to provide clear and practical guidance to courts on how to properly and fairly account for them under the Guidelines.

For that reason, we look forward to hearing from our expert witnesses today. Today's public hearing will focus on synthetic cathinones.

We will hear testimony from experts on the pharmacological effects of these drugs and their chemical structure, observations from the medical community, and the challenges these drugs pose to law enforcement.

We look forward to a thoughtful and engaging discussion. Each witness has been allotted five minutes for their statements. Your

time will begin when the light turns green. Yellow means there is one minute left and red means your time has expired.

Our first panel will examine the pharmacological effects of synthetic cathinones. The panelists are Dr. Cassandra Prioleau, Dr. Michael Gatch, and Dr. Travis Worst.

Dr. Prioleau is a drug science specialist for the Drug Enforcement Administration. Before joining the DEA, Dr. Prioleau worked as a pharmacologist for the Consumer Product Safety Commission. She has also completed fellowships in Paris and at the Mount Sinai School of Medicine in New York City.

Dr. Prioleau received her bachelor of science in chemistry from the University of Connecticut in 1990. She received her PhD in pharmacology from the University of North Carolina in 1998.

Dr. Gatch is an Assistant Professor of Biomedical Sciences at the University of North Texas Health Science Center at Fort Worth. He has been with the University of North Texas since

1996, serving as a research assistant professor until assuming his current title in 2013.

Dr. Gatch focuses his research on preclinical models of drug abuse, in particular, the development of medications for the treatment of psychostimulant addiction.

Dr. Gatch received his bachelor of arts in behavioral science from the University of Chicago and his master of arts in behavioral science from the University of Houston. Thereafter, he earned his PhD in psychology from Utah State University.

Dr. Worst is an Instructor of Forensic Science at Bowling Green State University, as well as an Adjunct Assistant Professor for the University of Maryland University College.

Before joining Bowling Green State -- is it Bowling Green State or is it just now Bowling Green University?

DR. WORST: It's Bowling Green State, sir.

ACTING CHAIR PRYOR: All right -- Bowling Green State, Dr. Worst worked as a

forensic scientist for the Drug Identification Laboratory in the Ohio Bureau of Criminal Investigation.

Dr. Worst received his bachelor of science degree with a major in pharmacy, minors in chemistry and biochemistry, from Ohio Northern University in 1999. He received his PhD in physiology and pharmacy from Wake Forest University School of Medicine in 2003.

We will begin with Dr. Prioleau.

DR. PRIOLEAU: Good morning, Judge Pryor and Members of the Sentencing Commission. As already mentioned, I am a pharmacologist at the Drug Enforcement Administration.

At the DEA, I routinely evaluate drugs for potential control under the Controlled Substances Act. I also testify across the country at hearings on the pharmacological effects of synthetic cathinones.

Thank you for the opportunity to briefly discuss the pharmacology of synthetic cathinones. It is important to acknowledge that the pharmacological and toxic effects of

cathinones have not been thoroughly investigated.

There are little or no controlled human studies investigating the pharmacological effects of synthetic cathinones. However, publications regarding the pharmacological effect of synthetic cathinones obtained from animal studies have recently increased.

DEA has also obtained animal pharmacology data on some cathinones through interagency agreements with other federal agencies and through research contracts. These data show that synthetic cathinones, similar to stimulant drugs of abuse, namely cocaine and amphetamines, such as methamphetamine and MDMA, primarily affect monoaminergic systems.

The data obtained by DEA on 19 synthetic cathinones showed that these cathinones mimic the behavioral effects of both methamphetamine and cocaine.

Although the pharmacology, toxicology, abuse potential, and dependence liability of most of the synthetic cathinones have not been extensively studied, the existing pharmacological

data show that all synthetic cathinones that have been tested so far possess stimulant-like behavioral effects.

Limited studies have compared the effects of synthetic cathinones to MDMA. To my knowledge, two synthetic cathinones, namely ethylone and methylone, have been studied and both fully mimic the behavioral effects of MDMA in rats.

Another study in humans showed that the subjective effects of mephedrone are substantially similar to MDMA. Accordingly, synthetic cathinones are promoted by drug traffickers as replacements for psychomotor stimulants or hallucinogens, such as cocaine, methamphetamine, MDMA, and methcathinone.

For example, a user of synthetic cathinones testified in a court hearing that these drugs had been substituted for other drugs of abuse, including methamphetamine.

Surveys of drug user populations indicate that synthetic cathinones, like MDMA and cocaine, are mainly used and abused by youths and

young adults in the settings of nightclubs and dance parties and the users are likely to be young males.

Clinical case reports also confirm the findings from animal studies that cathinones produce effects similar to those of stimulants, such as cocaine, methamphetamine, and MDMA.

For example, desired effects reported by users of synthetic cathinones include euphoria, sense of well-being, increased sociability, energy, empathy, increased alertness, and improved concentration and focus.

Synthetic cathinones have been reported to produce a number of stimulant-like adverse effects, such as palpitations, seizures, vomiting, sweating, headache, hypertension, tachycardia, and even death.

Other adverse effects reported include hallucinations, psychosis, paranoia, and delusions. Bizarre behavior, such as self-mutilation and episodes of delirium with persecution, have also been associated with cathinone abuse. Chronic use of synthetic

cathinones has been shown to cause substance use disorder.

A measure of drug activity that is important in pharmacology is potency. Potency is the concentration or amount of a drug that is required to produce a given or desired effect. For example, users can simply adjust the dose of a given drug to achieve the desired effects.

Therefore, it is not advisable to use the pharmacological potency of the drug as the sole factor in determining the marijuana equivalency. Other factors, such as history, pattern, scope, and significance of abuse, and adverse impact on the public health and social fabric also need to be considered.

In summary, available data indicate that synthetic cathinones possess stimulant-like pharmacological effects. Thus, one may classify these substances under one broad pharmacological category. The abuse of synthetic cathinones, similar to stimulant drugs of abuse, can lead to serious adverse health problems, including death.

Thank you for this opportunity to

briefly discuss the pharmacology of synthetic cathinones. I will be happy to answer any questions that you may have.

ACTING CHAIR PRYOR: Thank you. Dr. Gatch.

DR. GATCH: Members of the Commission, thank you for the opportunity to discuss the pharmacology of synthetic cathinones. My lab has been testing these synthetic cathinones pretty much since they were first observed in 2009.

The purpose of this statement is to address the pharmacological basis for considering cathinones to be a single class of compounds with similar abuse liability and harm potential.

So, I will do this by addressing the criteria that we use to determine the abuse liability in terms of chemical structure, pharmacological mechanism, subjective effects, rewarding or reinforcing effects, and, finally, likelihood of adverse effects.

The definition of synthetic cathinone compounds is based on a common structure, which is quite similar to psychostimulants in general,

which are in turn quite similar to the structure of dopamine, which, of course, is a neurotransmitter well known to be very important in learning, memory, and reward.

The cathinones are easily distinguished from the amphetamine class of psychostimulants, merely by having an oxygen attached by a double-bond in a particular place in the carbon atom, in the structure.

Hence, cathinone looks pretty much just like amphetamine with this oxygen attached. Methcathinone looks just like methamphetamine with the oxygen. And methylone is just like MDMA with the additional oxygen.

Not surprisingly, the cathinone compounds act very similarly to these amphetamine compounds that they resemble, so methamphetamine is very similar to methcathinone, whereas methylone is very similar to MDMA.

In terms of mechanism, all drugs of abuse increase dopamine levels in the rewards centers of the brain. Psychostimulants which directly produce strong dopamine receptor

effects, like methamphetamine, are highly likely to engender compulsive seeking and addiction.

Now, compounds like MDMA that increase both dopamine and serotonin are widely taken recreationally, but seldom progress to addiction, and so, the theory now is because of that serotonin effect.

And to summarize, the cathinones all act to increase levels of dopamine. Some of the cathinones also increase serotonin levels.

People are able to give consistent and reliable descriptions for the drugs they experience, which then provides the basis for the subjective effects we talk about.

Now, it's not possible to ask nonhuman animals about their drug experience, but we can train them to distinguish between the presence or absence of a drug, or even between two different drugs.

This drug discrimination test provides a highly reliable animal model of the subjective effects of different drugs. Thus far, all the cathinones we've tested in the drug

discrimination tests, in our lab and other labs across the country, produce subjective effects either fully like cocaine or fully like methamphetamine.

The few that have not, generally run between 50-60 percent drug-like. A few cathinones, about seven or eight now, have been also tested for MDMA-like effects and most, but not all, produce these MDMA-like effects.

In terms of rewarding effects, all the cathinones tested so far produced reward and/or reinforcing effects and are likely to be used recreationally by humans. A few cathinones have been tested for reward strength in a particular kind of self-administration assay.

Most of these produced levels of responding similar to cocaine and methamphetamine. A couple produced levels that are remarkably high and at least one produced much lower levels, similar to those of MDMA.

Now, it is possible there are some cathinones which will be MDMA-like, rather than psychostimulant like, likely those with serotonin

effects as well as the dopamine effects.

In terms of potency, the potencies of the cathinones tested so far pretty much fall in-between those of cocaine and methamphetamine. So, a single standard based on the potency would likely accurately describe most of the compounds.

Now, there have been a few compounds that have been less potent than cocaine or methamphetamine producing subject effects, however, these compounds produce either reward-like effects or adverse effects with similar potency in the same dose range of that of cocaine or methamphetamine.

The degree to which a compound is likely to produce harm is also an important issue. Some of the cathinone compounds produce extremely high blood pressure, convulsions, confusion, psychotic-like, or aggressive behaviors.

Others produce long-term harm, that is serious damage to brain, heart, kidney, liver, even after just a couple doses. Even those compounds that may be less rewarding still

produce toxic effects.

So, to summarize, the cathinones have a common and easily identifiable structural identity. The compounds all produce subjective effects similar to those of either methamphetamine or cocaine, and a few like MDMA.

The cathinones have a range of rewarding effects, from those that drive highly compulsive drug-seeking to those that may have only mildly rewarding effects. The potency of these compounds tends to similar, lying between the potencies of cocaine and of methamphetamine.

And all the cathinones tested so far produce some sort of harm, either high risk for addiction, short-term toxic effects, or long-term damage to the heart, brain, liver, or kidney. Thank you.

ACTING CHAIR PRYOR: Thank you. Dr. Worst?

DR. WORST: Good morning. Thank you for the opportunity. Real quick question, if that turns red, do I get zapped? No? Okay. My job is to teach.

ACTING CHAIR PRYOR: We have security that will just remove you.

(Laughter.)

DR. WORST: Okay. As long as I get to talk first, that's fine. My job is to teach. Before I got to teach students, which has only been a little over a year now, I had to testify. In six years, I tested over 4,300 chemistry cases for the State of Ohio. Testified 31 times for those.

And at that point, my job was to teach the jury, these are what the drugs are. Issues that we had was that we'd never seen these drugs before.

So, they come in off the street, they're a white powder, you do your presumptive testing, you go based off of that, and then you get a mass spec and it's something you've never seen before. So, then, it took some time. We had to figure out, based on the mass spec, what the structure was and then, classify them.

All of that led to the creation of what I provided you and I call the "pharmacophore

rule". One of my pharmacy professors that I worked with had the idea, can we make a large class of cathinones? Because the core structure of this compound should bind to the receptors, should have an effect. All cathinones share that common core.

So, we went to the State Board of Pharmacy, who has emergency scheduling rights in the state of Ohio, wrote up what we were calling the pharmacophore rule, presented it to them, and it's now out there.

Now, some of my lawyer friends say, it's not been tested, because everybody keeps pleading. It's not actually gone to a court of law, it's not actually gone through an appeals process. From my point of view, if it doesn't make it to the court of law, it's still a win, right? Because they're off the street.

So, the issue that my colleagues are addressing, structurally, I think we can make a cathinone class. Pharmacologically and behaviorally, it gets a little dicey at that point, because these effects are different.

Dr. Sprague, who I actually work with now, again, 25 years later and we're both a little bit more grey, is currently doing animal studies with methylone, because it's just like MDMA. He studied MDMA for 25 years.

And it causes you to essentially boil from the inside-out. Methylone does the same thing. So, these drugs are very similar to MDMA. They have stimulant properties that are somewhere between cocaine and methamphetamine.

I guess, ideally, they would have some sort of comparison to one of those three drugs, I just kind of feel bad for the Committee, because you have to decide where.

So, that's all I've got. Thank you.

ACTING CHAIR PRYOR: Thank you. Okay. Questions?

COMMISSIONER BREYER: Well, I have some questions, maybe of Dr. Worst. I mean, our job is to try to figure out, as you point out, where it fits in this panoply of harms.

And I thought your article was very interesting, because it suggests to me that we're

almost on a fool's errand, because you can start and then, there could be this tweak, this could be changed slightly, who knows what the discernible effects are.

It may be highly individualized and suddenly, we're assigning penalties to very different things in which maybe the penalty isn't the same. I don't know where we go from here.

I think we're trying to figure out some rules that we can put into place that won't depend necessarily on some chemist out there figuring out how to tweak it and therefore, escape the impact of the rule.

I don't know whether you're the panel who's going to talk about behavioral aspects of it, you've identified some of them, but let's take your rule in Ohio, because it has the beauty of being relatively simple, relatively direct.

Are you of the opinion that when you employed this rule, that it is adequate to take care of the tweaks, to take care of the changes? And also, to take care of the differences in harm that's caused by the differences in the

drug? Do you feel that that's been your experience or has it not been your experience?

DR. WORST: I guess the issue there is, my goal is to get it off the street and to make it illegal, so that it was no longer sold. That, I think we've accomplished. I don't know that I can address the differences in tweaks having different effects. That's the tricky part.

I think it's enough to say that it is a cathinone and we know that cathinones, no matter at what level, are harmful, at least to the level of cocaine, if not greater. Unfortunately --

ACTING CHAIR PRYOR: At least?

DR. WORST: I would say at least, yes. Cathinone itself is kind of an outlier, I think it's effects are closer to amphetamine itself, but the khat plant, which we see that in Ohio a lot too, has not been an issue, because it's all the synthetic stuff.

And quite honestly, most of the drug dealers, most of the people that we see on the streets in Ohio, they want the stuff that's going

to have an effect and cathinone itself is more of a stimulant effect.

As soon as you add that methyl group and make it methcathinone, now it's got the bigger effect. So, we haven't seen the khat plant, I think in probably four or five years, at least. That's where you get the cathinone problem, it's all been the synthetic stuff, because that's where they're moving.

COMMISSIONER BARKOW: Can I ask, if we were to take a class-based approach, this is really for all of you, to the extent you have testified, there are some of these differences among the different kinds, even though they share a chemical structure, that they have some different effects.

I think, Dr. Gatch, you say in your testimony, if we use the same standard, but we base it on potency, that that might be the way to kind of differentiate the different kinds of effects that they're having on people, but I sort of heard your testimony, Dr. Prioleau, saying potency isn't the answer.

So, I guess I'd kind of just like to get your reactions about a class-based approach, but that then, within it, would distinguish on the basis of potency. Because if we're trying to make the most easily administrable rule, that also gets at the proportionality of harms, is that a pretty good fit or are there reasons we should be cautious about that?

DR. WORST: If you can do it. The problem is --

DR. GATCH: If you could do it.

COMMISSIONER BARKOW: Okay.

DR. WORST: -- like she had mentioned, the lack of research. So, we have seen more drugs on the street than have actually been researched and we know the effects of.

COMMISSIONER BARKOW: So, even if we had in a particular case, get the drug, we know it's a cathinone, because you do your chemical structure thing and it's got that core, can it be tested for potency once you bring it in, to kind of get a sense of how potent it is or no, is that just like not administrable?

DR. GATCH: Oh, that's what I do. So, we test it in those various behavioral assays and my behavioral assay is much more substance abuse liability oriented, so we don't do a lot of the other sort of medicinal kind of things, we're just looking at the substance abuse liability.

So, in terms of its subjective effects and in terms of its reinforcing effects. And as I mentioned, so far, they've pretty much fallen within that range between cocaine and methamphetamine.

And in the small number of cases in which, like one of the compounds might have a subjective effect that's slightly outside of that range, its reinforcing effects or its toxic effects will be within that range.

So, in some -- in its overall harm, I think we could probably -- it will fall in that range in a general way.

COMMISSIONER REEVES: So, if I could, so if there's a baseline, it's between methamphetamine and cocaine, the effects may pull it above or pull it below, based on potency and

some other factors?

DR. GATCH: Yes. Not just one of the effects, overall, if you look --

COMMISSIONER REEVES: How difficult would it be, in terms of testimony before a court, to come in and distinguish the effects? If we have a baseline, if we set a baseline between methamphetamine and cocaine, we have it somewhere in the middle, how difficult is it for us to distinguish then higher and lower from that baseline, within a range?

DR. GATCH: I think it would be more, it's just falling within that baseline overall. I don't really know how to answer that, because it hasn't been tested. I do know that the Department of Justice lawyers have been using the potency data, because so far, they've been just doing drug-by-drug, comparing it's potency with marijuana apparently.

And apparently, I've been told, this last meeting, last June, that so far, it's held up in court every time, that drug discrimination data we've used. So, it seems to be robust, at

least at this point.

DR. PRIOLEAU: I think --

COMMISSIONER BREYER: Is potency a good indication, in your view, is potency a good indication of harm? The more potent, the greater the harm?

DR. PRIOLEAU: The toxicity is in the dose. And a lot of the users can simply just take a dose and get the harm. So, the doses are not so great that they can't compensate by taking more of the drug. So, I don't think that potency should be such a big factor, because you can still get harm just by taking more.

COMMISSIONER BARKOW: Okay. What about potency plus quantity? Like dosage?

DR. PRIOLEAU: The doses that you need to take for the harm are not so -- they're in the milligram quantities.

COMMISSIONER BREYER: Okay.

DR. PRIOLEAU: And so, you can still take enough to achieve that harm.

DR. WORST: And everybody's different, too, in terms of tolerances and everything else.

DR. GATCH: Yes.

DR. WORST: So, what one dose is for one person is half a dose for somebody else.

ACTING CHAIR PRYOR: To the extent that we try to make these distinctions based on potency, dosage, toxicity, we're then leading ourselves back into the problem that we're here to try to deal with, right? Which is, battles of experts in sentence hearings, right?

DR. WORST: Right, yes. The lowest common denominator, you pick the level that you feel is appropriate, but is not going above. I mean, until you have more research and you can say what the effects of all these different drugs are, you can't really appropriately place them, I think.

COMMISSIONER BREYER: But your view is that, as a baseline, it's at least as dangerous as cocaine? Is that --

DR. WORST: I would say that, yes.

ACTING CHAIR PRYOR: Do you both agree with that?

DR. GATCH: Yes.

DR. PRIOLEAU: Yes, I agree.

COMMISSIONER BREYER: That's helpful.

ACTING CHAIR PRYOR: Okay. That's very helpful. Okay. Unless you have anything you'd like to add, we'll move on to our next panel. Thank you very much for your help today and for your written testimony as well.

(Whereupon, the above-entitled matter went off the record at 10:06 a.m. and resumed at 10:10 a.m.)

ACTING CHAIR PRYOR: Okay. For our next panel, we will hear the perspective of three experts from the medical and treatment provider communities and their observations on synthetic cathinones. Our panelists are Dr. Heather Borek, Dr. Christopher Holstege, and Dr. Darryl Inaba.

Dr. Borek is an Assistant Professor of Emergency Medicine, as well as the Associate Fellowship Director for Medical Toxicology at the University of Virginia School of Medicine. Dr. Borek's research areas include clinical toxicology and management of the critically ill patient.

Dr. Borek received her bachelor of science in chemistry from the University of Virginia in 2003 and her MD from the University of Connecticut School of Medicine in 2007. Thereafter, she completed an emergency medicine residency at the University of Virginia, obtained a public health certificate from the University of Virginia, and completed a medical toxicology fellowship at the Blue Ridge Poison Center.

Dr. Holstege is a Professor of Emergency Medicine and Pediatrics, as well as the Chief of the Division of Medical Toxicology at the University of Virginia School of Medicine. He also holds positions as the University's Executive Director of Student Health and as the Medical Director for the Blue Ridge Poison Center. His research focuses include clinical toxicology, substance abuse trends among students, and the emergence of new substances of abuse.

Dr. Holstege received his bachelor of science in chemistry from Calvin College in 1988 and his MD from Wayne State University School of

Medicine in 1993. Thereafter, he completed an emergency medicine residency at Butterworth Hospital and a fellowship in medical toxicology at Indiana University.

Dr. Inaba is the Director of Clinical and Behavioral Health Sciences at the Addictions Recovery Center and the Director of Education and Training for CNS Productions, Inc., a company that creates substance abuse information media.

He also holds instructing positions at the College of San Mateo and the University of California at San Francisco and as a consultant and instructor for the University of Utah School on Alcoholism and Other Drug Dependencies. Dr. Inaba is a Certified Pharmacist in the State of California and is a Certified Alcohol and Drug Counselor III.

Dr. Inaba received his undergraduate education at California State University Fresno from 1964 to 1967 and obtained his PharmD from the University of California San Francisco School of Pharmacy in 1971.

Dr. Borek?

DR. BOREK: Thank you for the introduction. So, just wanted to make the point that Dr. Holstege and I are both physicians, we're double-boarded in toxicology and emergency medicine.

And so, we're there on the ground, we're the ones that are actively managing these patients when they come into the hospital and following them throughout their course in the hospital.

What I'd like to start with is going through a case to describe some of the clinical effects that we were seeing.

This is a case that we had published in 2012 that really just exemplifies the effects that we were seeing of the specific cathinone known as MDPV. And in this case, this was the only substance that was identified, so the effects are purely from this substance.

This is a case of a 25-year-old gentleman who had injected bath salts containing MDPV and was subsequently found running wildly throughout the neighborhood, foaming at the

mouth, very agitated and combative.

It took nine police officers to be able to bring him into the emergency department. When he arrived into the emergency department, he was, again, very agitated, combative, took multiple personnel to be able to even perform an initial assessment of him.

His heart rate was 175, with a normal upper limit being 100, so significantly elevated. And his temperature was 106.3 degrees Fahrenheit. He was very ill at that time, he required multiple medications to be able to calm him down.

He was immediately put on life support and required multiple sedating medications in order to continue to safely manage and evaluate him. Immediately on his arrival, he already showed signs of multi-organ injury, including injury to his liver, injury to his heart, injury to his kidneys.

Those got progressively worse throughout his hospitalization. He went into full renal failure and needed to be placed on

dialysis continuously. His liver failed. He had a heart attack and had reduced ability of his heart to pump throughout the hospitalization.

He had significant signs of muscle injury and, in fact, his lab tests that we check for that was the highest I've ever seen in my clinical practice. He required hospitalization for 18 days and even after discharge, he still needed to be on dialysis for a few weeks after that, due to the injuries from this.

We did extensive drug testing on him. These were send-out tests, not readily available at any hospitals, but we were able to get some specialized testing at the time and MDPV was the only substance isolated from his system.

And so, I think, what I just wanted to highlight with this case was really the multi-organ effects that it's causing, from neurologic injury to cardiac injury, really every organ system was affected by this drug.

The other thing is, just the degree of agitation that we saw with him, requiring first responder personnel and putting them at risk for

injury with a violent and agitated patient and then, once he arrived to the hospital, there was a continued risk to healthcare providers, nursing staff, physicians, and all ancillary staff, as well, during his hospitalization until they were able to adequately control his behavior.

His case took a lot of healthcare resources. He had started out at one of our community hospitals and because of the degree of effects, he had to be transferred to a higher level of care, where we could get all the consultants involved.

To be able to take care of him, he required a prolonged stay in the intensive care unit and, again, resources and costs associated with dialysis and the other treatments that he received.

One of the things to note is, the drug screens that are available in the hospital do not test for these substances. And so, as I mentioned, this required special send-out testing.

And so, at the time we are seeing

these patients, we really don't know exactly what they took, all we know is we have an agitated patient who is overheated to the point of burning their cells and directly causing cellular injury.

But it was not for a week or two that we had any test results back on what this gentleman actually took. And so, in real-time, we had to treat kind of a stimulant and that was all we knew at the time, that it was some sort of stimulant, but not specifically what the substance was.

ACTING CHAIR PRYOR: Thank you, Dr. Borek.

I should have mentioned earlier for this panel, as I did for the earlier panel, we have a traffic light system. We'd ask you to try to keep your comments within, your testimony within about five minutes. When the yellow light shows, you have a minute.

Dr. Holstege?

DR. HOLSTEGE: Yes, I'll be brief. What Dr. Borek depicts is what we saw over a time period in a large number of these cases. We

published this case in part to exemplify what was going on and what others could expect.

If you look at the data, the data is difficult, right, to the clinical effects and what we saw when these came in, because we didn't always know, because we couldn't do the analytics.

In 2009, we saw zero, the Poison Center saw zero cases. In 2010, we had four. The Poison Center had 304. In 2011, we had 90. The Poison Center reported 6,138.

Those are ones with cases where either we knew, based on history, they took these substances or we did the analytics. With many of these, we couldn't, because it's too costly to do analytics on these cases.

Then, it started to drop off when the laws went into effect. One was, they were not telling us, so part of it is a reporting bias, because they're not going to say they're doing these substances if they're illegal, whereas, before they were very open about talking to us about doing it.

I will tell you, at the University of Virginia, though, and with our Poison Center, we had a six-month time period where I've never seen anything like it in my career, and I've been practicing for over 20 years and in large cities, and I've seen cocaine, I've seen amphetamines for years, but I literally had a person in my ICU every other week, at least, who was on life support because of these agents.

It's a challenging time for us. These are markedly agitated patients. The data does show, the clinical data that we have, that about 80 percent of these are exhibiting combative psychotic behavior. It puts my medical professionals, certainly, at work, both pre-hospital and outside of the hospital.

The other thing that's a bit unique on these, and you can certainly see organ damage from other things, which you heard in the previous testimony, cocaine and amphetamines, but we saw a lot more of it with this, and I'm not sure why.

I do not understand and I still to

this day don't understand why so many of my patients had leakage of what they call troponin, with the heart, which was damage to heart cells. And it was actually a global hit, it was not a focal, where the blood vessels will narrow, or a vasoconstriction, like we see with some amphetamines and cocaine.

We actually saw this large leak of troponin, meaning many cells were damage and then, what we describe as what is called as a global hypokinesis, where the entire heart is just slowly pumping, just not pumping well, not a focal area. Including liver, kidneys, and other areas.

If we were able to get them over and aggressively treat them, we could get them -- and they did have recovery. But, again, these were exceedingly challenging times for us for about six months.

You mentioned that I oversee student health now and that came in 2013, I've been at the University for some time. The reason they pulled me into student health administratively is

we had a death associated with these, one of our top students.

And we are working diligently to combat the issues of substance abuse in the collegiate population right now, which is a tremendous challenge. Especially with the rapid emergence of some of these synthetics that come out.

And certainly put a danger to our students, because they come under names that are unassuming, they're kind of enticing, and we really don't have any data on these when they first come out, what they really do. And sadly, again, we've had quite a few of our collegiate population who have died from these.

And so, from a clinical standpoint, very unique time for us in toxicology, for those of us who treated patients, and in emergency medicine, when these agents were really prolific in society.

We still see them and we do have cases that will come up that we pretty much can pigeon-hole that this is most likely one of the

synthetic cathinones. But I'm glad to say that, with the laws that have been in place, they have decreased somewhat.

ACTING CHAIR PRYOR: Thank you, Dr. Holstege. Dr. Inaba?

DR. INABA: Yes. Thank you, Judge Pryor and Commissioners. Thank you for this opportunity.

Let me share my concerns and my experience with, not just the cathinones, really I'll speak on the cathinones, because I was asked to, but it's a concern about this whole new psychoactive substances, the whole synthetic drug situation, designer drug situation that's impacting America now with synthetic cannabinoids and also, the synthetic opioids.

In addition to your introductions, I also want to mention that I'm a lifetime fellow with the Haight-Ashbury Free Clinics, where I spent 40 years treating thousands of addicts, as well as, we have something called Rock Medicine, which we do event, concerts and other event medicine, where we go out and treat people who go

to these things and we've seen a number of overdoses and a number of toxic problems associated with these new psychoactive substances.

In fact, I was there at the origin of Haight-Ashbury Free Clinics in 1967 and from the 1960s through the 1970s, I witnessed what some have described as the largest uncontrolled human drug experiment in the world.

And it had its roots in the United States or had its epicenter in the United States and really, its center was right in where I was working at the Haight-Ashbury Clinic, where synthetic drugs like PCP, STP, 2C-B, and a whole bunch of these new psychoactive substances started hitting the street.

Many were unleashed with very little to no previous research or no previous knowledge of how they were going to affect the human being. So, in fact, the substance abusing subculture was used as human guinea pigs.

These things were released with theoretical psychoactive effects and the people

who took them were actually the test witnesses to tell us what they did, how toxic they were, what the dosage should be, how dangerous they were. And, unfortunately, I had to witness a lot of tremendous tragedies in the past due to this experience.

I think what we're now in is much larger. I mean, these were rogue chemists and these were small-time operators, just street pharmacologists creating new substances. I think this current situation is a much more broad situation, much larger operations involved and I think it's a real danger to our society.

The cathinones themselves are synthetic, I won't talk about the pharmacology or toxicology that you have experts here to talk about, but I want to focus my talks pretty much on my clinical interactions with these individuals.

As previously presented, these are real challenges to us in medicine and to the drug treatment field.

Oh, I should have mentioned, I'm also

speaking as a member of the National Association of Alcohol and Drug Abuse Counselors, NAADAC, which asked me to make public hearing on this as well.

But these are real challenges, because we don't know what we're seeing, we have toxic reactions at rock concerts and on the street in which we can do stat or emergency toxicology on, but they often come up negative, because there's no standard, there's no analyte, there's no way for telling what these things are, so we have to go on our clinical experiences and what we're seeing on-hand in order to treat these individuals.

Just in the strange thing, my interactions are that these cathinones have a wide range of effects. They can go anywhere from stimulation to extremely toxic, overwhelming effects where individuals almost turn like zombies, very blank stare, very dilated pupils, their mouths form oftentimes like Edvard Munch "Scream", round mouth features.

They also have a vocalization which is

very weird, sometimes they start growling. Some of them are hyperactive, some of them are totally just non-mobile, except they can move and act.

So, these things are real challenges and sometimes we've just got to guess that they're under bath salts or under some sort of psychoactive substance when we're treating them and interacting with them.

The treatment is very, very difficult, as mentioned previously. We see rhabdomyloysis due to extreme hyperthermia. There is an extreme high blood temperature, body temperature that goes up to the point that blood begins to coagulate and get muscle dying off. It clogs up the kidneys, the kidneys shut down and we have to treat them.

And that's one of the clinical treatment concerns. When people come in for bath salt treatment for addiction, we have to really monitor them more closely, watch their body temperature a lot, watch their body symptoms, because they may have much more toxic effects that people just coming in for methamphetamine or

for cocaine abuse.

So, my program is a pretty much a medically -- it goes up to what we call Level III treatment in Oregon, which means we do medically monitored treatment.

We don't have the full hospital-based treatment that's a IV treatment system, but it gives us a real challenge and we, as much as possible, have to refer a lot of these people to our medical emergency rooms and things like this, where they have nothing but troubles in them.

In terms of the treatment -- oh, I'm over, but in addiction treatment, they are a little bit more difficult to treat. They do have a lot of relapses. We can't monitor their urine, because you can't find anything in their urine.

They have -- they circumvent the drug court system, they circumvent our clinical interactions, and they offer us a lot more concerns in treatment.

But we do manage them, like methamphetamine addiction. And some of them are now combining their bath salts with the fentanyl

and the opiates to do something called speedballing, and that's a new concern of ours.

Thank you very much.

ACTING CHAIR PRYOR: Thank you, Dr. Inaba. Questions?

COMMISSIONER BREYER: I have a specific question about your case that you told us and then, a general question that the panel can answer.

But the first question is, did you have any understanding, which you've arrived at subsequently, to his immediate treatment as to what his drug history was? And what led him to take the drug that you've described? Did you find out anything about that?

DR. BOREK: So, a lot of times in these -- we did not and that's very common in these cases. He was unable to participate in giving us any history, because of how acutely ill he was. We had gotten some history from his girlfriend, who said that he had injected these.

But a lot of times, we don't know the history on these people. Sometimes, we don't

even know their names and we have to enter them as a John Doe in our system in order to treat them.

COMMISSIONER BREYER: But is there a pattern that you've seen with these drugs that there is some gateway to it, they've tried X, they've tried Y, and now, they're into Z, into this? Is there a pattern or is it just random?

DR. HOLSTEGE: So our colleagues at the University of Virginia, in psychiatry, again, it's about sampling size, right, how big.

But part of it, the two top things that came up, when they sampled their patients who were coming to their addiction clinic on why they used this, one was to try a new high and the other was to beat drug screens.

COMMISSIONER BREYER: To be what?

DR. HOLSTEGE: Beat the drug screens.

COMMISSIONER BREYER: Beat the drug screen?

DR. HOLSTEGE: Yes, beating the drug screen, and this is a huge problem in my practice also in regards to occupational medicine too,

because they're only doing the original NIDA-5 plus others, but you can't detect these.

So, in occupational medicine, this is a huge problem for them right now, because if nothing's detected, where's the causality?

But they've -- the internet has opened up Pandora's Box, one to access, the other thing is to learn about these things to beat the drug screens and know that you can't find these, unless something, of course, detrimental really occurs, like in this case, where we have a public health need to do testing for it.

DR. INABA: Might I add to that, there's also, because of the internet, probably, or maybe in addition to it, these drugs are more available, strangely. They can get them easier and they're cheaper.

And that's the other reason, they can get them cheaper than other street drugs, and that's what many of our clients start off, as the profile might be.

They are drug-seekers, they are in the frequent drug user subculture. Most of these are

amphetamine aficionados or stimulant, they like stimulant drugs, and this is a natural progression to experiment with these drugs.

They're available, they're cheaper, and if you're in any kind of legal situation, or even if you're in treatment, that's our concern, they're in treatment and this takes away our real scrutiny here to monitor their progress in treatment.

COMMISSIONER SMOOT: I have a really quick question. Is there any -- I know that you said that you couldn't really treat him for what he took or how much he had taken until a week later, but do you have any idea how much of what he took he took to get to that effect, to have that kind of effect?

DR. BOREK: No.

COMMISSIONER BREYER: Is it highly individualized? In other words, does it depend, X quantity will have this reaction with Person A, that reaction, different reaction with Person B? Some can tolerate it, some obviously couldn't?

DR. BOREK: As I think the previous

panel, the speaker had alluded to, it depends on the dose and it does depend on the person.

There's probably factors we haven't figured out now, genetic factors or other things that would make some people more susceptible to the effects or more significant effects, perhaps, than another person.

And so, it is individual and a lot of times --

COMMISSIONER BREYER: Is there a benign effect? That is to say, is there some dosage, some potency, and some person, who could take these drugs and just experience a, quote, high, without experiencing these horrible, horrible effects? Or is the drug such that you take it and you're going to have this type of --

DR. INABA: I think the deal is, it's the drugs, there's not just one.

COMMISSIONER BREYER: Okay.

DR. INABA: There's multitudes out there and each one, just a simple modification of a molecule on that substance creates a tremendous different profile on how that drug's going to

affect the individual and how strong it's going to be, what it's dose is going to be.

There are individual differences, there's these other things we talked about, but the individual drugs themselves, we find as they come out. They come out every year, there's a new one hitting the street.

COMMISSIONER BARKOW: And is that, what you're saying, within the class of cathinones or do you mean cathinoids, cannabinoids, the fentanyl? Like, if we were just looking at the cathinoids --

DR. INABA: Just looking at cathinones themselves, there's a big difference in the different potencies and different toxicities of cathinones.

But then, there's other new drugs that are not chemically cathinone, but maintain, I think one of the testifiers originally talked about, I forget the term he used, but the structure-activity relationship is what we use.

You get -- once you figure out what it takes in certain atoms, how to be together to

create certain effects, you can create a whole tinker toy, a bunch of new drugs that aren't technically cathinones, but fit that structure-activity relationship to do the same thing.

And so, that's -- there's new ones coming out that aren't even cathinones --

COMMISSIONER SMOOT: But then, how do you know --

DR. INABA: -- that do the same thing.

COMMISSIONER SMOOT: -- and I'm sorry to interrupt, but how do you know what that person took then?

DR. BOREK: So, in this case, we had sent out extensive testing to a specialized send-out lab and looked for extensive hallucinogenic compounds, amphetamine-like compounds, other cathinones. And at this point in time, a standard had been created for MDPV and so, it had come back positive.

DR. HOLSTEGE: Which is why we reported -- and realize, it gets to be a challenge. As the others alluded to, it's a grand human experiment that's going on with society right

now.

If you look at chemical structures, the beta-ketone substitution may be more so, but again, it's odd to me, I've been seeing cases of amphetamines, cocaine for years in my practice, they don't have the cellular destruction like this. And especially some of the cases that we've had with MDPV, methylone, mephedrone, those are some of the ones that we really saw some problems with.

And when you look at the literature, again, pretty hard to explain why during that time period, when it started to hit and then the laws came into effect, when we started to see a decline, many of us throughout the country who practice and take care of these patients saw a huge wave of people who came in with, again, multi-organ failure. Not always associated with fever either, there appeared to be some direct cellular damage.

The problem is, we cannot do these experiments on humans. We're not going to be able to give them these doses to see what effects

they have, we don't have that data right now.

And, again, they're changing quickly, because we saw flakka next, with alpha-PVP, which we saw similar effects with too.

COMMISSIONER BREYER: Can I ask about addiction? Are these -- because Dr. Inaba --

DR. INABA: Yes?

COMMISSIONER BREYER: -- suggested these are also addictive, is that your experience as well?

DR. BOREK: Yes, they cause release of dopamine, which creates that positive reward feeling and so, there is addiction.

COMMISSIONER BREYER: Have you had people who have repeated? Who have come in with this horrible --

DR. INABA: Yes.

COMMISSIONER BREYER: -- and then, going out and done it again?

DR. INABA: Yes. If a drug is addictive, with the dopamine release and the subconscious level, really in the mesocortex, it creates -- it hijacks the survival mechanism or

instinct in the individual.

And people will -- the definition of addiction is continued use despite catastrophic consequences.

COMMISSIONER BREYER: Okay.

DR. INABA: So, no matter what happens -- so, they go back and they use and they relapse. And that's one of our biggest challenges in treating addicts is the tendency to relapse.

COMMISSIONER BOLITHO: In a previous testimony, there was discussion of comparing these to cocaine and methamphetamine and where within that continuum these might fit. In terms of dangerousness to the user, where would you all put these drugs on that continuum? More dangerous to the user than cocaine? More than meth? Less?

DR. HOLSTEGE: It's all about dose, right, and we don't always know the dose, and where damage occurs. But I will tell you, again, in clinical practice and what we've had, in talking to my colleagues, we've never seen

anything quite like this.

And so, from a clinical perspective and what we saw and the people who are using this either admitted to using them or the analytics show that they were using them, had unbelievable effects from these.

Again, I see a lot of cocaine abusers and amphetamine abusers, they're not in my ICU like this. It's very rare to have them in my intensive care unit. They might come into the emergency department agitated, but they calm down and then, we can discharge them. They're not in for 18 days like this.

Yes, if you took a massive dose of cocaine, could you get there? And that's where you can get some of the discussions on, what about dose? Again, there's something unique in these substances that we saw too, that does appear to just have some direct cellular damage, that I've just never seen before with a drug of abuse.

COMMISSIONER BOLITHO: And if I could ask one follow-up related to that, you mentioned

the combativeness and the violence, do you see that more pronounced with these drugs than you do with people who come to the emergency room with cocaine or methamphetamine? Or is it similar?

DR. BOREK: I would say you certainly can see that with cocaine. I think there are a number of cases out there that this is a predominate effect with these synthetic cathinones and seems to be the norm.

I've seen a number of people who have done cocaine who maybe complain of some chest pain who are calm and cooperative. And close to 80 percent of the people that are using bath salts are combative. So, I'd say it's a more predominate effect.

COMMISSIONER REEVES: Just one question. You mentioned that some other universities and hospitals were seeing similar effects. Are you able to say, is this nationwide? Is this East Coast? South?

DR. HOLSTEGE: This was nationwide when it came out. So, when you look at 2011, the beginning of 2011 especially is when things

really hit. And that was nationwide.

Only a few of our colleagues have the analytical capabilities to be able to really determine what was going on, had very tight alignment. It's changed for us at the University of Virginia, we hired an epidemiologist to work full-time so we could track this quicker for the State.

And also, we are working much closer with our analytical colleagues at the Division of Consolidated Labs and others, so that once we start recognizing that something's changed in our patient population, we can get analytics done as quick as possible, because they're going to have back-extrapolate to figure out what it is if it's a new substance.

COMMISSIONER BREYER: Have you seen a higher incidence of this use as a result of, like, concerts where kids go and -- maybe I have to ask that of enforcement --

DR. HOLSTEGE: So, in our --

COMMISSIONER BREYER: -- the enforcement panel, but I would be interested in

your experience.

DR. HOLSTEGE: So, in the college population, tremendous concern by, certainly, our administration at the University and other universities.

Our student drove up by bus to D.C. to a concert, which is where she then started to act abnormally and by the time she made it to the emergency department, she had cardiac arrest.

At that time, there was a concert in New York, and I'm trying to remember which one, where two others had died, where they actually had to stop the concert, where those two also had synthetic cathinones, that's my understanding based on the media reports, in their system.

So, yes, for the youth, it's a big concern that these are passed around. And, again, you can do these substances, we saw every way, they were trying -- they shoot them up, they snort them, they'll take them as a tablet, and some people were doing it rectally.

So, there's a number of different ways people were doing these, to try and see, how is

the best -- what kind of effect would they get from these substances? Which we see with our drug abusers.

But the tablets are what really worry me about the collegiate population, because they see that as a safer thing and then, they put names on them. We know that's in molly, for example, which used to be ecstasy, it's being found in there.

But they put it in kind of unassuming names that our collegiate population don't have any idea what they just got into. Yes.

DR. INABA: Concerts offer a huge sales opportunity for the traffickers of these drugs to get new people interested, buy them at the concerts, cheap prices. And we've seen clusters of these when they appear.

Like molly was supposed to be pure MDMA or ecstasy, but it appeared at a concert and turned out to be one of the cathinone derivatives. It had several toxic effects and then, that's how they find out how toxic these things are at the doses they're selling it.

COMMISSIONER BARKOW: Can I ask you a question about, when you were saying that now they're combining the chemical structures, so they're not pure cathinones.

So, just in terms of staying ahead of this or thinking about what comes next, so if we were to figure out some kind of categorical approach that deals with cathinones, cannabinoids, fentanyl, you're saying there's an additional -- there's an endless amount of combinations that places them outside even those existing categories that --

DR. INABA: Yes, that's the scary part of this. But the thing is, you also have legitimate medications and legitimate products that are also within those categories and that's what you have to sort of -- what is the intent here?

It's interesting, the bath salts are -- oftentimes, they're sold as jewelry cleaners, they're sold as plant food, they're sold as lady bug -- I mean, they're sold as anything. But the giveaway for us is, not for human consumption

very prominently on the label packages.

And that's a giveaway for people, this new kid on the block, to shoot up or --

ACTING CHAIR PRYOR: It'll say poison on it.

DR. INABA: Yes.

ACTING CHAIR PRYOR: What about that one?

DR. INABA: So, that's a concern we have for these compounds. Yes, you can -- like, right now, I think there are nine to 11 chemical families, not single chemicals, 11 chemical families used to make synthetic cannabinoid-like substances or things that act like marijuana.

So, that's huge to try and keep on track of, in terms of what you're suggesting here, but there is a structure-activity relationship that pharmacologists talk about in terms of knowing where the atoms have to be in certain places to do certain effects.

And that might be a road to do it, but it also means it's going to incorporate a lot of other substances that might not be evolved for

abuse.

ACTING CHAIR PRYOR: Okay. Thank you. We appreciate your presentations this morning, the answers to our questions, and your written presentations as well. We're going to take a break and assemble back here at 11:00 to hear from our third panel. Thank you.

(Whereupon, the above-entitled matter went off the record at 10:44 a.m. and resumed at 11:02 a.m.)

COMMISSIONER PRYOR: Our third panel will focus on the chemical structure of synthetic cathinones. Our panelists are Dr. Terrence Boos and Dr. Gregory Dudley.

Dr. Boos is the section chief of the Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration. Dr. Boos's responsibilities include managing a multidisciplinary group of scientists.

The group routinely initiates studies to increase and apply scientific knowledge as it pertains to drugs of abuse and chemicals for

regulatory control and provides scientific support to federal, state, and local public health and law enforcement officials related to drugs of abuse. Additionally, the section provides scientific support to federal prosecutors.

Before joining DEA, Dr. Boos was a research fellow at the National Institute on Drug Abuse in the Drug Design and Synthesis Section.

Dr. Dudley is the Eberly Family Distinguished Professor and Chair of the C. Eugene Bennett Department of Chemistry at West Virginia University since 2016.

Previously, he was on the faculty in the Department of Chemistry and Biochemistry at the Florida State University from 2002-2016, during which time he also served, first informally then formally, on the graduate faculty in the College of Pharmacy and Pharmaceutical Sciences at Florida A&M University in Tallahassee.

In addition to his numerous scientific publications, Dr. Dudley has provided expert

testimony in many federal and state court cases involving synthetic controlled substances. Dr. Dudley received a Bachelor of Arts in Chemistry from Florida State University in 1995 and a PhD in Organic Chemistry from the Massachusetts Institute of Technology in 2000.

Dr. Boos.

DR. BOOS: Good morning, Judge Pryor and distinguished members of the United States Sentencing Commission. On behalf of the DEA, I'd like to thank you for the opportunity to briefly discuss synthetic cathinones and to really provide some information on this very important issue.

Synthetic cathinones represent a structural class of substances that have rapidly appeared on the designer drug market. And in response to traffic and abuse of these substances, DEA has been required to utilize all tools in a response to protect the public.

The rapid proliferation of the cathinones represents a continued challenge for both law enforcement and public health. This is

highly relevant, for in some cases these cathinones have become the psychostimulant of choice for users.

Substances from this class continue to be slightly altered in their chemical structure in an attempt to circumvent regulatory controls while maintaining that ever-important pharmacological effect. In a straightforward manner, the cathinone class is easily recognizable and serves as a means of grouping substances that share a minimum cathinone skeleton.

It remains evident traffickers are trolling the scientific and patent literature for new cathinones to introduce on the designer drug market. As new substances from this class appear, the DEA rapidly mobilizes to collect information on the specific substance.

The chemical structure is extremely critical. It plays a guiding role in our activities and what tests we are going to conduct. This information is used to prioritize the most harmful and persistent substances for

regulatory control, but it also is used in legal proceedings.

In attempt to keep pace with the new substances being encountered, some countries have responded with class controls on the cathinones based on their chemical structure. The scientists in DEA's Drug Chemical Evaluation Section are frequently required to testify at sentencing hearings in order for a court to determine that substance in a guideline most similar to the newly controlled substance or possibly the analog.

Our section often provides both a chemist and pharmacologist to testify as to the criteria established by the Commission under application note 6. These are resource-intensive for all involved, especially considered testimony may be requested for the same substance in multiple cases.

Likewise, the defense will also provide experts at a sentencing hearing. These hearings at times are contested, and yet, and the court must weigh through complicated scientific

evidence. Even after one court reaches a conclusion about a guideline, comparison to other courts can and do relitigate the issue, sometimes with disparate results

The consideration of providing sentencing equivalencies for a drug class would assist courts, prosecutors, and defense attorneys in providing greater certainty for all involved. This remains an issue, for there are many cathinones that remain possible.

DEA is committed to doing everything we can do to address this threat. We look forward to working with the Commission to address these substances. Again, thank you for considering this issue, and I'll be happy to take any questions.

COMMISSIONER PRYOR: Thank you, Dr. Boos. Dr. Dudley.

DR. DUDLEY: Thank you for the opportunity to return and testify before the Commission.

In April I advanced the idea of a categorical coverage for synthetic cathinones.

This is an idea that I think has merit. It's certainly not without particular complications with regard to the pharmacological effects, but in terms of chemical structure, it can certainly bring a lot of clarity to the guideline coverage for cathinones.

So my opinions and recommendations here focus on cathinones as a structure class, with the understanding in the background that cathinones are generally associated with stimulant properties. There are cathinones in medicine, including bupropion, Wellbutrin, which is prescribed for depression, anxiety and smoking cessation; and diethylpropion, trade name Amfepramone, which I believe is prescribed for obesity, for short-term treatment of obesity as an appetite suppressant; and Pyrovalerone, which has shown some use for chronic fatigue.

Cathinone drugs of abuse include methylone, pentylone, alpha-PVP, MDPV, mephedrone, etc. Then that etcetera encompasses many substances that are continuing to emerge. And I support the idea of guideline revisions to

address synthetic cathinones. I think this is a timely and important task.

The goal should be to provide reasonably harsh penalties for emerging synthetic cathinones that are consistent with the current guidelines and that allow the guidelines to keep pace with emerging trends and emerging substances. My recommendations are primarily two.

One is to list specifically methylone, alpha-PVP, and MDPV, along with methcathinone, which is already in the guidelines, and/or cathinone itself as the parent of the class of compounds. And either a) allow the courts to extrapolate from these listed substances to other substances like methadrone and ethylone. Or, b) also provide categorical coverage that provides guidance on cathinone substances that can be definitively identified as cathinones but are not otherwise specifically listed.

Second recommendation would be to provide categorical coverage for synthetic cathinones based on chemical structure.

Along with that categorical coverage should be, in my opinion, a) a definition of the category so that there's no ambiguity as to what is intended to be covered by the structure of cathinone derivatives. And/or b) illustrative examples. For example, methylone, alpha-PVP, MDPV, methcathinone and/or cathinone itself.

It is my belief that categorical coverage of cathinones as a class, a structure class, plus specific examples would provide substantial guidance to the courts in providing logical and consistent sentencing for these and other synthetic cathinones within the stimulant category.

A few comments on cathinone as a structure class. These are synthetic cathinones or designer cathinones, are chemical derivatives of cathinone, which is a naturally occurring molecular substance. Similarly, amphetamines are chemical derivatives of amphetamine.

The chemical structure of a cathinone of a substance in question once it has been identified as a cathinone, we can take it as

given that the chemical structure is known and unambiguously assigned to the substance, and that the substance can unambiguously be placed into the cathinone structural category. In contrast to pharmacological effects, which are often having to be guessed at, based on, for example, the chemical structure.

In terms of where synthetic cathinones are most appropriately placed within the guidelines, I think guideline coverage for the amphetamines, the chemical substances derived from amphetamine, provides a logical framework for listing the cathinone derivatives.

For example, there are many amphetamines listed in the guidelines, methamphetamine and amphetamine at the high end. MDMA is also listed as the methylenedioxy derivative of methamphetamine. And dimethylamphetamine is also listed among others that encompass a range from about 40 to one to in their marijuana equivalency, up to methamphetamine, which is dually listed at 2000 to one and 20,000 to one.

In those series of compounds, I note that the parent compound, amphetamine or methamphetamine, is the most severe, and that there are certain structural features that have been added that can be associated with different penalties.

Therefore, in conclusion, I would propose that the cathinone or methcathinone derivatives should be added to the guidelines both specifically and categorically relative to methcathinone in the way that many amphetamines are added to the guidelines or have been added relative to amphetamine and methamphetamine.

I believe this structural classification of cathinones will cover cathinone substances. Stimulant abuse is of course broader than cathinones, but this categorical coverage of cathinones would address the emerging synthetic cathinones.

COMMISSIONER BREYER: Let me ask you, Dr. Dudley about your, the etcetera.

DR. DUDLEY: Yes.

COMMISSIONER BREYER: Because I think

in the etcetera is in my view perhaps a large part of the problem, because we don't know where these things are going. Your proposal is you say one gram of other synthetic cathinone substances. So you sort of, you talk about specific synthetics, and then you say other, which I have to believe is the etcetera. Is that --

DR. DUDLEY: Yes.

COMMISSIONER BREYER: Am I right on that? And you say 100 grams of marijuana, the equivalency.

DR. DUDLEY: That, yes.

COMMISSIONER BREYER: Okay, so my question is how do we get there? Why is that, that is roughly 25% of some of these other things.

DR. DUDLEY: And roughly two and a half times some of the others. There are, for example, N,N-dimethylamphetamine is at 40 to one. MDMA is at 500 to one. So there's a range of amphetamines, and there are a range of stimulants.

There's also methylphenidate, which is

another structural class. It doesn't fall into either of those structural classes, but falls under the stimulant category.

COMMISSIONER BREYER: So how do you arrive, how do you -- you know, you say a gram of cathinone is 380.

DR. DUDLEY: Yes, that is my personal recommendation.

COMMISSIONER BREYER: Pardon?

DR. DUDLEY: That would be my personal recommendation for listing cathinone as equivalent to at the same level as methcathinone, similarly to the way amphetamine and methamphetamine are at the same point in the guidelines.

COMMISSIONER REEVES: How does that conversion, would apply to methamphetamine?

DR. DUDLEY: I'm sorry?

COMMISSIONER REEVES: If you could give us the equivalent. This is substantially lower than methamphetamine with the conversion to marijuana equivalents.

DR. DUDLEY: Right, so amphetamine and

methamphetamine are both already listed in the guidelines. Methcathinone is already listed in the guidelines. and I would propose, I would recommend adding cathinone to the guidelines at the same level as methcathinone.

And then the substituted derivatives of cathinone and methcathinone like methylone, which is the MD derivative of methcathinone, I would propose, I would recommend listing that new substance as something lower than methcathinone itself, in the same way that the MD derivative of methamphetamine is listed lower than methamphetamine itself.

So MDMA is at 500 to one, methamphetamine is at 2000 or 20,000 to one.

COMMISSIONER BREYER: And that's what I understood you to say. But I'm trying to figure out, what you've constructed here is sort of a chart to give an overall, in your view, an overall coherence to the relative treatment for these drugs that we've given to other drugs.

DR. DUDLEY: Yes.

COMMISSIONER BREYER: That's what I

hear you say. And I don't whether what we've done with other drugs makes sense or not. But I'm asking -- the testimony I've heard today is pretty frightening in terms of impact on an individual who takes these drugs. So I don't know where I come out.

I'm trying to figure out why you've come out to saying, well, it should be 25% or 30% of some other drug. And is it because you think, and I don't want to put words in your mouth, but is it because you think that really overall, the harm that's caused by this drug in question is maybe, is less harmful by a factor of two or three or four than the other drug?

Is that your, been your experience? Or is it just sort of a formula of convenience, that's what I'm trying to figure out. The underpinning of it.

DR. DUDLEY: Right. So what I think broadly is that stimulant abuse is a big problem. And the testimony that we've heard this morning about people overdosing on new cathinones reflects a combination of the danger of specific

synthetic cathinone substances, coupled to the availability, the novelty, and the lack of information, in particular with regards to what is a toxic dose.

There is a larger history, for example, with cocaine abuse that might allow a new user to differentiate between what is the dose that might produce the desired effect for that particular user and what is likely to put someone in the emergency room or worse. That information may not have been available to people who are experimenting with new designer cathinones.

That would be, my general opinion is that experimentation and abuse of stimulants in general is dangerous and is appropriate to regulate. As it comes to specific cathinone substances, I would recommend a, again, reasonably harsh penalties that would address the concerns of the emerging cathinones.

If they're set too low or too high, there can be unintended consequences, potentially shifting people to non-cathinone stimulants that

then resets the cycle of experimenting with new substances.

How I got to these specific numbers is subjective. And I included specific numbers because I was asked for recommendations to the Commission, and I thought it would be appropriate to provide specific numbers. How I got to those numbers was from looking at the broader guidelines and seeing what made sense to me, what would fit within the broader guidelines.

COMMISSIONER BARKOW: Can I ask you a quick question. I'm sorry. So the methcathinone at 380 grams is preexisting standard. And so if I'm understanding you correctly, is it your opinion then that if we take that as our anchor, if methcathinone is 380, your assessment of these other variations is that they're not as harmful, or they're--

Because they're listed in a way that suggests, other than cathinone, which you put on par with it, which I guess is similar to the amphetamine-methamphetamine parallel. But for the other forms, is the reason that you decided

to do those at level that's less, is it -- I guess it's a similar question.

Is it based on how we've dealt with other derivative substances elsewhere in the guidelines? And/or is it also saying that you're saying these other forms are not as harmful or as potent as methcathinone? I'm just trying to get a sense of if we use that as our anchor why you have them as less.

DR. DUDLEY: Why I have them less.

COMMISSIONER BARKOW: Yes, separate and apart from the specific number, kind of why they are less.

COMMISSIONER BREYER: Right, right. The answer to that is because while I am familiar with the pharmacological effects as they are understood for some of these substances, if we are talking about a structural classification, then chemical structure is the guiding set of facts behind constructing a logical sentence, logical equivalencies.

And the closest analogy in the current guidelines to the cathinones, in terms of

chemical structure, is the amphetamines.

And so I'm suggesting using methcathinone as the anchor, and then listing other substituted derivatives in the cases that I identified as lower, because there are parallels in the amphetamine series that is more broadly, where there is broader guidance in the guidelines.

So it was an attempt to be, in terms of chemical structure, consistent with the current guidelines.

COMMISSIONER BARKOW: Thank you.

COMMISSIONER BOLITHO: One of the chemicals that you have listed is MDPV.

COMMISSIONER BREYER: Yes.

COMMISSIONER BOLITHO: And you have that listed at one to 40, is that right?

COMMISSIONER BREYER: Yes.

COMMISSIONER BOLITHO: And if my understanding of the prior testimony is correct, that actually is the substance that the two physicians from the University of Virginia testified that their patient had all those

terrible effects from, right?

COMMISSIONER BREYER: Yes.

COMMISSIONER BOLITHO: And so in your opinion, that drug should receive a ratio of one to 40, which is one of the lowest ratios in the guidelines.

DR. DUDLEY: There are certainly lower ratios than one to 40. But among the Schedule I, Schedule II stimulants, that is at the low end. And again, I think any of the, any stimulant can be subject to abuse and can result in severe health consequences for taking too much of them.

And part of the problem with the emerging synthetic cathinones was a lack of information coupled with easy availability. That, in my estimation, certainly could be seen as a recipe for overdoses. Whereas the specific substance could have, was MDPV in the particular case, any number of stimulants taken at a high level could produce severe health consequences, if not fatalities.

The rationale for where I had recommended listing MDPV is again based on

chemical structure, relative in this case to alpha-PVP, or Flakka, where MDPV is the derivative of Flakka, of alpha-PVP, that has that methylenedioxy ring.

COMMISSIONER BOLITHO: Dr. Boos, do you have any reaction to the testimony from Dr. Dudley, or what's your sense?

DR. BOOS: Yeah, I'm struggling a little bit to follow the logic of why you would place these substances below that of methcathinone and others. I will share that based on our experience, the cathinones have been the most harmful and persistent substances we've encountered on the designer drug market.

The effects and just, we heard a portion from that panel earlier. It's been, they're of great concern. The user doesn't know what they're getting a hold of. They're overdosing on a substance and they're not sure, when they present medically, how to treat them, other than the conditions they present.

And so for us as an agency trying to protect the public, they're an incredible

challenge for us. But the harm is well established as to what they're causing to the community.

COMMISSIONER BREYER: To follow up with a question. I'm interested in what the DEA has found, if they have, as to the potency of any particular quantity in the field. It always mystifies me, you know that judges frequently don't look at, in terms of sentencing, well, this was 80% pure or this was five percent pure.

It was cut this way, it was cut that way and so forth. But it obviously must have an impact on a user who may, witting or unwittingly, have a sense, because it's a white powder, have a sense of what is the purity, what is the level of toxicity, I guess is the right word.

Do you have any experience in that area, or is that something that we should look at, or what do you think?

DR. BOOS: The purity of the drug, especially what's encountered on the illicit market, is highly dependent on where it's at in that supply.

COMMISSIONER BREYER: Right.

DR. BOOS: And we've noticed that a lot of these substances come in from a foreign source. They're immediately packaged and sent out. And often what we encounter on the illicit market is a highly pure substance. They haven't been cut.

There are examples where they have been cut, and in our written testimony, I gave a product, a glass cleaner, that had been combined with multiple cathinones, other stimulants, that's an example of somebody that's marketing a specific product to the user. They're asking for a strongly, a product that's a strongly powerful stimulant.

It's very -- but those studies as to quantitating, they're just not conducted by the forensic laboratories. It would be a special study.

COMMISSIONER BREYER: And if I could ask one question just on the chemistry point to see if there is some agreement here. Do you both agree that there is a core to these cathinones

that, regardless if it's a new designer drug, we could put this chemical structure in front of you, Dr. Dudley, and you, Dr. Boos, and others, and there would be general agreement that this is a cathinone.

DR. DUDLEY: Yes, I think there certainly should be.

DR. BOOS: I'd agree to that. There's a skeleton that's associated with this that would align an entire class of substances.

COMMISSIONER BREYER: So did you hear the testimony from one of the earlier witnesses, I forget whether it was Utah or Ohio, they had this screen that said it's pretty easy, if it fits within this screen, it's cathinone and we can deal with it. That seemed like a very attractive approach for the Commission to take because it's simple, it's clear.

DR. BOOS: I think, and based on my experience of the scientific community and based on what's also published in the literature, the class itself is very well defined and accepted.

DR. DUDLEY: Yes, I agree. A

categorical listing of synthetic cathinones would be generally, and I think immediately and universally recommended. It would cover then all of the emerging substances that have that cathinone core. It would not necessarily capture all the emerging stimulants, but it would capture the synthetic cathinones.

COMMISSIONER BREYER: So to follow Mr. Bolitho's question, you were here earlier when these cases were described and we could see and hear, and your recommendation is, I think, what, that it be treated as 100 grams?

DR. DUDLEY: Yes.

COMMISSIONER BREYER: All right, so of course the harm is extreme in those cases. Forty?

DR. DUDLEY: Yeah, I think --

COMMISSIONER BREYER: Well, whatever. I mean it's a -- it's not -- however, the harm caused in these cases was as frightening as you could imagine. And actually, in the testimony there's examples of it.

Do we know anything about, or will we

be able to determine anything about, the dosage that any individual took, and is that sort of in a sense idiosyncratic? Would you come to the conclusion, based upon what you'd seen, well, he took, obviously he overdosed and took a much large quantity of the drug than is traditionally dealt out on the street?

It's the equivalent of going into some place in Colorado and buying a whole box of cookies and eating them at one time. I mean, you just don't do that. You know, you're going to have a terrible, terrible reaction. Do we know whether that happens in the case of cathinones?

DR. BOOS: So for example, when you look at the pharmacology of the drug and it's comparable to that in methamphetamine. It's at least as potent as methamphetamine, if not more. We need to talk about MDPV. You put in a separate category the toxicity associated with MDPV.

It is extremely toxic. As you heard earlier, multiple organs are affected by the drug. So you have a pharmacology that shows that

it's comparative, what it's comparative is as to its stimulant properties.

Then you have another whole category of toxicity associated with the drug.

COMMISSIONER BARKOW: Doctor, just can I ask you for how would you describe the effects of methcathinone? So if that's our existing anchor, how would these other types compare to that, which has, you know, is set already at 380?

DR. BOOS: It would be a great comparative. Methcathinone isn't an extensively studied drug. Your extensively studied --

COMMISSIONER BARKOW: It's not?

DR. BOOS: It's not an extensive--. so for example, the pharmacologist testifying on that earlier panel, their primarily compared cocaine, methamphetamine, and MDMA as some of the comparatives that are traditional drugs.

COMMISSIONER BARKOW: And that's true of cathinone too, so methcathinone or cathinone, either one, we just don't know.

DR. DUDLEY: And if I could address the question as well regarding the MDPV overdoses

for example. I don't believe that clear information on the dose would have been available on at least many of the anecdotal case reports and the hospital presentations.

There are serious medical consequences of overdosing on other stimulants. There are, for example, caffeine has been sold in nutrition, concentrated forms of caffeine have been sold over the counter and have led to people overdosing and dying from caffeine consumption.

COMMISSIONER REEVES: Well, what would you say would be an accidental overdose amount, five grams?

DR. DUDLEY: I don't know.

COMMISSIONER REEVES: If we say, let's say it's five grams. That's the equivalent of 200 grams of marijuana under your conversion chart. That's range of probation for the seller that would have sold those drugs that would have caused all those consequences. Would you say that's a reasonably harsh penalty?

DR. DUDLEY: I think one could look at the specific number for doses to the extent that

those are available. And that data, those pharmacological effects data, can and should inform the scheduling of specific substances.

But if we're talking about or when we are talking about the pharmacological effects, those then become more specific to specific substances. Whereas what I'm proposing for the categorical coverage is based on chemical structure.

To further address the statements that MDPV versus methamphetamine, I would point out that they have similar but slightly different mechanisms of action that make head-to-head comparisons complicated. MDPV is a re-uptake inhibitor, whereas methamphetamine is more of a, stimulates the release of the various neurotransmitters.

And this can have consequences, or this can result in different outcomes depending on how you set up the experiment. And yes, the emerging synthetic cathinones have typically been compared to cocaine, MDMA, or methamphetamine.

By virtue of those compounds being the

compounds chosen by the experimenter, the experimenter could similarly have chosen methylphenidate or Ritalin as the comparative substance, and then dimethylamphetamine or other stimulants that are currently in Schedule I or Schedule II.

COMMISSIONER PRYOR: Okay, thank you for your presentations, thank you too, for your written presentations. We're going to go to our final panel.

(Pause)

COMMISSIONER PRYOR: So our fourth panel and final witness, Mr. Neil Doherty, focuses on the trafficking patterns of synthetic cathinones.

Mr. Doherty has served as the Associate Deputy Assistant Administrator in the Office of Diversion Control at the Drug Enforcement Administration since January of last year. Before his current appointment, Mr. Doherty served as the Assistant Special Agent-in-Charge of the DEA's Phoenix field division.

He is a graduate of Norwich University

and has completed executive leadership management programs at the University of Notre Dame and U.S. Army War College. Mr. Doherty.

MR. DOHERTY: Judge Pryor and members of the Sentencing Commission, thank you for holding this important hearing and the opportunity to appear before you today to talk about synthetic drug trafficking and the effects that we all see in this country relative to synthetic drugs, specifically cathinones.

I'm currently a member of DEA's Diversion Control Division, and I think it's important for context to point out that the Diversion Control Division within DEA has both a regulatory and enforcement function for the Agency in that we regulate the approximate 1.8 million registrants in the country that are authorized to manufacture, distribute, prescribe, and handle controlled substances.

On the operation and enforcement side of the house, we also provide programmatic oversight to our criminal investigations throughout the country, targeting those

prescribers and registrants operating outside the law, the dirty doctors, rogue pharmacists, pill mill operators. And we also track NPS synthetic drugs and provide support to our workforce relative to these investigations.

Synthetic substances continue to cross our borders at an alarming rate and put all citizens of all ages, especially our youth, at risk of permanent injury or death. The drug threat remains a focus for DEA, along with the opioid crisis, which has been compounded in complexity with the advent of illicit fentanyl pouring into our country.

The convergence of synthetic drug trafficking and the opioid epidemic represent a deadly perfect storm which this nation has never experienced. Synthetic cathinones are highly dangerous substances that are marketed as a legal high and have adverse effects that are unpredictable in their psychological and physical impact on each user.

These substances are easily available through various outlets, from the internet,

convenience stores, gas stations, street dealers, and drug trafficking organizations. Anyone can easily order these substances, have them directly shipped to their doorstep without detection, or purchase them locally without scrutiny.

These substances are marketed to consumers as glass cleaner, bath salt, plant food, and often are labeled not for human consumption as a means, false means, to defend against the government's utilization of the Federal Controlled Analogue Enforcement Act, the Analogue Act, which requires proof that substances were indeed intended for human consumption.

Synthetic cathinones are primarily manufactured in and imported into the U.S. from China. They are produced from a variation of chemicals by foreign chemists and shipped into the U.S., usually in powder form. After entering the U.S., the substances are often mixed with other substances and placed in capsule, tablet, or powder form.

They are then packaged for

distribution as various brand names, such as Molly and Flakka, throughout U.S. distribution warehouses within our borders.

These substances can range, and the traffickers dealing with these substances, can range from large-scale poly-drug trafficking organizations to individuals who either package the substances for resale in small quantities, or distribute the drugs in kilogram quantities.

What is the reason for the sustained criminal interest in synthetics, what is the motivation behind the often deadly tactics relative to the struggle? In a word, profit. Synthetic cathinones provide criminal organizations with highly elevated margins for profit in illicit revenue.

For example, one kilogram of a synthetic cathinone purchased in China for between two and five thousand dollars can reap $250,000 once that kilogram is broken down into one or two gram packages within our borders and sold for $20 each per package.

Even though we have had success

against members of criminal synthetic organizations, there remains frustration. Foreign-based cathinone manufacturers and their domestic collaborators often operate with impunity because they exploit loopholes in the analogue provisions of the Controlled Substance Act and capitalize on the lengthy, resource intensive and reactive process required to temporarily or permanently schedule these dangerous substances.

As we speak, criminal chemists in foreign countries are tweaking the molecular structure of different synthetic cathinones, keeping the same dangerous pharmacological properties as the controlled substances, but helping the manufacturers and distributors avoid criminal exposure because of an altered molecular state.

DEA has utilized emergency control authority on 15 occasions to place 45 designer drugs, to include 13 cathinones, temporarily into Schedule I. Recently DEA published two notices of intent to temporarily initiate the control of

four additional synthetic drugs for possible control.

This is critically important, but we realize this is reactive, resource intensive process that leaves us steps behind the criminals that we investigate. We will continue to do everything we can on the scheduling front. However, simultaneously, this esteemed body could provide DEA and our law enforcement partners with immediate relief by adopting a class approach to these deadly substances.

DEA understands the unique challenges posed by this constantly evolving threat and remains hopeful for a class approach that would treat a new synthetic cathinone the same as others in the same drug class.

For DEA and our federal, state, and local partners to be successful in dealing with this threat, we need a balanced, whole-of-government approach, one that attacks supply and also works to reduce demand. We need to lean forward and use all available investigative techniques to identify, infiltrate, indict,

capture, and convict all members of these foreign organizations, foreign and domestic.

With 221 domestic offices in 21 field divisions and 92 foreign offices in 70 countries, DEA, through domestic and international collaboration, is well positioned to engage in this fight. Our most challenging victories were won through teamwork across agency lines, and stemming the tide of threat will similarly require all hands on deck.

The brave men and women of the DEA remain committed to doing everything they can to address this threat. Thank you for the opportunity to appear before you today, and I look forward to any questions that you may have.

COMMISSIONER BREYER: If I may, in your testimony, and in your written testimony as well as your oral testimony today, you use the example of a kilogram coming in from China that then costs or to be sold, it's $2000-5000.

Then you go on to say and then it's cut and broken down to one to two gram packages. When you say it's cut, are you saying it's then,

the cut is mixing it with other chemicals, other substances?

MR. DOHERTY: So can I share -- that's an excellent question. We see this come in in kilogram form from China, usually and generally via mail systems, private mail and the U.S. mail. Once it is within our borders, many times it's packaged in its intended form, in its pure form as it comes in.

Many times it's cut. It's cut with amphetamine, it's cut with other drugs. Traffickers try to maximize that kilogram for the most profit. But many times it doesn't need to be cut. But we have seen instances where it is cut with other substances.

COMMISSIONER BREYER: And I'm trying to figure out, let's say you have a street dealer who is, goes to a rave party or something and sells these things for, as you point out, $20 a package, and has ten packages. So that's a particular quantity.

I'm trying to figure out whether we could really address the harm that could be

caused by that if you don't take into account, or if you do take into account, how it's been cut down.

Do you think that it ought to be, from the DEA's point of view, should you take a look at it to see whether it's cut? Or should you take a look at, or should you ignore that and simply weigh it and see if it has some trace of the cathinone.

MR. DOHERTY: Well, Commissioner, that's an excellent point. And from DEA's perspective with our forensic laboratories, take Molly for example, which is marketed under the false pretense of being the purest form of MDMA.

Our laboratory investigations show that Molly, purported Molly, seemingly pure MDMA that the individuals think they're taking, is extremely dangerous and contains variations of several cathinones, some scheduled and some not. So to your point, that is something that we take into consideration.

COMMISSIONER BARKOW: What if it's sold like the bath salts or the glass, so they're

not going to a dealer. So if we, I'm just trying to get a handle on then when it's sold as these other products. So it's a gas station or it's some kind of store and it's the bath salts.

What's your enforcement strategy for something like that? How do you investigate a case like that to figure out who's responsible for putting that where it is and that it's not really bath salts? I mean, I guess it's a little weird if it's in your gas station.

But how do you go about kind of taking what is otherwise a lawful product if it was for the intended use of a bath, or glass cleaner, and trace it back to a drug distribution network? How do you investigate those things?

MR. DOHERTY: So again, and another excellent question. That is certainly a challenge for law enforcement based on prosecutions under the Analogue Act, which requires proof that the substance is indeed intended for human consumption.

However, like any investigation that DEA conducts, we rely on a series of traditional

and nontraditional law enforcement techniques. Tips, confidential informants, and ground troops with respect to intelligence with our state and local partners. Many times our synthetic investigations start with local police departments bringing us information and we expand upon the investigation from there.

As I said, the bulk of material coming in is shipped into the country misbranded, mislabeled.

And then once it arrives here, the DTOs, the drug trafficking organizations, and collaborators here within the continental United States will package and repackage that, sometimes as Molly or Flakka, as we saw the trend in South Florida. Or sometimes under other seemingly innocuous brand names to be sold in the stores that you mentioned, gas stations and other places.

So in terms of we always enter any criminal investigation at the appropriate point in terms of the evidence and the information that we have. But to your point, if we're looking at,

say, a gas station that has packages on the counter and we know that indeed is a synthetic drug, then we would investigate the establishment.

COMMISSIONER BARKOW: Do you make much money off those? Like how much are those sold for when they're?

MR. DOHERTY: Ten to twenty dollars.

COMMISSIONER BARKOW: Oh, so it's like a $20 pack of bath salts.

MR. DOHERTY: Potentially, yeah.

COMMISSIONER BARKOW: Okay.

COMMISSIONER REEVES: If we take this class approach, and I think everyone here is pretty much in favor of doing that, but if we set the penalties too low that it doesn't provide a deterrent, are we creating more of a problem than we have now?

MR. DOHERTY: I think, well, it's a excellent point. And I think that from DEA's perspective with the challenges that we currently face, we would encourage a class approach with appropriate set penalties. So to your point,

Commissioner, the penalties being set too low may be problematic.

COMMISSIONER REEVES: It may encourage more use perhaps than deter conduct.

MR. DOHERTY: Correct.

COMMISSIONER BREYER: Have you seen, in law enforce the last couple of years, have you seen an uptick or a change in how these drugs are being sold to the public?

MR. DOHERTY: Well, sir, some of our major enforcement operations during 2002, Operation Log Jam, which was the first synthetic takedown of its kind nationally with our state, local, and federal partners had a deterrent effect. And certainly as scheduling actions, both from a permanent basis and a temporary emergency basis, also have a deterrent effect.

Our second major iteration of a national takedown was Project Synergy. That had three separate takedowns, 2013, '14, and '15 respectively. So while the aggressive enforcement posture that DEA has taken on this matter has had a deterrent, we still see these

substances crossing our border.

Are they as prevalent? I think they've gone underground quite a bit. I think the internet and the darknet traffics these things a lot more heavily than they did when they were readily available in the streets.

COMMISSIONER BREYER: So are you saying it's harder to detect it? That they go in underground and so DEA is having a problem --

MR. DOHERTY: Yes, Commissioner.

COMMISSIONER BREYER: In detecting.

MR. DOHERTY: Yes, Commissioner, one of our major challenges is certainly the internet trafficking of these substances and the darknet. I would also to the --

COMMISSIONER BREYER: The Silk Road.

MR. DOHERTY: I'm sorry, sir?

COMMISSIONER BREYER: The Silk Road.

MR. DOHERTY: Silk Road, sure. The Silk Road, Tor, the onion router, anonymity. It provides the shipper and the receiver a curtain to hide behind, both on the receiving and distribution end. We had some success recently

with the AlphaBay takedown, which was a national takedown. Again, they will find a way to traffic these things on the internet after enforcement actions.

COMMISSIONER PRYOR: Thank you, Mr. Doherty.

MR. DOHERTY: Thank you, Commissioner.

COMMISSIONER PRYOR: That concludes our public hearing. We are adjourned.

(Whereupon, the above-entitled matter went off the record at 11:49 a.m.)