UNITED STATES SENTENCING COMMISSION

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PUBLIC HEARING ON FENTANYL AND FENTANYL ANALOGUES AND SYNTHETIC CANNABINOIDS

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TUESDAY,
DECEMBER 5, 2017

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The Commission met in Suite 2-500, One Columbus Circle, NE, Washington, DC, at 9:00 a.m., Hon. William H. Pryor, Acting Chair, presiding.

PRESENT:

WILLIAM H. PRYOR, JR., Acting Chair
RACHEL E. BARKOW, Commissioner
CHARLES R. BREYER, Commissioner*
DANNY C. REEVES, Commissioner
ZACHARY BOLITHO, Commissioner (Ex officio)

* via telephone

ALSO PRESENT:

MATTHEW BARBER, Detective, Lubbock Police Department, Street Crimes/SWAT, Lubbock, Texas
DR. BRIAN J. BROWNE, Chair, Department of Emergency Medicine Section, University of Maryland, School of Medicine
MAJOR JUAN COLON, New Jersey State Police, Office of the Attorney General, New Jersey Office of Drug Addiction and Control
CHAD CURRY, Training Chief, University Medical Center Emergency Medical Services, Lubbock, Texas
MICHAEL GATCH, PhD, Associate Professor,

Biomedical Sciences, University of North Texas
DR. HOWARD HAFT, Deputy Secretary for Public Health, Maryland Department of Health and Mental Hygiene
BARRY K. LOGAN, PhD, F-ABFT, NMS Labs, Senior Vice President of Forensic Science Initiatives, Chief of Forensic Toxicology
DR. ROGER A. MITCHELL, Chief Medical Examiner, Office of Chief Medical Examiner, Washington, DC
ROBERT PEREZ, Acting Executive Assistant Commissioner, Operations Support, U.S. Customs and Border Protection
JOE SCHLEIGH, Acting Chief, Synthetic Drugs and Chemicals Section, Diversion Control Division (Special Agent), U.S. Drug and Enforcement Administration
DR. SRIHARI TELLA, Unit Chief, Pharmacologist, Drug and Chemical Evaluation Section, Diversion Control Division, U.S. Drug Enforcement Administration
DR. JORDAN TRECKI, Pharmacologist, Drug and Chemical Evaluation Section, Diversion Control Division, U.S. Drug Enforcement Administration
GERAD TROUTMAN, MD, MBA, FACEP, EMS Medical Director, University Medical Center Emergency Medical Services, President Elect of the Texas College of Emergency Physicians, Co-Founder and CEO of ER Now, Amarillo, Texas
DR. MICHAEL VAN LINN, Drug Science Specialist/Chemist, Drug and Chemical Evaluation Section, Diversion Control Division, U.S. Drug Enforcement Administration
DR. DANIEL WILLENBRING, Drug Specialist/Chemistry, Drug and Chemical Evaluation Section, Diversion Control Division, U.S. Drug Enforcement Administration

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

9:00 a.m.

ACTING CHAIR PRYOR: Good morning.

Welcome to the United States Sentencing Commission's Hearing on Fentanyl, Fentanyl Analogues and Synthetic Cannabinoids.

The Commission appreciates the attendance of those joining us here as well as those watching our live steam 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 want to start by introducing the other members of the Commission. To my immediate left is Commissioner Rachel Barkow. Commissioner Barkow is the Segal Family Professor of Regulatory Law and Policy at the New York University School of Law and serves as the Faculty Director of the Center on the Administration of Criminal Law at the law school.

Judge Charles Breyer joins us by telephone. Judge Breyer, can you hear us?

COMMISSIONER BREYER: Yes, I can.

ACTING CHAIR PRYOR: Good deal.

Judge Breyer is a Senior District Judge for the Northern District of California and has served as the United States District Judge since 1998.

Judge Danny Reeves, to my right, is a District Judge for the Eastern District of Kentucky and has served in that position since 2001 and joined the Commission this year.

And, finally, Zachary Bolitho is 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 the hearing, I would like to update briefly the public on some of the Commission's most recent work.

Since our last meeting on October 4th, the Commission has released two publications. On

October 25th, the Commission issued a report analyzing drug mandatory minimum penalties for drug offenses in the federal system.

The report provides sentencing data on offenses carrying drug mandatory minimums, the impact on the federal prison population and differences observed when analyzing each of the five main drug types.

It also highlights important changes and trends in mandatory minimum sentencing since the Commission's 2011 report.

And, on November 14th, the Commission issued a report that examines the relationships between demographic factors such as race and gender and sentencing outcomes.

This report is an update of the analysis the Commission performed for its 2011 Booker Report.

Also, the Commission has collected and included data about violence and an offender's criminal history which was not included in our previous analysis.

The Commission will release one more publication before the end of the year which focuses on the relationship between age and recidivism.

The Commission has also continued its work on the emerging and urgent issue of public concern, synthetic drugs.

This is our third public hearing on the general issue of synthetic drugs. We held a public hearing for synthetic drugs on April 18th, which was within weeks of the Commission regaining its quorum.

And, another on October 4th, which focused on synthetic cathinones.

The issues raised by these emerging synthetic drugs are very complicated and novel in many respects and it 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 fentanyl, fentanyl analogues and synthetic cannabinoids.

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.

At the end of each panel's testimony, panelists may receive questions from the Commission members and I will then give Judge Breyer enough opportunity to ask his questions over the phone.

We look forward to a thoughtful and engaging discussion.

Each witness has been allotted five minutes for their statements. You will begin when the light turns green. Yellow means there's one minute left and red means your time has expired and we'd appreciate you then bringing your remarks to a close.

Our first panel consists of members of the law enforcement community. Our panelists are

Mr. Robert Perez, Mr. Joseph Schleigh and Major Juan Colon.

Mr. Perez is the Acting Assistant Commissioner, Operations Support of the United States Customs and Border Protection.

Previously, Mr. Perez served as the Director of Field Operations for CBP's New York Field Office as Director of Field Operations and Port Director in Detroit, Michigan and as the first Director of the Customs Trade Partnership Against Terrorism in Washington where he oversaw the development and implementation of all the anti-terrorism industry partnership programs for CBP.

Mr. Perez is a graduate of the Senior Executive Fellows Program at Harvard University's John F. Kennedy School of Government and earned his undergraduate degree in economics from Rutgers University.

Mr. Schleigh is the Acting Section Chief of the Synthetic Drugs and Chemical Sections, Diversion Control Division of the

United States Drug Enforcement Administration.

He was assigned to DOS, I can't avoid acronyms this morning, in October 2014 as a Staff Coordinator where his duties included liaison with Joint Interagency Task Force West on shipments of precursor chemicals from Asia to the Americas as well as covering Mexico, Central Africa and the Far East Region.

Before his assignment to DEA Headquarters, he was a Group Supervisor to the DEA in Lima, Peru in the country office from 2008 to 2014 and in the DEA Tampa District Office assigned to the High Intensity Drug Trafficking Area, HIDTA, Task Force concentrating on methamphetamine and cocaine trafficking in Florida.

Major Colon is a 24-and-a-half-year veteran of the New Jersey State Police and he is currently assigned to the New Jersey Attorney General's Office under the Office of Drug Addiction Control working on drug policy.

As the architect of New Jersey's Drug

Monitoring Initiative, he maintains oversight of the Initiative and is also involved in several state working groups to drive state level counter drug efforts.

During most of his career, Major Colon has focused on the intelligence function and he has extensive experience with street gangs and organized crime.

As an intelligence collector targeting these groups, he managed numerous informants and has conducted several undercover operations.

Major Colon earned his undergraduate degree in Public Administration from Fairleigh Dickinson University.

He has received several awards for his accomplishments and was nominated for the 2014 Trooper of the Year Award.

We'll begin with Major Colon.

MAJ COLON: Thank you, Judge.

And, it's truly an honor and a privilege to be here before you. Thank you for

the opportunity.

So, I'm going to be speaking about the state level perspective of fentanyl.

So, highly potent opioids such as fentanyl and its analogues are driving New Jersey's high rate of drug related deaths which increased 163 percent between 2010 and 2016 where there were more than 2200 deaths.

Although millions of dollars have been invested to support various efforts against the scourge, illicit drug distributors have countered these efforts by introducing fentanyl and its analogues into the state's drug environment.

The presence and increased prevalence of potent fentanyl analogues such as cyclopropyl fentanyl and carfentanil are -- they could raise the 2017 death toll to as high as 2,600, translating to an average of 7 drug related deaths per day in the State of New Jersey.

How did we get here?

Well, the first phase of this epidemic is attributed to the high number of prescription

opioids dispensed during the 1990s.

The second phase evolved as many users who became addicted to prescription opioids transitioned to using heroin.

Since the year 2000 heroin and prescription opioids have been driving the state's rise in number of fatal and non-fatal overdoses as well as the violent crimes and burglaries that we're experiencing every day in the state.

To understand the scope of the problem in 2009, we began the Drug Monitoring Initiative which helps us identify the presence and prevalence of drugs by tracking the number of times specific drugs are involved in deaths, overdoses as well as arrests.

We're also able to identify suspected drug overdose spikes and hot spots by tracking the last known deployments by law enforcement and EMS throughout the state and all of the information helps us identify the overall impact on public safety and public health.

The third phase was identified in 2014 when a drug specimen was submitted for analysis and it revealed that there was no heroin involved in that packet. But, it was, in fact, all fentanyl.

As a result of this finding, we asked the nine crime labs to start identifying all of the substances that were being mixed with or sold as heroin.

Several cases from 2013 were reexamined and reclassified as fentanyl involved.

This is a clear indication that fentanyl had been in the state's drug environment and that it was not being identified, reported or monitored.

Since then, crime labs and medical examiners have identified two U-series opioids and 14 fentanyl class compounds which are extremely potent and these include cyclopropyl fentanyl as well as carfentanil.

To speak about the potency, one kilogram of fentanyl can kill half a million

people and it's estimated that one kilogram of carfentanil can kill as many as 50 million people.

These fentanyl class compounds pose occupational hazards and there have been several exposures. Because of the increased presence of fentanyl, Naloxone administrations climbed from 5,175 during 2014 to 12,200 this year so far.

Meanwhile, we have this drug saving drug that's supposed to save lives, but yet deaths continue to rise year over year.

We're now into the fourth phase of this synthetic storm as fake prescription pills are being pressed with fentanyl analogues.

Why is this happening?

It's all economics as we see it in the state. It started with the pharmaceutical companies and now it's the illicit drug market making the big profits.

One kilogram of fentanyl can be purchased for approximately $200 from China when purchased directly.

This same kilogram yields the equivalent of 20 to 25 kilograms of heroin costing approximately $1.2 million, but gross approximately $5 million.

While wholesale heroin transactions involve cartel and gang members, fentanyl can discretely be purchased via the dark web and delivered by legitimate parcel services.

So, where are we headed?

Well, fentanyl is here to stay because of its advantages over heroin. It is much cheaper to produce, much more potent, easier to smuggle and much easier to acquire by any citizen in the state.

ACTING CHAIR PRYOR: Thank you, Major.

Mr. Schleigh?

MR. SCHLEIGH: Judge Pryor and members of the Sentencing Commission, on behalf of the Drug Enforcement Administration, thank you for the opportunity to discuss the threat posed by fentanyl, fentanyl analogues and synthetic

cannabinoids.

Synthetic designer drugs, also known as new psychoactive substances, NPS, refer to the synthetic drugs designed to mimic the effects of known licit and illicit controlled substances.

These substances are often times unscheduled, unregulated.

There are a variety of synthetic designer drugs which are categorized based on the types of controlled substances they are intended to mimic, namely cannabinoids and opioids.

Synthetic drugs have flooded the United States and have put not only our adult citizens, but our children at risk of death of permanent injury.

This tragedy is a primary focus for DEA that is overwhelming our country and law enforcement.

Synthetic cannabinoids are dangerous substances that are marketed as a legal high and have severe adverse effects that are unpredictable in their psychological and physical

impacts on each individual.

Since 2009, DEA has received an increasing number of reports from poison control centers, hospitals and law enforcement agencies concerning products containing synthetic cannabinoids.

Emergency room physicians report that individuals use these types of products experience dangerous side effects including convulsions, agitation, dangerously elevated heart rates, vomiting, seizures, violent behavior, coma and even death.

These synthetic drugs are intended to mimic the effects of THC, the primary psychoactive ingredient in marijuana. But, they are much more powerful.

These substances are easily available through various outlets from the internet, convenience stores, gas stations, street dealers and drug trafficking organizations.

Anyone is easily able to order these substances directly to their doorstep without

detection or purchase them locally with little scrutiny.

These synthetic powders are transported into the United States in powder form via common carrier, processed, then distributed throughout the country under various brand names.

Synthetic cannabinoids are primarily manufactured in and imported into the U.S. from China. They are produced by foreign chemists, usually in powder form and without quality control.

After entering the U.S., the substances are commonly mixed with plant material, acetone, color and flavoring to create most cannabinoid designer substances.

They may also be mixed with other substances and placed in capsule, tablet or powder form.

DEA has become increasingly alarmed over the proliferation of illicitly clandestine produced fentanyl and its analogues.

These substances have been added to

heroin and other illicit substances and have also been encountered as counterfeit tablets resembling controlled prescription drugs.

Clandestinely produced fentanyl and fentanyl analogues are potent synthetic opioids which present a serious risk of overdose and death by those who use these illicit drugs.

The 2015 market for misused opioid prescription pain relievers was 12.5 million people. And, an additional 2.1 million new misusers in 2016.

If illicit fentanyl is introduced into even a small portion of that overall market, there is a risk that overdoses will increase.

The high potency of fentanyl and its analogues makes it particularly dangerous for public safety personnel who encounter fentanyl during the course of their daily operations.

Fentanyl and fentanyl analogues represent a deadly convergence of synthetic drug threat and a current national opioid epidemic.

It should be noted that illicitly

clandestine produced fentanyl is still the prevalent synthetic opioid encountered in the United States.

In conclusion, synthetic cannabinoids and opioids such as fentanyl and fentanyl analogues will continue to pose a nationwide threat for the foreseeable future.

Synthetic drug producers continue to modify and experiment with chemical structures in search of new compounds. Once a new drug is formulated, the internet and social media are used to market the product allowing for its fast adoption and use.

Distributors continue to reap significant profits before new legislative and regulatory controls of these specific synthetic compounds are implemented.

The DEA, in conjunction with federal, state and local partners, will continue to address this threat by pursuing those who have brought tremendous harm to our citizens and communities.

DEA is committed to doing everything can can to address this threat.

Thank you, and I'll be happy to answer any questions you may have.

ACTING CHAIR PRYOR: Thank you, Mr. Schleigh.

Mr. Perez?

MR. PEREZ: Acting Chair Pryor and distinguished Commissioners, thank you for the opportunity to appear today to discuss the role of U.S. Customs and Border Protection in combating the flow of dangerous synthetic opioids, particularly fentanyl into the United States.

As America's unified Border Agency, CBP plays a critical role in preventing dangerous drugs, including fentanyl and its analogues from reaching the American public.

The majority of illicit synthetic drugs smuggled into the U.S. has done so through international mail facilities, express consignment carrier facilities or through our

ports of entry along the southern border.

CBP seizures of fentanyl have significantly increased over the past few years from approximately two pounds seized in 2013 to over 400 pounds in 2016 to what we expect to be over 1,000 pounds seized so far this year.

Fentanyl is CBP's most frequently seized illicit synthetic opioid.

Interdiction efforts at and between the ports of entry, leveraging, targeting and intelligence-driven strategies and working with our partners to combat drug traffickers and transnational criminal organizations are key components of our multilayered, risk-based approach to enhance security of our borders.

Interdicting illicit drugs, particularly synthetic opioids, are challenging and complex.

Along our southern border, heroin is often spiked with fentanyl. Fentanyl is also sometimes spiked with other substances and sold as synthetic heroin.

In the mail and express consignment environments, individual purchasers move fentanyl in small quantities to try to evade detection and Interdiction by law enforcement.

CBP uses the same drug Interdiction methods to seize fentanyl as it uses to detect other drugs coming across the border.

For example, at our National Targeting Centers, CBP leverages advance information alongside law enforcement and intelligence records to identify smuggling trends and target shipments that may contain illicit substances or related equipment being diverted for illicit use such as pill presses, tablet machines and precursor chemicals.

The National Targeting Center also serves as a critical focal point of daily collaboration between CBP and many critical law enforcement partners, including the DEA, Immigration and Customs Enforcement, Homeland Security investigations, the FBI and members of the intelligence community.

In addition to their experience and training, CBP officers and agents use various forms of technology and equipment to detect synthetic drugs hidden on people, in cargo containers and in other conveyances.

In the express consignment environment, CBP can place an electronic hold and notify carriers that a parcel needs to be presented for inspection.

Together with the U.S. Postal Service, CBP is working to develop the same capability in the international mail environment through an advanced data pilot program.

Through CBP's Field Triage Infrared Reach Back program, infrared spectrometers are utilized to collect data from substances believed to be or to contain synthetic drugs, which is subsequently transmitted to our laboratories for interpretation.

Trained scientists are then able to identify classes of drugs and flag them for comprehensive testing, even if the drugs had not

been seen before.

K-9 operations are another invaluable component of CBP's counternarcotic operations.

Since the completion of a pilot program earlier this year, CBP has begun to add fentanyl as a trained odor to deployed narcotic detection K-9 teams at our ports of entry. Over 100 CBP K-9 teams are now trained to detect fentanyl.

CBP has also implemented a program to provide training and equipment to keep our front line employees safe from accidental opioid overdose.

Through our ongoing pilot program, CBP officers and agents are trained to recognize the signs and symptoms of an opioid overdose and administer Naloxone, a potentially lifesaving drug for the treatment of opioid overdoses.

CBP will continue to do all we can to refine and enhance the effectiveness of our detection and Interdiction of fentanyl and other dangerous synthetic opioids being smuggled into

the United States.

Acting Chair Pryor and distinguished Commissioners, thank you for the opportunity to testify today. I look forward to your questions.

ACTING CHAIR PRYOR: Okay, questions?

COMMISSIONER BARKOW: You may not know the answer to this, but do you know along the drug distribution chain the knowledge that fentanyl is in the product?

So, you know, clearly, the chemist making it knows that it's in there. As you go further down the chain, how many of the people know that the product that they're selling has fentanyl in it?

Or, do you have sellers that don't even know what it is that they're selling?

MR. SCHLEIGH: Most often, ma'am, they do not know.

COMMISSIONER BARKOW: They don’t know?

MR. SCHLEIGH: They do not know. Sometimes, they may. It depends on -- it's

customer based, if a trafficker, they may say, okay, what's your coffee of the day? Which will be maybe heroin with some fentanyl in it. Right?

So, most often, they may not know, but they may know. It's hard to say the way the business is.

MAJ COLON: If I can just add, there are indications often times that they do know because some of the mills that are being raided, you're finding personal protective equipment in there which is something that you did not see when it was just purely heroin.

But, with now more of fentanyl in the drugs, you're finding more equipment in these mills.

ACTING CHAIR PRYOR: So, the sign of the equipment means that they're aware of the risk associated? They would only know that if it is fentanyl?

MAJ COLON: Yes.

ACTING CHAIR PRYOR: Okay.

COMMISSIONER REEVES: One question,

Major Colon, we may get into this a little bit later with some other panels, but are the laboratories in New Jersey able to keep up with the testing?

MAJ COLON: From personnel, yes. You know, the backlog started to increase as new analogues were being introduced. And, they just couldn't keep up.

So, it was a justification to increase the workforce by 40 additional personnel. And now, getting the new standards in, you know, to make positive identification, their capabilities have been increased.

But, we were maybe at a two week backlog. Then we went up to almost four months. But now, we're coming back up to it because they recognize the challenges that fentanyl was posing.

COMMISSIONER REEVES: Would that be for fentanyl as well as the analogues such as carfentanil or the --

MAJ COLON: It's of fentanyl, all of

the analogues, yes.

COMMISSIONER REEVES: Thank you.

ACTING CHAIR PRYOR: Judge Breyer, do you have any questions?

COMMISSIONER BREYER: Yes.

I'm trying to understand the distribution of the drug. For example, what was interesting in the testimony was that people could simply mail order, go online, I guess, and get this from some source outside the United States.

Is that common? Is that the way it's generally distributed? Or, is there some other method?

In other words, does it -- is it -- are there suppliers in the United States that are manufacturing or supplying the fentanyl or is it coming from abroad? And, if so, how do people order it and what is law enforcement doing to sort of stop?

ACTING CHAIR PRYOR: Do you want to deal with that, Mr. Perez?

MR. PEREZ: Yes, absolutely, Commissioner.

So, the vast majority of what CBP encounters is coming from China and/or Mexico along the southwest border.

What we have found is that, in smaller quantities along and/or within the supply chains of express consignment parcels and/or the U.S. Postal Service is by and large the quantity of seizures that we are Interdicting.

Now, as far as the quantity of the drug, when it does come through in mail parcels or special consignment packages, it's usually very small, although exceedingly pure, at times, over 90 percent pure.

The larger quantities, although less numbers of seizures are occurring along the southwest border where also emanating from China and heading into clandestine labs in Mexico and often times being cut with heroin or other substances then being trafficked across the southern border typically on persons or in cars

in that way.

That's the vast majority, again, of what we've been seeing trending as far as CBP's intradictions are concerned.

COMMISSIONER BARKOW: Can the dogs detect both fentanyl and its analogues?

MR. PEREZ: That's what we've trained them to do, Commissioner. So, we're, again, quite optimistic about what we were able to pilot earlier this year with the training of the odor detection by the K-9s.

As I mentioned in my opening statement, a little -- over a hundred have already been trained. We've, as you might imagine, strategically deployed these to where we're seizing the most of these drugs. And, we expect that by the end of this fiscal year, all of our narcotic detection K-9 teams at the ports of entry will be trained on fentanyl and the odors emanating from the analogues as well.

COMMISSION BARKOW: Do the analogues share in common the same --

MR. PEREZ: Well, you know, again, not being the K-9 expert within the Agency, but knowing enough to be able to share with you that, yes, there is enough commonality within the odor for it to, at least at this time, detect all the analogues that we've encountered to date.

ACTING CHAIR PRYOR: Any other questions, Judge Breyer?

COMMISSIONER BREYER: No, thank you.

ACTING CHAIR PRYOR: Okay.

Thank you very much for your testimony this morning. And, we have your more extensive written testimony in the record as well. We appreciate you being here.

MR. PEREZ: Thank you.

ACTING CHAIR PRYOR: For our next panel, we will hear from three experts on the structural chemistry and pharmacological effects of fentanyl and fentanyl analogues.

Our panelists are Dr. Michael Van Linn, Dr. Srihari Tella and Dr. Barry Logan.

Dr. Van Linn is a drug science

specialist/chemist in the Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration.

His professional responsibilities include collecting data and information on newly emergent psychoactive substances and chemical diversion trends, evaluating available information and drafting scheduling actions, providing scientific insight for domestic and international drug control policies and providing expert testimony in controlled substance and controlled substance analogue prosecutions.

Dr. Van Linn earned his PhD in organic chemistry from the University of Wisconsin, Milwaukee and conducted post-doctoral research at Drexel University College of Medicine.

He earned his undergraduate degree in chemistry and biology from the University of Wisconsin Stevens Point.

Dr. Tella has been a Unit Chief of the Drug and Chemical Control Unit of the U.S. Drug Enforcement Administration since 2009. His

current responsibilities include managing a group of scientific staff involved in reviewing drugs and other substances with abuse potential for control under the federal Controlled Substances Act.

Dr. Tella's unit routinely provides support to federal prosecutors by serving as scientific experts in federal drug cases pursued under the Controlled Substances Act.

Dr. Tella earned his PhD in pharmacology from the All India Institute of Medical Sciences, New Delhi. He received his post-doctoral training at National Institute on Drug Abuse, National Institute of Health in Baltimore.

And, following post-doctoral training, he served as a faculty member in the Department of Pharmacology of Georgetown University School of Medicine.

Dr. Logan is a Vice President of Forensic Science Initiatives at NSM Labs, a leading United States provider of esoteric

toxicological testing services specializing in new drug detection and forensic analysis for the prosecution and defense in criminal justice and death investigation agencies.

He has over 90 publications in toxicology and analytical chemistry including treatises on the post mortem redistribution of drugs and the toxicology and chemistry of novel psychoactive substances.

Dr. Logan is Board Certified by the American Board of Forensic Toxicologists. He graduated from the University of Glasgow with degrees in chemistry and forensic toxicology.

Dr. Logan did his post doctoral training in forensic toxicology at the University of Tennessee Center for Health Sciences.

Dr. Van Linn?

DR. VAN LINN: Good morning, Chair Pryor, distinguished members of the United States Sentencing Commission. Thank you for the opportunity to briefly discuss chemical structures of both fentanyl and its analogues.

Fentanyl belongs to the propionylanilino piperidine structural class which is a group of substances that have been well-studied for their potential analgesic effects.

Fentanyl analogues have chemical structures that are similar to that of fentanyl, but with small chemical structural modifications.

The synthesis of fentanyl and fentanyl analogues require some familiarity with synthetic organic chemistry. However, the design of new fentanyl analogues is quite straightforward.

With substitution of one or more of the chemicals used in the synthetic process, a new fentanyl analogue can be produced.

The scientific literature describes a diversity of structural modifications that have been made to this chemical structure of fentanyl to create structure activity relationships often accompanied by pharmacological data and detailed instructions for their synthesis.

Some fentanyl analogues have emerged

on the illicit market that were previously reported in the scientific and patent literature.

The ease of creating new fentanyl analogues is attractive to medicinal chemists' research in the structural class. Unfortunately, the same can be said for the clandestine chemists.

They can utilize the same scientific knowledge and continually produce fentanyl analogues with the intent to circumvent laws.

The recent dramatic increase in trafficking and abuse of fentanyl and fentanyl analogues are tightly intertwined with the opioid abuse in the United States, which is already at alarming levels.

This topic needs little introduction, however, I would like to mention common occurrence that I've observed while working on six emergency control actions to control nine fentanyl analogues in Schedule I.

The DEA collects reports on fatal overdoses involving fentanyl analogues on an ad

hoc basis from state and local medical examiner and toxicology labs as well as coroner's offices.

One case describes the fatal overdose of a 20-year-old male from Maryland. The victim was found unresponsive in his bedroom, kneeling on the floor and leaning over a bed.

Upon moving this individual, a syringe was discovered in his hand. Toxicology revealed that the decedent died of an overdose of heroin and acrylfentanyl which is a fentanyl analogue that is similar in chemical structure to that of fentanyl.

Many of the fentanyl analogues that have been temporarily controlled have been involved in similar cases.

Other fatal overdose cases have occurred with many of these fentanyl analogues where a needle is still found in the decedent's arm. Others have occurred at drug treatment facilities and others have involved multiple victims at the same location.

The DEA is closely tracking fentanyl

analogues as the emerging illicit market, both internationally and domestically. Unfortunately, in many cases, we are notified of a new fentanyl analogue when there are deaths and the substances are identified in post mortem toxicology.

When we learn of a new substance, we immediately begin collecting data and information on that specific fentanyl analogue. This information is evaluated and utilized as part of a potential scheduling action.

Since 2015, the DEA has completed six temporary scheduling actions to temporarily control nine fentanyl analogues in Schedule I of the Controlled Substances Act.

We are also made public notice of intent to control another fentanyl analogue in Schedule I, a substance known as cyclopropyl fentanyl which you've heard from Major Colon in the previous panel.

Cyclopropyl fentanyl like other fentanyl analogues has a chemical structure that

is closely related to fentanyl but has not been previously reported in the scientific literature.

We first became aware of this substance in early June of 2017 when it was identified in a white powder submitted to a local drug forensic chemistry laboratory.

The following week, the media reported on a group of more than 40 overdoses in the State of Georgia involving counterfeit Percoset tablets. Upon analysis, cyclopropyl fentanyl was identified in combination with another substance known as U-47700 which is another synthetic opioid.

The presentation on cyclopropyl fentanyl in powder form and disguised as an opioid pharmaceutical product show that fentanyl analogues are introduced to target the opioid dependent population.

In summary, the fentanyl analogues have been identified in drug evidence and post mortem toxicology show that traffickers are utilizing the scientific literature to introduce

already known fentanyl analogues as well as using the information from structure activity relationships to design new fentanyl analogues for introduction into the illicit drug market.

Responding to the introduction of new fentanyl analogues in the illicit drug market remains a priority for the DEA and we look forward to working with the Commission to address these substances.

Thank you for the opportunity to discuss this important issue and I'll be happy to answer any questions you have.

ACTING CHAIR PRYOR: Thank you, Dr. Van Linn.

Dr. Tella?

DR. TELLA: Good morning, Judge Pryor and distinguished members of the Sentencing Commission.

I thank the Commission for providing me this opportunity to discuss pharmacology of fentanyl and related substances.

Pharmacological and toxic effects of

fentanyl and its mechanism of action are in general similar to heroin and various commonly used opioid analgesics as morphine, hydrocodone and oxycodone, et cetera.

However, there are two main differences between fentanyl and other commonly used opioid analgesics.

The first difference relates to the potency. Fentanyl is more potent than commonly used opioid analgesics and heroin in producing its pharmacological and toxic effects.

The second difference relates to its kinetics, fentanyl has a rapid onset and short induce nerve action as compared to the commonly used opioid analgesics.

With regard to the pharmacology of fentanyl related substances that have been recently encountered by law enforcement, there is limited or no information.

DEA has obtained formulated pharmacology data on over 35 fentanyl related substances through interagency agreement with

other federal agencies and through research contracts.

These data show that these fentanyl analogues similar to fentanyl act as potent new opioid receptor agonists.

Thus, these novel fentanyl analogues are likely to have a toxicity and abuse potential similar to fentanyl.

The two main pharmacological effects of opioid analgesics play a central role in their adverse impact on the public health.

First, opioid analgesics are a highly addictive class of drugs that activate reward pathways in the brain to produce intense euphoria.

And, second, in high doses, opioid analgesics consistently depress respiratory center in the brain.

Deaths resulting from overdoses with these substances are most often due to respiratory depression leading to complete failure of breathing.

Fentanyl or its analogues similar to other opioid analgesics carry high risk of causing serious health consequences including deaths.

Because illicitly produced fentanyl and its analogues are manufactured in non-pharmaceutical settings under non-controlled conditions using crude methods, the purity of the final product is uncertain and inconsistent.

Users of these products may end up consuming unknown amount of active drug or drugs and are at a high risk of adverse health outcomes.

Recent CDC data demonstrated that intravenous injection is the most common route of administration in deaths related to fentanyl and its analogues.

Because intravenous route of administration puts these drugs directly into the blood stream, it speeds up the accessibility of these drugs to their site of action in the brain, thus, leading to enhanced effects and toxicity.

The intravenous route of

administration combined with high potencies of fentanyl and its analogues and distribution of product with the unknown composition of drugs and their amounts collectively put individuals who consume these products at even higher risk of overdose and overdose deaths.

Thank you for this opportunity to briefly discuss pharmacology, toxicity, adverse impact on public health related to these substances.

I'll be happy to answer any questions you may have.

Thank you.

ACTING CHAIR PRYOR: Thank you, Dr. Tella.

Dr. Logan?

DR. LOGAN: Chair Pryor, Commissioners, again, thank you for the opportunity to address the Commission this morning.

As was mentioned in my introduction, I represent a laboratory that performs toxicology

and seized drug testing for -- on behalf of law enforcement agencies and coroners and medical examiners offices.

We have a pretty broad perspective on the extent of the impact of the opioid epidemic by virtue of the fact we tested over 60,000 death investigation cases for coroners and medical examiners last year and examined over 68,000 exhibits -- seized drug exhibits from law enforcement agencies, some in support of backlog elimination projects as was referenced in one of the earlier questions.

Based on our experience, the continued increase in rates of positivity for fentanyls in our case work has continued this year.

In the 18 months leading up to September of 2017, we had over 17,000 death investigation cases that were positive for fentanyl from testing coroner and medical examiner case work.

That was approximately double the rate in the prior 18 months. And, our data from this

year indicates that the positivity for the year will likely be 30 percent in 2017 over what it was in 2016.

The impact of the increase in opioid availability is not limited, however, just to fatalities. In our drug impaired driving case work and vehicular homicide case work, it took four years from 2011 for fentanyl positivity in these cases to increase by a factor of three.

However, the rate of positivity increased threefold again in 2016 alone and has increased by a further 30 percent in 2017.

In total, about 14 percent of our drug-involved DUI cases now are positive for fentanyl.

In terms of challenges for laboratories, the number of compounds in the fentanyl category that our laboratory tests for has increased dramatically, putting additional demands on resources in the laboratory.

And, that's also the experience of laboratories in the public sector.

We were testing for four fentanyl analogues in 2011, seven in 2014, 22 in 2016 and this year, over 35 different unique chemical compounds are part of our testing menu.

When you consider other non-fentanyl opioids including, as was mentioned, U-47700, and some analogues of that substance which are now appearing, we're testing for over 40 new opioids over and above the traditional morphine, heroin and oxycodone drugs.

That puts a significant burden on laboratories. We, as a large laboratory, have more resources for research and development, but many of the smaller laboratories at the state and local level do struggle in keeping up with the changing menu of substances and they do rely on laboratories like ours as a resource for assistance.

The second issue I wanted to address was about the impact of some of the unknowns regarding the toxicity of these substances.

As forensic toxicologists, myself and

my staff are called to go to court to testify about the significance of toxicology findings in death investigation cases.

And, frequently the question that asked is, but for the presence of a particular opioid, would the decedent have lived or died?

When new substances are -- new drugs are created by pharmaceutical companies, they go through an extensive testing process that starts with in vitro studies in the laboratory, progressing to animal studies and then to careful human trials and then, subsequently to post launch monitoring of adverse effects of these substances.

None of these safeguards or screenings are done for these illicit substances.

So, a lot of the information we have about drug toxicity for pharmaceutical drugs, we simply don't have that for some of these novel illicit clandestine drugs like fentanyl and its analogues.

So, that does limit the extent to

which that question can be reliably answered. And, I know that that is frequently a frustration for investigators and in the prosecution of drug delivery, homicide and drug intoxication cases.

There are some positive changes that have taken place that support the laboratories that are responding to this crisis including availability of new technology with greater sensitivity and better discriminating power.

Those technologies tend to be quite expensive and many laboratories don't have access to them.

But, we have a better understanding of the mechanisms and methods for identifying new substances as they appear. And, I think we're doing a better job of keeping up now than we were a couple of years ago.

Thank you.

ACTING CHAIR PRYOR: So, Dr. Logan, I understand from your written submission that you think that fentanyl analogues do constitute a class that are subject to core structure

scheduling, is that right?

DR. LOGAN: Yes.

ACTING CHAIR PRYOR: Why is that?

DR. LOGAN: When you look at the chemical composition of the substances, they have three characteristic domains. And, those are shared to one -- to some extent in everything that would be considered to be part of that class.

Some minor modifications to those domains do impact the potency of the drug, but if you identify the presence of these chemical constituents on the molecule, if all three of them are present, then a chemist can recognize them as being related to or derived from fentanyl.

ACTING CHAIR PRYOR: Thank you.

COMMISSIONER REEVES: I have one question dealing with potency of the analogues.

Are you able to state with any certainty whether the vast majority of analogues that you're seeing are significantly more potent than fentanyl itself?

DR. TELLA: I can answer that.

We recently tested seven fentanyl analogues. They were slightly less potent than fentanyl but more potent than morphine.

But, some of the fentanyl analogues we encountered in late 1970s and '80s, they were almost close to fentanyl in terms of the potency.

But, the recent ones, so far, we tested in animal studies, seven of them showed slightly less potent than fentanyl, but more potent than morphine.

But, we are still in the process of testing 20 more fentanyl analogues. We don't have the data but in vitro data, we have about over 35 substances. All of them are close to, not actually close, but some of them are less, some of them are more potent. But, a lot of them are close to fentanyl.

But, this is, again, in vitro data so we really can't extrapolate exactly what it is going to do once we inject it into the system body in animals instead of humans.

So, but based on the in vitro data, it looks like a lot of them are potent.

COMMISSIONER REEVES: Dr. Logan, do you agree with that or do you -- are you seeing things different in the laboratories?

DR. LOGAN: From reading the literature, I would agree with that assessment.

We recently did a review of a number of the patents from the 1970s and 1980s where pharmaceutical companies were developing and experimenting with a variety of different fentanyl analogues.

There are over 600 fentanyl related compounds in those early patents. A small percentage of them do have animal data that support quite a range in terms of potency from many 100 times more potent in animal models for analgesia than fentanyl to compounds that are less potent.

And, in some cases, the molecule is modified sufficiently very little potency.

ACTING CHAIR PRYOR: Judge Breyer, do

you have any questions?

COMMISSIONER BREYER: Yes, I do.

Dr. Logan, I have two questions, maybe the first one may be fairly obvious.

Does fentanyl in and of itself have addictive characteristics or quality? That's one question.

The other question is, is there any scientific evidence as to the quantity of fentanyl in terms of being mixed with heroin that would be a safe dose or would be a lethal dose? Is it simply a trace of fentanyl that is used in heroin that would cause a death or does it have to be more than that?

If you could answer those questions.

DR. LOGAN: Well, to address the first question, the fentanyl acts on the same receptors in the brain and the central nervous system that morphine or heroin or other opioids act on.

So, it does produce the same constellation of effects and it does produce the same potential for becoming addicted or

habituated to the drug.

With respect to the effect of combinations of the drug, I think our experience is that the composition of drug mixtures is extremely variable. Sometimes the fentanyl is a trace in heroin products, sometimes it's the inverse.

But, for drugs that act on the same receptors as heroin, fentanyl, fentanyl analogues do, they're all contained in the same purchased dose of an opioid.

Their effects will be at least additive if not synergistic, meaning multiple dose rather than additive.

COMMISSIONER BREYER: Well, let me follow up on that.

What I'm trying to figure out is whether we have to be concerned that if some quantity of heroin has a trace of fentanyl in it, that would render it either potentially lethal or certainly lethal.

Or, is there a certain percentage of

fentanyl in a heroin -- combined with heroin that one could say, well, that -- the sale of that kilo of heroin with X amount of fentanyl in it would certainly constitute a lethal dose.

And, I understand there are a lot of variable, the cut and so forth and so on. But, I'm just trying to figure out, to what extent, since fentanyl seems to be far more lethal than heroin, as I understand it, potentially lethal.

I'm trying to figure out in my mind, is there some quantity of fentanyl in a heroin compound or a mix that would increase the risk -- substantially increase the risk of death?

DR. LOGAN: So, I would be reluctant to try to put any quantitative number to that in terms of what the incremental risk is from the addition of fentanyl to heroin.

Both are inherently dangerous. The users typically have no idea what the dose is when they are taking the product. They certainly wouldn't know the relative amounts of the drugs in the substance that they've purchased.

COMMISSIONER BREYER: Would not?

DR. LOGAN: Would not.

So, I think it's difficult to say, is there a threshold amount of fentanyl that you could add to heroin that would not make it more dangerous. I mean, there is, but what that number is, I think is not known.

COMMISSIONER BREYER: Well, let me follow up on that.

In other words, as it is now, we punish people who purchase -- who furnish drugs based upon, one, the nature of the drug and, two, the quantity that's sold.

So, you take that -- now, let's look at it in terms of fentanyl. And, is there any way you can say this quantity of heroin, because it has fentanyl in it is twice, five times, ten times more dangerous than simply the heroin uncut or unadulterated by fentanyl? Is there -- do we have some evidence on that issue or is that simply still unknown?

DR. LOGAN: Well, for fentanyl

itself, since it was developed as a pharmaceutical, there are data that indicate what the relative potencies of fentanyl and are to morphine or to heroin.

So, you could calculate the relative potency of mixtures with different proportions of heroin and fentanyl and compare that back to the potency of unadulterated heroin.

However, for the vast majority of the analogues, there is no such equivalency or data that would allow you to do that kind of calculation.

COMMISSIONER BREYER: Thank you.

COMMISSIONER REEVES: Just one follow up. Of course, at the street level, you're not getting an exact mixture anyway, are you? You may have one gram of fentanyl mixed with a kilogram and one portion of the kilogram and one user may get all of that.

I mean, it's not a --

DR. LOGAN: Yes, there's very little quality control.

COMMISSIONER REEVES: That other follow up question I had for you was the, I think you referred to as the synergistic effect.

And, I'm interested in drug users that are not using the same type of substance such as heroin and opioids but methamphetamine has different effects on the --

DR. LOGAN: Yes.

COMMISSIONER REEVES: Have you observed that and have you been able to testify about that or --

DR. LOGAN: We do see many polydrug cases, both in death investigation case work and impaired driving case work.

The constellation of effects is a mixture. Certainly, if you take a stimulant and a depressant, they don't cancel each other out, you tend to see the worst of both drug classes in terms of their adverse effects.

ACTING CHAIR PRYOR: Okay, thank you, Dr. Van Linn, Dr. Tella and Dr. Logan. We appreciate your oral presentation this morning.

Of course, we have your more extensive written testimony as well. And, thank you for being here.

We'll move to our third panel.

For our third panel, we will hear from three medical experts on the health consequences of fentanyl and fentanyl analogues.

Our panelists are Dr. Brian Browne, Dr. Roger Mitchell and Dr. Howard Haft.

Dr. Browne is the Chair of the University of Maryland Emergency Medicine Department and oversees a staff of 75 faculty members and 50 residents.

He developed the Maryland Emergency Medicine Network which encompasses 14 emergency departments in rural, suburban and urban communities in Maryland where 550,000 patients are treated every year.

Dr. Browne has published numerous articles in medical journals and he is a frequent speaker at professional forums in the United States and abroad.

He earned his MD from the State University of New York Downstate Medical Center in the College of Medicine and did his residency in internal medicine at St. Vincent's Hospital and Medical Center.

He earned his Master's of Science from Niagara University and Roswell Park Memorial Institute and his Bachelor of Science from Syracuse University.

Dr. Mitchell is the Chief Medical Examiner for the District of Columbia. Previously, Dr. Mitchell served two years as the Regional Medical Examiner for the Northern Regional Medical Examiner Office in Newark, New Jersey.

And, served four years as the Assistant Deputy Chief Medical Examiner in charge of Medical Legal Death Investigations at the Harris County Texas Institute of Forensic Sciences.

Dr. Mitchell has performed over 1,300 autopsy examinations and has testified as an

expert in numerous cases.

He is a graduate of Howard University in Washington, DC and the UMDNJ New Jersey Medical School in Newark, New Jersey.

He performed his pathology residency at George Washington University Hospital where he served as Chief Resident.

Dr. Mitchell is Board Certified in atomic and forensic pathology by the American Board of Pathology and is a Fellow with the American Society of Clinical Pathology and the National Association of Medical Examiners.

Dr. Haft is the Deputy Secretary for the Maryland Department of Health and Mental Hygiene.

Dr. Haft has 27 years of clinical experience in primary internal medicine and ten years hospital based emergency medical, clinical and leadership experience.

He has served as an adjunct professorial lecturer at the Georgetown University McDonough Graduate School of Business.

He has served as Co-chair of the Maryland State Medical Society Physician Leadership Committee and has served as a member of the Maryland State Telemedicine Advisory Committee, several Maryland health services cost review commission committees and, the Maryland Healthcare Commission Advisory Panels.

Dr. Haft earned his medical degree from Penn State University and completed his internship and residency in internal medicine at Brown University.

We will begin with Dr. Browne.

DR. BROWNE: Members of the United States Sentencing Commission, it's my honor to speak to you today about the problem that has strong, negative impacts on the Baltimore City, the illicit use of fentanyl.

Fentanyl has a place in the physician’s armamentarium, especially in the emergency department where I and my colleagues use it regularly to treat acute pain and provide sedation.

However, the arrival of illicit fentanyl has had a devastating effect on the State Maryland.

There are 29 fentanyl related deaths reported in 2012. 2016, that was 1,119 related fentanyl related deaths in Maryland.

This trend seems to be worsening because the State Health Department reported there were 799 fentanyl related deaths in the first six months of this year.

More than a third of these deaths, 35 percent, occurred in Baltimore City where I and my faculty practice.

We have seen a steady increase in the number of patients coming to our emergency departments as a result of opioid overdoses. And, while Baltimore City has struggled with the issue of heroin for some time, fentanyl adds a substantial burden to an already disadvantaged community in our medical system.

I'd like to supplement what I've handed over to you with just a couple of examples

of what we're talking about.

The first is a 54-year-old grandmother. Her family found her poorly responsive and on her bathroom floor. They called 911. When the paramedics arrived, they recognized the signs of opioid overdose, gave some Naloxone, transported her to our emergency department.

As she responded to treatment, she became more alert. She was able to describe what happened.

It turns out that she had been using heroin for more than 20 years. This was the first time she had ever overdosed. She stated that she had always bought the same amount of heroin, the same dealer on a daily basis for years.

However, on that day, she bought some from someone else and not the usual source. She didn't notice any differences until she insufflated the powder and then lost consciousness.

The story is typical of many of the steady opioid users in Baltimore. Many have been using steady constant amounts only to accidently overdose because unexpectedly, fentanyl has been in the preparation.

My second story relates to a 24-year-old woman who recently moved to Baltimore from upstate New York.

She had been in the area for a few months, decided to go to a concert with a few friends.

Halfway through the show, friends noticed that she had been gone to the bathroom too long. They had security open the stalls where they found her with a needle in her arm without a pulse.

Chest compressions were started, Naloxone was given. EMS transported her to our emergency department. But there, despite our best efforts, she never regained consciousness or a pulse and died.

It's a terrible -- it's terrible,

really, to inform the mother that her only daughter is dead. Her father told us that this was not the first time that she had taken -- a problem with drugs. But, she had been sober for several years.

Stories like this have become common in Baltimore where patients with substance abuse problems will relapse as part of the disease of addiction.

But now, with fentanyl mixed in the supplemented heroin, many users are -- who have been sober will overdose when they relapse because they are so much stronger and more dangerous.

My last story is about a 34-year-old mother of three and a nurse in our emergency department.

She was working one weekday afternoon when EMS brought in a young man who had apparently overdosed. He was unresponsive. EMS gave him some Naloxone.

The patient became very alert, as

expected. But then began to hallucinate, became combative. EMS had to strap him down on the stretcher.

When the nurse who had not seen this young man before walked over to take the patient's vital signs, the patient spotted her, slipped out of the restraints and chased her around the emergency room while screaming, I never meant to hurt you.

She was able to safely barricade herself into the bathroom while security, you know, was able to restrain him. But, the patient had to be -- had just been revived with lifesaving medication, had to be sedated all over again.

These reactions pose a clear threat to the patients and everyone else taking care of them.

I'd like to summarize by saying illicit fentanyl has had a strong, negative impact on Baltimore. There are steady users who believe they are buying heroin but accidently overdose because they're given fentanyl instead

or fentanyl laced heroin.

There are those patients who have been sober for a while relapse and accidentally overdose when they are now exposed to fentanyl they've never been exposed to it before.

And, lastly, they're seeing patients with this apparent opioid overdose who become dangerous to the medical staff once they're resuscitated.

I think that there are probably 1,100 other stories, but I wanted to highlight these because you might not have thought of this series that we're taking a look at.

Thanks very much for your time.

ACTING CHAIR PRYOR: Thank you, Dr. Browne.

Dr. Mitchell?

DR. MITCHELL: To the Honorable Judge Pryor and the Commissioners, I want to thank you for inviting me here today. I'm humbled to share my thoughts and expertise surrounding this opioid crisis and the perspective of the medical

examiner.

One thing that I wanted to add is that I also sit on the National Association of Medical Examiners Strategic Planning Subcommittee where we handle and analyze the strengths, weaknesses, opportunities and threats to the discipline as well as to the organization.

And the opioid crisis is a definite threat to the National Association of Medical Examiners and the medical examiners system. And, I'll be highlighting that throughout my testimony.

In the short time that I have today, I'll clarify the role of the medical examiner in the response to the opioid crisis.

I'll give some background as to structure and function of the opiates in the human subject and how it imposes at least lethal effects on the body.

I'll provide some general national statistics that you may already know.

And then, I'll focus on the straining

effects of the epidemic on the medical examiner system and talk about some highlighting challenges to the District of Columbia.

Most of -- most medical systems, medical examiner systems, are 24 hours, 7 days a week. The role of the medical examiners to investigate all unnatural, sudden and violent causes of death.

The investigation normally includes seeing documentation, body transport, medical chart and police document review, full and partial autopsy examination and the toxicological testing, all for the establishment of cause and manner of death.

There are five manners of death. There are homicides, suicides, accidents, naturals and undetermineds.

Opioid drug overdoses in this country are to be considered and usually are considered as accidents. They therefore, fall directly under the jurisdiction of the medical examiner or coroner.

Let's put this in perspective. In late 2014 and late 2015 -- early 2015, we started seeing this uptick in these opiate overdoses.

There are now more than 33,000 deaths due to opioids each year in this country including the prescription opiates as well as non-pharmaceutical fentanyl.

As a matter of fact, the CDC has called that there are 91 Americans that die every day due to this crisis.

So, the medical examiner system is in a unique position to understand the crisis the way others may not. And so, these 33,000 deaths annually and these 91 deaths every day are investigated, examined and certified by the local coroner or medical examiner.

The drug mixture profiles found within the bodies of the overdose victims are being identified by the toxicologist and pathologist of these local jurisdictions.

So, these are drug profiles that are not often able to be identified in the normal

hospital setting.

The medical examiner offices all over the country are being inundated by these deaths. And, to the point in which national accreditation is being challenged.

Many of our offices are losing or downgraded their national accreditation because of the number of deaths per doctor. Each doctor has a prescribed number of autopsies that you can do each year and it's important to stay under that number or you will lose your accreditation.

Although the Office of the Chief Medical Examiner in D.C. is not at that risk, we have seen 178 percent increase in the number of overdoses from opiate use disorder between 2014 when there were 83 and 2016 when there were 231.

This doesn't seem to be decreasing in the foreseeable future. If we keep on the rate that we are in 2017, which we're about 216 by September, then we're scheduled to have about one per year, so over 300 opiate overdose deaths in the District of Columbia.

The majority of D.C. OCME cases are mixed drug toxicity that came in other testimonies. Seventy percent of all deaths have heroin, 72 percent all have fentanyl or a fentanyl analogue.

The highest number in 2017, in August, there were 88 percent of opioid overdoses had a fentanyl or fentanyl analogue on board.

So, we're seeing many of the fentanyls, fentanyl, norfentanyl, acetylfentanyl, furanylfentanyl, the fentanyl precursor of 4-ANPP. And then, we're also seeing U-47700 as well as carfentanil, the known elephant tranquilizer.

Why is this important?

Well, we know that fentanyl is 50 to 100 times more potent than normal -- than morphine and it acts on the respiratory centers where it really sleeps you to death.

One of the things that we're seeing on scene now that we've not seen before is, and it's spoken back at another part of the hearing, is

that the syringe is found on scene.

These users are not able to put that syringe away. They are what I say is dying at the end of the plunger.

We have a program here in DC where we're actually taking those syringes and having them tested to see whether or not we can see anything different in the syringe that we're seeing in the body.

We have some preliminary results that I can talk about.

One thing I'll end with here is that the nation is seeing this opioid crisis in the 20 to 35 year olds, 80 percent of the opioid overdose deaths are 20 to 35-year-old white men and women.

But, here in the District of Columbia and Dr. Browne alluded to this, is that we're seeing the 50 to 60-year-old black men that are dying from opioid overdose deaths.

And so, they're known heroin users, have been using it for 30 years and now are getting the fentanyl laced heroin and are dying

from that.

So, there's no single solution to this problem. There'll be a need for a multidisciplinary approach to this public health issue to sustain positive outcomes.

There is no doubt that there's a need to support the addition of more medical examiners and toxicologists in order to deal with this issue. But, the solution will entail improved availability of in treatment, prevention, testing and deterrents.

And, again, I want to applaud the Commission for taking time to gather information from a multiple of sectors as you develop a response to this very important public health issue.

I'm available for questions when that time comes.

Thank you.

ACTING CHAIR PRYOR: Thank you, Dr. Mitchell.

Dr. Haft?

DR. HAFT: Acting Chair and Commissioners, it's a great pleasure to be here today and to be able to provide some hopefully meaningful testimony regarding this public health crisis that we're in the midst of.

As you know, there's been a dramatic increase in the number of deaths from unintentional opioid overdoses in the past several years. You've heard several people testify about the magnitude.

The CDC even reports that there may be more than 50,000 deaths in the prior year from unintentional opioid overdoses which overshadows the total number of people who died during the entire span of the Vietnam War.

And, is clearly an enormous crisis. And, sadly, this is just another example of how financial gain by some overshadows the concern for the health of the public.

I want to comment on four things that I think really are relevant now and then be open for questions.

Number one would be the potency of this particular drug and its similar congeners.

Number two is the cost.

Number three is the fact that it has in terms of the addiction potential and the attraction that it has for individuals who happen to be suffering from substance use disorders.

And then, a picture of what the future might look like, what the present is and what the future might look like based on what we know now.

And, first, in terms of potency, it's very clear that fentanyl is much more potent than heroin. It's 50 to -- 50 times more potent than heroin. And, in fact, I think your toxicology testimony previously said that as little as one milligram of fentanyl can be lethal. One milligram is a tiny amount.

But then, we look at some of the other more designer versions of fentanyl like carfentanil which is a 1,000 times more potent than morphine in which 50 micrograms, which you couldn't even be able to see 50 micrograms, but

that's lethal.

And then, there are drugs that have been produced already in labs for many years and could be on the fast track to be even more potent than carfentanil, like ohmefentanyl which is 6,300 times more potent than morphine. And, less than one microgram of that can be fatal.

So, we have a very potent group of drugs that are easily produced by backroom chemists.

But, the cost of those drugs is really what drives the death and the lethal factors in this epidemic.

And, that is that there's a strong advantage to individuals if they can produce a more potent drug cheaper and sell it cheaper than heroin or sell it cheaper than oxycontin.

So, for instance, fentanyl, at the street level, costs about $2,000 per kilogram, $2,000 per kilogram.

Heroin is about $64,000, maybe as much as $100,000 per kilogram.

So, fentanyl per kilogram is cheaper. But the potency factor really leverages the value of that in the producer’s mind.

And, if you take a kilogram of fentanyl, you can produce about 500,000 two milligram pills that would look like oxycontin or some kind of pill to get people high with a street value of $10 to $20 for each of those pills, so we're talking about on a $2,000 investment, $5 to $10 million worth of street value. That's dramatic. That's an incentive that drives a lot of illicit behavior.

And then, there's this other paradoxical thing is that people who are in the throes of addiction, who have substance use disorders, those individuals are driven by a biological urge.

I mean, this is -- these drugs like fentanyl and carfentanil bind to the Mu receptors in the brain which release dopamine to an area in the brain which it develops euphoria.

But, it's one of those really

primitive areas in the brain that are responsible for our basic biological urges also like hunger and thirst and breathing. All those are compacted around the same areas.

So, when people get these drugs, they bind to these areas and release this substance, this dopamine substance. It gives them a euphoria and makes them absolutely need to come back to that again. They're strongly driven to come back biologically. They cannot resist it, it's the nature of addiction.

And, these drugs are more addictive than heroin or oxycontin. So, fentanyl is more of a high for individuals who want to get drugs.

So, even though they may understand there's a risk associated, it's still the good stuff. So, they may -- somebody selling the good stuff, not the heroin users that have been using heroin that was recounted here for 20 years in DC, but the newer individuals who come on the train of the addicted to oral opioids.

They will look for these selectively

better highs and it's like Russian roulette because, as you've heard before, the admixture of these is hardly anything that's scientific, whether it's a little fentanyl or a lot of fentanyl, it's unknown to the user, probably unknown to the person who's distributing at the street. It's only known to those individuals who are producing it in China or Mexico or where ever that might be.

So, it's the -- that's the next part of this is that they're so strongly addictive.

The last part is what we have to see in the future, and that is the fact that, by some estimates, up to 4 percent of individuals 11 years old or older in this country have some degree of substance use disorder or are addicted to opioids.

Because we've flooded the market over the last 10 or 15 years. We've been giving oxycontin and other long acting opioids to treat pain when we should have been doing perhaps other things.

The end result is enormous number of people now are in the throw of substance use disorder who may be still using oxycontin. But, many of those will march down the pathway from oral oxycontin and oral opioids when they find that they're no longer available because we've appropriately tamped down on the distribution of those.

And, that they've become expensive on the street, that they can get heroin that's cheaper, far cheaper than oxycontin. And that heroin then is admixed with fentanyl and carfentanil and other things and it becomes absolutely like Russian roulette.

So, we're just seeing the tip of this epidemic right now as those additional people, those 10 or 11 million people in our country who suffer from substance use disorders become more exposed to heroin and to fentanyl. The death rates will continue to rise.

So, it's up to us to do something about it and this is absolutely a public health

crisis.

Thank you for your time.

ACTING CHAIR PRYOR: Thank you, Dr. Haft.

Questions?

COMMISSIONER BARKOW: I don't know if it's possible to know whether or not the harm to the human body -- does it vary between fentanyl and the analogues or what you see? Do they have different effects on the health outcomes for people?

DR. HAFT; So, absolutely in terms of the potency, so the exposure to carfentanil, even a casual exposure to carfentanil can cause death. I think that's the big harm.

And, what we're talking about in terms of harm for all these drugs is that they unexpectedly cause sudden respiratory depression, so within a minute or less, you stop breathing. And, within three minutes, you're dead, five minutes, you're brain dead and it's all over.

So, not even enough time, many times, to do -- to give Naloxone or other kind of lifesaving interventions.

COMMISSIONER BARKOW: But, that would be key to the potency then? So, it wouldn't have to --

DR. HAFT: Key to the potency.

COMMISSIONER BARKOW: -- we have to know how potent and then we have to know how much somebody actually ingested to know what --

DR. MITCHELL: Let me be clear, here in D.C., again, we were chugging along at about 80 or so heroin deaths a year. And now, we're at 231, close to 300. The balance of them have fentanyl.

So, fentanyl is the culprit. I mean, we've had heroin addiction in this country for centuries and this up tick that we're seeing is fentanyl directed.

And, like you've heard before, the amount of fentanyl in the heroin, all of that is very difficult to understand.

I just spoke with my epidemiologist who came with me, I said that's another study we need to do and figure that out.

But, fentanyl is invariably in the reason why people are dying at the highest rate now.

DR. BROWNE: Yes, when you -- when this stuff is made, it's not being created by professionals in expert laboratories, but street pharmacists. And, quite frankly, and the adulterants.

There's no quality control. So, from the source, it's not known what -- how much it is. The mixture with heroin or the adulterants, the mixture is not known.

It's not homogeneous to anything in the preparation they might have. And so, a lot of the cases I gave, they were unknown.

But, there are people who know they're about to use the stuff and that it's been laced with something stronger, but they don't even know what it's going to do. They don't know from one

shot to another, it's the same or different.

It's extremely lethal no matter what you're mixing it with.

COMMISSIONER REEVES: The injuries that you're saying in addition to deaths, you're seeing injuries, strokes and other injuries that you see from lack of oxygen to the brain?

DR. HAFT: So the ICUs in many of our hospitals, the intensive care units in many of our hospitals are now filled with people who are on respirators, who have brain death or other kinds of serious conditions who were resuscitated but not completely resuscitated.

So, the tragic consequences of that, the economic consequences, all those things are yet to be counted.

COMMISSIONER BOLITHO: Dr. Browne, I think my question is probably for you and it relates to Naloxone administration.

DR. BROWNE: Yes?

COMMISSIONER BOLITHO: Could you explain how -- I've always wondered how that

process works. How does Naloxone work? And also, whether you're seeing that with these fentanyls, you're having to do more Naloxone than you have in the past with heroin overdoses?

DR. BROWNE: Yes, the -- there is receptors -- opioid receptors in the brain. You know, it's not a coincidence that here are the drugs that work on those receptors that are naturally in the brain.

And, these various drugs, heroin, has a certain affinity for those things and you have an effect.

These fentanyl intensely stronger and greater affinity for those same receptors.

Naloxone competes, it attaches to the same receptor. By attaching it without the physiological effect, it competes and blocks the other one from having the effect.

For heroin, we got used to a certain amount of Narcan--Naloxone. You give it to them and, quite frankly, predictably wake up. It lasts longer than heroin and so they do pretty

well.

In fact, many of the EMS community we're giving small amounts because they could -- they didn't want their patients getting so sick, they just want them to be revived and come to the ED. So, it was very small amounts.

But, without clinically knowing that it's fentanyl, you find that suddenly now, the paramedics are realizing that they give some and it's not working because the intensity and the strength of the fentanyl and the analogues is binding stronger. So, they have to give more of it. You have to give more.

And so, all of a sudden you realize that they didn't test for it, but the circumstance, the clinical circumstance is indicating this is not the usual narcotic overdose, opioid overdose.

They're giving a great deal more and it doesn't last as long. So, they have to give more of it or infusions.

The thought they were having to give

the Narcan is just a proxy that you are now dealing not with heroin any longer but with something else in it.

I spoke to the Chief of the EMS in the City of Baltimore just yesterday, anticipating coming here today. He said a couple of years ago, his budget, his annual budget for Narcan in Baltimore was about $600,000. That's a lot, that surprised me that's how much it was.

At the moment, it's over $900,000 and going up. And, that's a substantial increase in just the amount of Narcan being used in order to revive or get some effect for these patients.

ACTING CHAIR PRYOR: Judge Breyer?

COMMISSIONER BREYER: Yes, I have a question of Dr. Mitchell, but maybe there are others who want to respond.

Dr. Mitchell, in your written testimony, you say the following. You say, according to the Centers for Disease Control and Prevention, CDC, there are now more than 33,000 deaths due to opioids each year, including

prescription opioids, heroin and non-pharmaceutical fentanyl.

As a matter of fact, the CDC report said 91 Americans die every day from the use of opioids.

So, I take from that, obviously, we have a terrible opioid fight. What I'm interested in is whether there are any statistics that show what percentage of the 33,000 deaths are due to non-prescription fentanyl as distinct from overdosing or suffering the effects of prescription drugs?

Because, I mean, I'm sure you know, there are many lawsuits that are presently pending dealing with the use of prescription opioids. And, obviously, a number of them cause some percentage of these deaths.

So, we're addressing today, as I understand it, the non-prescription use. The fact that fentanyl may be in heroin and sold illicitly.

Do we have any statistics that show

what percentage of the deaths are the non-prescription?

DR. MITCHELL: So, that's a really, really good question because the circumstances surrounding the drug use and drug overdose and deaths are often not recorded on the death certificate that is giving us these statistics.

Many of those statistics we can understand through the circumstances. So, the majority of my fentanyl deaths are illicit fentanyl that is found admixed with heroin or being used purely as fentanyl illicitly and non-prescribed.

Not clear whether or not those fentanyl at some point was diverted as a function of the prescription supply diverted illicitly or manufactured illicitly.

There's a series of non-pharmaceutical fentanyls that you just cannot get prescribed.

And so, when those are listed, you know that those are indeed illicit fentanyl

analogues. And so, you can surmise that without the circumstances.

One of the things that the CDC and the National Health Statistics is vying against is that many medical examiners and coroners are not listing each drug on their death certificate.

And so, they're using terms like mixed drug toxicity, accident and not listing them.

And so, once that's done, there's no way for National Statistics to delineate whether or not it's a fentanyl, fentanyl analogue, whether it's heroin, cocaine or above.

D.C. actually is the best at listing those out. That report just came out.

And so, that's what I would answer to the question. Local jurisdictions would know it, your circumstances would know it. But, when it gets to the national level and you're bringing those 33,000 deaths and those 91 a year at that level of the statistics, they're not going to know it.

COMMISSIONER REEVES: Dr. Mitchell,

didn't you say earlier that you were going along at about 80 deaths a year, that you're attributing to overdoses or to heroin and then suddenly it's up to 231, almost a three to one or three times increase that you attributed to fentanyl or the analogues?

DR. MITCHELL: Yes, so, the majority of that increase we're seeing are fentanyl -- have fentanyl on board. And, we can fill the gap with the fentanyl increase.

DR. BROWNE: For years, in Baltimore, I staffing five emergency departments in West Baltimore. We saw about maybe one overdose death every other day, predictably and you can see that number.

Well, we're seeing two a day now. That's a substantial increase.

The numbers of opioids -- prescription opioids that are causing these deaths has been remaining pretty flat over the years.

And, the -- this sudden increase that we're seeing, the speed where they're going, from

a clinical point of view, it's painting a different picture that suddenly there's more Narcan being used.

This is characteristic of fentanyl. But, I have to admit, we're not actually testing all the time because it's not adding to the treatment. It would be great to know, I suppose, but not adding any knowledge to that particular case.

So, that specific information is a little lacking.

DR. HAFT: In regard to Maryland, so the Chief Medical Examiner's office is in my administration in Maryland. And, I can tell you that the increase seen in deaths which has been now over 2,000 last year was entirely fueled by fentanyl.

We find fentanyl in deaths with heroin. We find it with in deaths associated with cocaine. We find it in deaths -- so I would say with virtually every other drug.

So, fentanyl is the thing that is

being used to juice pretty much every illicit drug that's on the street. And, a majority of cases we see with unintentional overdoses from opioids, fentanyl is the root cause.

COMMISSIONER REEVES: Thank you.

What would increasing the dose by a factor of three to four times --

DR. MITCHELL: Yes.

COMMISSIONER REEVES: -- look like?

DR. MITCHELL: And, what I want to add is that you can't forget, however, the increase of new users. So, that has a variable because if you have new users in the system, then you can have more deaths in the system as well.

So, it's going to be fentanyl to potency but the variable of new users is quite, you know, as well unknown and need to be taken into consideration.

ACTING CHAIR PRYOR: Any other questions?

Okay, thank you very much, Dr. Browne, Dr. Mitchell and Dr. Haft for your oral

presentations this morning and for the written submissions you provided earlier that will be part of our record.

We appreciate you being here to help us today.

We're going to take a 15 minute break. So, we'll assemble back here at about 13 minutes before the hour.

(Whereupon, the above-entitled matter went off the record at 10:33 a.m. and resumed at 10:52 a.m.)

ACTING CHAIR PRYOR: Our last two panels will focus on synthetic cannabinoids.

Mr. Schleigh was previously introduced in our first panel and will now discuss law enforcement response to the increase in synthetic cannabinoids.

Mr. Schleigh, thank you.

MR. SCHLEIGH: Okay, thank you, sir.

Once again, it's a pleasure to be here in front of the Sentencing Commission and Judge Pryor.

So, I want to reiterate what we talked about a little earlier just to set the stage on it.

These synthetic designer drugs known as new psychoactive substances refer to manmade synthetic drugs designed to mimic the effects of known licit and illicit controlled substances.

These substances are often times unscheduled and unregulated.

Synthetic drugs have flooded the United States and have put not only our adult citizens but our children at risk of death and permanent injury. This tragedy is the primary focus for DEA that is overwhelming our country and law enforcement.

Synthetic cannabinoids are dangerous substances that are marketed as a legal high and have severe adverse effects that are unpredictable and the psychological and physical impact on each individual.

Emergency room physicians report that individuals who use these types of products

experience side effects including convulsions, agitation, dangerously elevated heart rates, vomiting, seizures, violent behavior, coma and even death.

These synthetic drugs are intended to mimic the effects of THC, the primary psychoactive ingredient in marijuana, but they are much more powerful.

These substances are easily available through various outlets from the internet, convenience stores, gas stations, street dealers and drug trafficking organizations.

Anyone is easily able to order these substances directly to their doorstep without detection or purchase them locally with little scrutiny.

The synthetic cannabinoids we're encountering are primarily manufactured in and imported into the United States from China.

They are produced by foreign chemists, usually in powder form and without quality control in rogue laboratories in China.

After entering the U.S., the substances are commonly mixed with plant material, acetone, color and flavoring to create most cannabinoid substances and they're also being mixed with other substances and placed in capsule, tablet or powder form.

In our experience in the investigations with the cannabinoid laboratories, they could be in your neighbor's garage. This could be done in your neighbor's basement. It could be done in a large warehouse.

And, they're volatile. And, as I mentioned here, the acetone, how this is done is the organic plant material like damiana leaf, marshmallow leaf is dried out, laid out on a garage floor or a basement floor, a closet floor.

The traffickers will throw acetone on the product, put it in a basically a cement mixer. They mix that, after it dries, they allow it to dry.

But, what happens in the meantime, in one instance in Florida, which is a public health

issue and a community issue, there was a laboratory there and the heater kicked on and it blew off the door, the garage door of the house and, thank God, no one was walking down the street.

So, it's a more or less a time bomb that can occur with this type of process because they're using acetone which is very flammable.

We've had instances where there were actually 24-hour workers in Tampa, Hillsborough County, which was one of the first largest labs seized. And, they had worked 24 hours and then for months, nobody recognized it.

Workers had shifts going in and out. I have photos of this but, you had a production side then you had a packing side.

And, they would -- the packing side would be working there and it would put the Spice, K-2, which is the street name for it, in these little envelopes and they're very shiny and eye catching, especially to younger children.

When we refer to the stores, being in

stores, we worked with the Attorney General's Office in Washington, D.C. We had a very good plan to pull licenses if they were selling things.

You probably read that which was effective, selling these K-2 and Spice out on the street.

The effects are dramatic to the point where one instance, there was a 16-year-old teenager driving his truck. He drove it right into a running train and killed himself.

So, the effects are very, very dangerous.

So, for a law enforcement perspective, yes, we do -- we see it. An example, we had a case in Newark, New Jersey where it's not only local traffickers but traffickers connected to terrorism.

And, when they arrested these -- this case and they took it down, that case was taken down and it was a fantastic case. And, there was over 750 kilograms of damiana leaf active

cannabinoids and several hundred thousand dollars in seizures.

So, we're talking big profit and the profit margin on this is very high, which was mentioned earlier.

You can buy from China, the product from China in powder form from $2,000 to $5,000 per kilogram at $20 each at one to two grams per package, the traffickers can generate a substantial profit in the excess of $250,000 per kilogram, that's substantial for a $2,000 investment.

The source is still we're seeing from China. I know we've been hearing about India as well, but not so much in the synthetic world.

We see chemicals, bulk chemicals come in from India, mostly related to methamphetamine.

So, which are precursors to precursors, something like benzaldehyde and other precursors that, once we schedule something, they go to another precursor. So, we see that coming out of India but no so much any of the synthetic

cannabinoids.

ACTING CHAIR PRYOR: Okay, Mr. Schleigh.

Any questions?

(NO RESPONSE)

ACTING CHAIR PRYOR: Judge Breyer, do you have any questions?

COMMISSIONER BREYER: No.

ACTING CHAIR PRYOR: Okay.

We thank you for your presentation this morning. We have your written testimony as well. And, we'll move on to the next panel.

Thank you for being here.

MR. SCHLEIGH: Thank you.

ACTING CHAIR PRYOR: Our fifth panel focuses on the structural chemistry and pharmacological effects of synthetic cannabinoids.

Our panelists are Dr. Jordan Trecki, Dr. Daniel Willenbring and Dr. Michael Gatch.

Dr. Trecki is a pharmacologist in the Drug and Chemical Evaluation Section of the

Diversion Control Division of the Drug Enforcement Administration. He serves as a technical consultant and expert witness for issues related to the Controlled Substances Act and new psychoactive substances.

Dr. Trecki has provided expert testimony in numerous federal hearings regarding pharmacology of controlled substances not referenced in the Sentencing Guidelines as well as for federal prosecutions under the Controlled Substances Analogue Act.

Dr. Trecki earned his PhD in pharmacology from Temple University and received his post doctoral training at the Georgetown University School of Medicine.

He also worked for the Environmental Protection Agency as a neuropharamcologist and neurotoxicologist.

Dr. Willenbring is a Drug Science Specialist in the Drug and Chemical Evaluation Section of the Drug Control Division of the Drug Enforcement Administration.

He serves as a technical consultant and expert witness for issues related to the Controlled Substances Act and novel psychoactive substances.

Dr. Willenbring has provided expert testimony in numerous federal hearings regarding the chemical structure of controlled substances not referenced in the Sentencing Guidelines as well as for federal prosecutions under the Controlled Substances Analogue Act.

Dr. Willenbring earned his PhD in chemistry from the University of California at Davis. He completed a post doctoral fellowship in the Department of Anesthesiology at the University of Pittsburgh, funded by the National Institutes of Health.

Dr. Gatch is an Assistant Professor of Biomedical Sciences at the University of North Texas Health Sciences 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 earned his PhD in psychology from Utah State University, his Master's of Arts in behavioral science from the University of Houston and his Bachelor of Arts in behavioral science from the University of Chicago.

Dr. Trecki?

DR. TRECKI: Good morning, Judge Pryor and members of the Sentencing Commission. My name is Dr. Jordan Trecki and I am a pharmacologist in the Drug and Chemical Evaluation Section with the Diversion Control Division of the DEA.

My primary responsibility within the division is to evaluate various drugs for their pharmacological effects in relation to the Controlled Substances Act.

In addition, I have served as an

expert witness for the government in over 40 federal court proceedings involving controlled substance analogues and the sentencing of these substances.

Thank you for the opportunity to briefly discuss the pharmacology of synthetic cannabinoids.

Synthetic cannabinoids represent a subclass of drugs commonly referred to as new psychoactive substances, or NPS.

The abuse of synthetic cannabinoids has been shown to cause serious adverse effects including excited delirium, agitation, seizures, hyperemesis syndrome, cardiac arrest, multi organ failure and death.

These drugs are trafficked to youth, those in drug rehab facilities, the homeless, users attempting to evade a positive drug screen and many other demographics and age groups.

Illicit manufacturers of synthetic cannabinoids continue to make small chemical modifications while retaining the

pharmacological effects users seek in attempt to avoid law enforcement detection.

Many of the synthetic cannabinoids available on the illicit market were originally designed by legitimate pharmaceutical researchers with the positive goal of finding new therapeutic drugs and targets to alleviate disease symptoms.

However, illicit manufacturers have minded the patent and scientific literature for structures with potential psychoactive effects thereby giving clandestine laboratories the blueprints to produce hundreds of synthetic cannabinoids for supplying the illicit market.

Thousands of new compounds are likely to be produced and subsequently introduced to unsuspecting users.

The synthetic cannabinoids encountered on the illicit market are predominately potent, full cannabinoid receptor agonists that are pharmacologically similar to the partial agonist THC.

Synthetic cannabinoids, like THC, bind to and activate the CB1 receptor while producing euphoric and hallucinogenic effects.

Synthetic cannabinoids represent a group of substances with a common pharmacological property, activation of the CB1 cannabinoid receptor.

A synthetic cannabinoid should be defined as a substance that acts as an agonist at the CB1 receptor.

Widespread overdose clusters and individual deaths across the country have grown in number and severity since the first United States reports in 2010 and 2011.

Marketed with street names including synthetic marijuana, Spice, K-2, Mojo and others manufacturers lace an inert plant material with a synthetic cannabinoid while dealers push users into assuming the effects are similar to marijuana.

The consequences of ingesting these chemicals is a pathway to addiction with

debilitating and often long lasting side effects, if the user is fortunate enough to live through the experiences.

Synthetic cannabinoids continue to demonstrate serious adverse effects across age brackets that greatly surpass those observed with THC.

These substances continue to be a threat to public safety, are frequently marketed to and abused by those of a young age, continue to be illegally imported into the United States and are mixed with plant material to produce a large number of doses per gram.

In our experience, novel synthetic cannabinoids continue to be introduced into the illicit drug market in an attempt to circumvent current drug controls within the United States.

Synthetic cannabinoids represent a group of pharmacologically similar substances that are commonly abused by a wide group of individuals with often serious and toxic consequences.

From the perspective of a pharmacologist, a class approach for synthetic cannabinoids would offer clarity and consistency.

I am hopeful that the Commission adopts a class approach to synthetic cannabinoids. And, I look forward to your questions.

ACTING CHAIR PRYOR: Dr. Willenbring?

DR. WILLENBRING: Good morning, Chair Pryor and distinguished members of the Commission. I'd like to thank you for the opportunity to briefly discuss the structural considerations related to synthetic cannabinoids.

I have provided testimony in a number of federal cases involving novel psychoactive substances including synthetic cannabinoids.

Since starting at DEA, the majority of my travel around the United States has involved testimony in sentencing hearings addressing issues related to and objections related to Application Note 6 substances not referenced in

the guidelines.

As you've heard, synthetic cannabinoids represent a class of manmade substances irrespective of their chemical structure that act on specific receptors in the central nervous system.

Substances from this class are continuously altered and introduced on the illicit market in an attempt to circumvent the regulatory controls while retaining that THC-like pharmacological effect.

Although some of the early synthetic cannabinoids seen on the illicit market did have some structural features in common with THC, most synthetic cannabinoids encountered on the illicit market today do not have structural similarity to THC.

Many of these substances originate from legitimate research. Researchers routinely will publish results from their work in patents and peer review papers. And, these publications provide a roadmap or instructions for the

chemical synthesis of these substances and the results from the experiments showing that they are active on the CB1 receptor.

So, illicit manufacturers mine this pool of hundreds of known synthetic cannabinoids. Increasingly, these same manufacturers will introduce additional chemical modifications not in the peer review literature and are mixing and matching substitutions from previously published structures.

So, for brand new substances that have never been produced before.

In 2012, Congress passed the Synthetic Drug Abuse Prevention Act, or SDAPA, to control synthetic cannabinoids based on a two-part definition that includes chemical structure and experiments to show that the substances are CB1 agonists.

As soon as this legislation was made public, before it was signed into law, substances began appearing on the illicit market that fell outside of the limited structural definitions in

SDAPA, but maintained those same effects on the CB1 receptor.

Most, but not all, of the synthetic cannabinoids in Schedule I are derived from chemicals known as indole or indazole. And moving forward, we expect to see trafficking of additional substances based on these core structures.

And, possibly based on other core structures that are described in the scientific literature.

Synthetic cannabinoids on the illicit market frequently stray from the simple structural definitions that are more suitable for other groups of novel psychoactive substances.

As you've heard, however, these synthetic cannabinoids all have at least one thing in common, they are agonists at that CB1 receptor.

We look forward to working with the Commission to address how synthetic cannabinoids are treated under the guidelines.

Thank you, and I'd be happy to answer any questions.

ACTING CHAIR PRYOR: Dr. Gatch?

DR. GATCH: Good morning. I'm honored that I've been asked to testify before this Commission.

I just want to thank you, Judge Pryor and the members of the Commission.

I have been, for that past eight years or so, testing for the DEA a number of these compounds including hallucinogens, sedative hypnotics, cathinones, cannabinoids and recently, this year, starting testing on synthetic fentanyl derivatives.

The focus of this, we're talking about cannabinoids and I want to emphasize three points that are in written testimony that I sent in.

First, as mentioned previously, the class of compounds labeled cannabinoid is defined based on their function.

So, including their in vitro activity of various receptors, a number of bioassays such

as the tetrad that are used to characterize these early compounds and in various behavioral effects that are used to find their substance abuse liability.

Second is that tetrahydrocannabinol-delta-9 is -- which is the most prevalent psychoactive compound in marijuana is likely the most appropriate standard for defining cannabinoid like effects.

Given it is the compound that likely drives the recreational use of marijuana and that most of the synthetic compounds are used as marijuana substitutes.

The third point that I wanted to emphasize was that despite the clear classification in terms of cannabinoid label, they're not at all homogeneous in terms of the potencies, efficacies, their time course or their side effects.

Now, all of them produce this well known set of effects like the tetrad and they bind at these receptors, but the potencies are

quite variable.

Synthetic compounds that I've tested in my lab have about a 300 fold range. So, you know, actually you could pick up someone with a given quantity in their pocket, there could be 3 doses or 900. Okay?

So, one, this is personal use, the other one is definitely trafficking. Okay?

Efficacy can also range extensively. Now, the bioassays that they use to test these receptors assays can test a really large range of effects and these synthetic compounds are full, very strong agonists.

And, we found that marijuana, that THC is actually a fairly weak partial agonist. And, in fact, we're finding that in order to produce the full effects of these bioassays or for the abuse liability assays, you only need to activate the receptors a small amount. Okay?

So, the synthetic cannabinoids have a very, very high efficacy, as I mentioned. But, this does not make them any more reinforcing or

increase their abuse liability. Okay? They sort of hit that threshold, so they're not really any more reinforcing or abuse liability than what THC is.

What it does appear to do is to increase the toxic effects. Okay? Some of these are mediated by CB1 and CB2 cannabinoid receptors, though some of them, particularly some of the newer ones, seem to be hitting some other receptor systems, some of the cardiac effects that are being noticed seem to be through serotonin receptors and other things, but that's very sketchily known right now.

So, the plant-based marijuana like endogenous cannabinoids have very, very mild adverse effects mostly.

Synthetic cannabinoids are significantly more toxic and some of the more recently induced synthetics are extremely toxic and even lethal. We've seen waves of when they've been introduced to areas and seen these waves of deaths and increased emergency room

visits and such.

And, on top of this, the sort of the therapeutic window of these vary. Like, when we're talking about the opioids, there's a fairly standard difference between the dose that will produce analgesia and the dose that'll produce respiratory depression. And, that's fairly consistent among the opioids.

That was ultimately the holy grails of opioid -- early opioid research made a find, one that would produce analgesia in much lower doses than would produce respiratory depression, they never could, so it's pretty closely locked in.

These compounds range greatly. Just to give an example of some of these varied effects, I had a compound that its effects hit almost instantly. So, in the time that I had injected it and put it into the apparatus I tested, the effects were already on, fully on. Okay?

The effects were completely gone within 60 minutes and there was no sign of any

kind of adverse effects whatsoever at all.

And, the other compound I tested, it took two hours for the compound to hit maximal effects. Okay? The effects lasted 48 hours. Okay?

Most of the rest that we were testing showed some sort of slowing of behaviors in the locomotor depression, it's one of the tetrad.

Some of them actually showed the rigid body, the catalepsy and one of them actually was completed rigid and ice cold. Okay? Again, hypothermia is one of the tetrad.

So, the full adverse effects of the tetrad were already on board at the dose. It was necessary in order to produce full marijuana like effects.

These adverse effects lasted several hours. They were mostly gone within eight to ten hours after testing, although the subjective marijuana like effects were present at 24 hours and they had the test after 48 hours before I lost those effects.

So, there's an enormous variety or range of variability in the magnitude of their cannabinoid like effects in terms of their adverse effects. The range of other kind of adverse effects, they had some listings before and I assumed the panel next after us will talk about some of the other medical effects that some of these compounds can produce.

So, thank you for your patience listening to me and I'm ready to answer any questions.

ACTING CHAIR PRYOR: Thank you, Dr. Gatch.

Questions?

COMMISSIONER BARKOW: I have a question. So, if -- as we think about a class-based approach, you know, I hear the need for that given the fact that you can't keep up with the kind of chemical innovation that the manufacturers have.

But, at the same time, it sounds like a class -- it's a variable class in terms of the

effects.

And so, if, in order to distinguish all the things that are in that are in that class in terms of harm, would that have to be based on dose? On something else?

Because it seems to me that, yes, they have this effect on the body that we could define it as, but that's not really getting at the harms or the kinds of actual physical effects on a human being that might be health related unless we looked at dose.

Is that correct or is there something that I'm missing in terms of how we would group these things together? I would love to hear from any of you on this because it seems to me that's the dilemma with this one, if we're not going to use a chemical structure and we're going to say the definition is based on how it affects this cannabinoid receptor, that, yes, that would group them all together, but they're actually not alike in all these other fundamental ways.

And so, I'm trying to figure out how

we could kind of mediate those -- that tension.

DR. GATCH: I have seen that the really new compounds, the last generation of these compounds are the ones that have been really, really dangerous that have hit at these waves of problems in terms of the emergency room visits and deaths and such.

So, it's possible there's some particular structural morbidities that are responsible for those sort of things but we don't know that yet.

I mean, it would be sort of like the opioids in which fentanyl is so much more dangerous, but that's a specific structural subtype within the functional class of opioids. Because, of course, opioids are defined functionally like cannabinoids are and yet they get the opioid receptors.

So, but, at this point, we don't -- we haven't had enough pharmacology yet just because we're still sort of -- we're not characterizing these compounds in a lab, we're sort of finding

them out in the street and in the wild and characterizing them after the fact.

ACTING CHAIR PRYOR: Do the other witnesses have something to add to that?

DR. TRECKI: So, I think a few points to consider.

Just to set the stage, to date, between Congress and the DEA, there are 33 synthetic cannabinoids listed in Schedule I.

In 2017 alone, DEA has identified over 70 new synthetic cannabinoids on the illicit market.

Cayman Chemical lists over 700 synthetic cannabinoids standards available that we're aware of.

So, that demonstrates how many synthetic cannabinoids are currently on the illicit U.S. market with thousands waiting in the wings in the patents or scientific literature.

When we look at the pharmacological effects, the pharmacological effects, I'm not talking about concentration or dose yet, the

pharmacological effects are similar, they are full agonists at the CB1 receptor.

When we go into what Dr. Gatch was demonstrating or talking about, there are a few chemicals that have that low potency, lower the THC. One example that comes to mind is RCS-4.

In Dr. Gatch's research, it showed 40 times less potent than THC in the drug discrimination assay.

Those kind of drugs, though, do not last on the illicit market. RCS-4 did show up in a few indictments. I have talked about it in court before.

However, the users want that potent euphoric strong effect. The drugs that are coming out now quickly displace the ones that are weaker.

When we look at drugs like JWH-018 and AM-2201, we see three, four and five fold more potent than THC.

We look at drugs like 5F-ADB or 5F-PB22 now are in the 15 and 20 times more potent

than THC.

So, the drugs the users want are multifold and I would personally believe that that's one consideration when you look at the class based approach, these are all potent substances that the manufacturers can then titrate the dose as they mix the chemical both correctly or incorrectly.

One thing mentioned before, there's no therapeutic dose of this. So, while I understand what Dr. Gatch was saying looking at that window compared to opioids, the substances, unlike fentanyl, there is no medical use for these substances.

And so, I do agree that the dose that people want the effect. Well, that's not a therapeutic in the medical community. It is wide ranging. It's unpredictable.

While one person may have a hyperthermic response, a body warming, others will have a hypothermia. One person has a seizure, one has cardiac arrest.

Clearly, the drugs are mostly are more potent than THC. The drugs are intended to give a euphoric response. The pharmacology in that respect is all similar.

Where you get the differences are one causes a seizure, one causes multi organ failure, one causes hyperemesis and the toxic effects that Dr. Gatch alluded to then have a wide disparity.

But, in terms of the pharmacology, all these substances are full agonists, even RCS-4 being less potent, is still a full agonist, it just took a little more of the drug to get the effects in animals or in humans.

I hope that answers your question.

COMMISSIONER BARKOW: It does, although, I guess it sounds like we would then need to know about dose for these drugs if we wanted to get the full range. Right?

If they all have that effect, if they're all full agonists, but the effects vary widely, in some way, even if you had a class based approach, though, you would have to go back to

this question of dose to really understand.

DR. TRECKI: And, with that question of dose, we could look to the animal data to look at relative potency, but once again, the manufacturers can always titrate their dose or not even know what chemical they're using.

We heard about like before, the fentanyls, just because a person orders XR-11 or acrylfentanyl, is that what they ordered? Do they know what they're mixing in the correct amounts?

So, if we got this perfect dose of all these cannabinoids, it doesn't always translate into what a manufacturer's using or how much a user is using.

So, I think there's multiple other factors like the trafficking, the young age that go into this evaluation.

We can give dose numbers based upon the animal data as far as possible, but there's a limit to that.

COMMISSIONER REEVES: Just as one

follow up, you said that most they're mostly more potent than THC and then you gave some examples of three to five times and then 15 to 20 times. Which would you say would be the most common in terms of potency that first group or the latter group?

DR. TRECKI: So, the first group is what we saw back in 2010, '11 and '12.

COMMISSIONER REEVES: So, looking back, it would be three to five -- looking now and forward it would be the higher potencies?

DR. TRECKI: The newer substances do have more common 10, 15, 20 times. That doesn't mean that a new drug might not fall under that three to five or that 10 to 20 times less potent.

As the manufacturers randomly choose these from patent or scientific literature, they may choose one that's less effective.

But, the trend perhaps my colleagues would care to opine.

DR. GATCH: The trend has tended to be more potent?

DR. TRECKI: It's been -- they're more and more potent as the drugs seem to come out.

COMMISSIONER REEVES: That would stand to reason.

COMMISSIONER BOLITHO: I have a question regarding the way in which this drug is applied to the leaves, as I understand it, and whether it is possible to take the leafy material that we have seized and determine how much of a cannabinoid is on a particular leaf as we're trying to determine drug quantities?

DR. WILLENBRING: I can address that.

I don't work in a laboratory system, but I've spoken with the laboratory system.

It would be a tremendous challenge for both our laboratory system and the state and local labs to determine how much chemical is actually applied to these leaves.

There's a problem with solubility trying to get the chemical back off the leaf. And then, there's also the issue of them having validated methods for every different synthetic

cannabinoid.

So, even if they've figured out this problem of dissolving the chemical off the leave and homogenizing the mixture, they would have to redo that whole process for every new substance they encounter.

And, even if they've done all of that, due to the way that these substances are manufactured, if they open one packet and take a sample of that packet and figure out how much drug is in that particular sample, there's no saying that applies to the rest of the packet or any of the other packets.

They use rudimentary techniques to manufacture these substances. So, cement mixers was mentioned, sometimes they lay out the plant material and they use a garden sprayer, so a pump up type leaf sprayers and they'll put their acetone and drug mixture in there.

The most recent trial I testified at, the sprayer was too slow so they started using a watering can.

So, you can imagine if they're sprinkling this on with a watering can, there's going to be portions of that mixture that have much more drug and portions that have much less drug.

And, for a laboratory to figure that out based on 1,000 packets would be a tremendous challenge.

COMMISSIONER BOLITHO: My second question relates to something that you were just talking about a moment ago, Dr. Trecki.

If we -- we have THC in the guidelines and if we use THC as a baseline, would you say that the synthetic cannabinoids that you are encountering are more or less dangerous than THC?

DR. TRECKI: The substances, even the ones that showed lower potency in some of the animal assays, are all substantially more dangerous than THC.

ACTING CHAIR PRYOR: Why?

DR. TRECKI: Because while the intended effect might be euphoria to

hallucinations, the adverse effects based upon how potent these substances are and how small of a dose can illicit some of these effects, you don't see multi organ failure, seizures or death when ingesting THC.

While THC concentrations in marijuana have increased over the last decade, even the high dose formulations of the new marijuana strains or some of the edibles, while they'll cause increased paranoia, you're still not seeing even close to the magnitude of adverse effects clinically with these cannabinoids compared to THC.

ACTING CHAIR PRYOR: Judge Breyer, do you have any?

COMMISSIONER BREYER: Yes, for Dr. Gatch.

Earlier today we heard a fair amount of testimony about the addictive nature of the fentanyl and opioids in general.

I'm interested in whether you have any opinion as to whether the synthetic drugs that

we're talking about now, how that -- these cannabinoids compare to fentanyl and that we've heard earlier in terms of its addictiveness quality?

DR. GATCH: Okay, so, as I understand, you're asking about the synthetic compounds compared to synthetic fentanyl as opposed to the THC?

COMMISSIONER BREYER: No, I was asking about fentanyl.

DR. GATCH: Oh, okay, yes.

In general --

ACTING CHAIR PRYOR: Well, I think -- let's make sure we understand this, Judge Breyer.

So, the question is about the addictive nature of the synthetic cannabinoids in contrast with say the addiction -- addictiveness of fentanyl, is that right?

COMMISSIONER BREYER: That's right.

DR. GATCH: Okay.

ACTING CHAIR PRYOR: If you know.

DR. GATCH: In general, the marijuana

and the cannabinoids are -- have less addictive liability than the -- they don't have the immediate reinforcing, they don't have the drive to dependence and they don't have the drive to binging that you typically do with the opioids or particularly with like the psychostimulants.

You tend to get slower paced sort of use which tends to -- people don't tend to get as addicted as much. And, the withdrawal signs are much more mild that they are with opioids.

And notwithstanding, people do addicted to the -- and it's -- to the cannabinoids whether they're natural or synthetic and it's still just as difficult to shake it as it is for the opioids.

DR. TRECKI: If I could add --

COMMISSIONER BREYER: Thank you.

DR. TRECKI: If I could add one caveat to that. One of the adverse effects I discussed was hyperemesis syndrome with the cannabinoids. While the addiction to cannabinoids may not be as severe as addiction to fentanyl, there are in

some chronic users of synthetic cannabinoids, one of these adverse effects, they hyperemesis syndrome is that, we usually talk about the receptors in the brain because that's where the psychoactive effects occur.

But, we have to understand the receptors are also located in other parts of the body, one being the intestines and the gut.

As you chronically ingest these cannabinoids, you have a hyperstimulation of these other receptors that result in this need to throw up, vomit. And, the only way to alleviate those symptoms are either to smoke the synthetic cannabinoid on the hour every hour of every day or one of the other ways to alleviate it is to take a hot shower pretty much all day long.

And, while that's not physically possible, this is just demonstrates one of the chronic conditions, not a favorable addiction to a drug, not that these drugs are favorable in that sort of sense, but a sort of, you get so addicted you must continue to smoke them every

hour of every day just to keep yourself from throwing up.

Those are some of the adverse effects that we see from these synthetic cannabinoids because they're so potent.

This has been seen with marijuana in extreme chronic users, but with these drugs potency, it comes on a lot quicker and we're seeing it more common with the synthetic cannabinoid users just like we did with chronic THC users.

ACTING CHAIR PRYOR: Thank you. We appreciate your appearance today and providing oral testimony. And, we appreciate, too, the written materials that you submitted earlier that are part of our record.

And, again, your testimony today will be helpful to our work.

Our final panel will discuss the impact of synthetic cannabinoids on communities.

Our panelists are Matthew Barber, Chad Curry and Dr. Gerad Troutman.

Dr. Barber has been a Texas Peace Officer with the Lubbock Police Department for 11 years, or over 11 years.

Since 2014, he has been assigned to the Special Operations Division which handles investigations including narcotics, gang, vice, human trafficking and other special assignments.

Detective Barber has been a member of the Lubbock Police Department's SWAT team since 2011 and is currently assigned to its sniper team.

Detective Barber earned his Bachelor's degree in sociology-criminology with a minor in Arabic foreign language from Texas Tech University.

Chad Curry has been employed as a paramedic at University Medical Center Emergency Medical Services since 1997.

UMC EMS is the sole EMS provider for the Lubbock, Texas area.

Before his current role as Training Chief, he was a field paramedic and field

training officer.

He also works as a flight paramedic on both helicopter and fixed wing air ambulances.

Mr. Curry holds numerous licenses and certifications as both a paramedic and an instructor, including paramedic certification from Texas Tech University.

He has created several training presentations for use by statewide and national medical and EMS organizations, including the National Association of Emergency Medical Physicians and the Texas State EMS Conference.

Dr. Troutman is a Board Certified Emergency Physician who serves as EMS Medical Director for University Medical Center EMS in Lubbock, Texas and for the City of Amarillo, Texas.

In those roles, he sets policy and medical protocols for EMS providers to follow in the field.

Dr. Troutman is also co-founder and CEO of a freestanding emergency center, ER Now,

in Amarillo and has -- and practiced emergency medicine for several years at University Medical Center in Lubbock and other hospitals.

Dr. Troutman is President-elect of the Texas College of Emergency Physicians and has served as an Assistant Professor at the Baylor University College of Medicine and the Texas Tech University Health Sciences Center.

Dr. Troutman earned his MD from Texas Tech and completed his residency in emergency medicine and was Chief Resident at the University of Mississippi Medical Center.

He earned his MBA from West Texas A & M University College of Business and a BS from Midwestern State University.

Detective Barber?

MR. BARBER: Good morning, thank you for having us here to kind of talk about how this is affecting our community on a local level and what we're doing to try to curb that -- those effects.

Typically, in Lubbock, you know, we're

seeing this marketed towards two or three groups, usually the youth for sure with packaging. You know, the bright, shiny characters, cartoony characters and, you know, cheap high for them.

Those who are maybe on meth or some other type of narcotic and they're needing to not be able to pop positive on a drug test, so they're using something like this because it's not showing up on their drug screens or their parole officers and whatnot.

And, recently, in the last few years, we've really seen it marketed towards our homeless population which has been a group that we've really been trying to push a lot of aid in our community towards because it does affect our community as far as when those have to get treated medically and they're not able to pay bills.

You know, our community is having to pick up pieces there.

And, just in general, you know, the population being spread out around the community.

We've kind of been chasing our tails

in law enforcement trying to catch up with this drug because, as I spoke earlier, they constantly change the chemical structure of it.

So, you know, we started out with a city ordinance against selling that type of stuff in the town. It didn't really do a whole lot to curb it because, you know, it's not very -- not much of a punishment for them.

In 2015, Texas, we kind of -- we gave it a little more teeth with the law to kind of go after them by making it a penalty group 2A.

What that did is, it didn't go after the user so much because it's still classified basically as weed is or marijuana is for the possession of it.

But, it gave us a little bit more to go after the charges on them for distribution.

Earlier this year, I kind of got tasked with going after the distribution of it in Lubbock. And, we started looking into our smoke shops which is primarily where it was being sold at, with our tobacco shops there in Lubbock.

In March, we ran a search warrant on one of the -- or three smoke shops and the owner's residence and all his banks and everything. And, we ended up seizing about 18,000 grams of the synthetic cannabinoids from him at that time through is smoke shops and at his residence.

And, what we were finding out was he was getting it from -- typically, it was coming in through California and it was being imported from China to that wholesaler, I guess, there in California.

And, he was sending it out in the prepackaged stuff. It wasn't being made locally like the other ones were.

So now, we're seeing it more as, it's actually marketed prepackaged, ready to go for the dealer to go ahead and sell.

After that one, we kind of -- we're looking at where to go next with it. Who was going to be selling it next?

And, the way we did it is we were kind of following our homeless population around town

and seeing where do they congregate. Because, you know, they're not able to drive very far to a dealer.

We started getting a lot of complaints from more of a central part of our town which isn't typically where the homeless were staying at, about them being passed out in their parking lots, passed out along their buildings and stuff like that.

And, it happened to be right next to a smoke shop where all that was going on.

So, a few months ago, we ran another search warrant on that smoke shop after doing some deals there and shut that one down.

And then, so now that we've kind of been known -- like we just recently got a 90-year sentence on a distributer there in Lubbock for selling this stuff because of the effects it was having on people and the effects it was having on our community.

The jury showed that they didn't want it there in the town with the sentence they handed

down.

Since then, most of our tobacco shops have stopped selling it. We are still seeing it now with the -- it's more of a street level selling of the drug.

We have a local park there called Moose Head Park that's the local law enforcement and the community around that have kind of come to call it Zombie Park is what it's known as. Because, that's typically where it is.

It's a bunch of our homeless population who just wander around like zombies because they are constantly high on this drug.

We get a lot of calls to service there. We get, you know, violent calls from them getting in fights over there.

We've been doing now is we've been watching them, see where they're going and there are a few houses over there we'll see them walk in, about three or four of them walk into a house just fine and coming out, you know, just a few minutes later even and coming out and stumbling

around or falling and just completely high on this drug.

We've also started to see through packages that we've intercepted through FedEx and UPS, you know, large bulk bags of this stuff that's just, you know, in big, big bags of it, I guess, coming in where they're packaging it themselves here and are in Lubbock.

And then, taking it out kind of like a food truck, I guess you would say, taking it out to the community and where these homeless population are going to be congregating at. And, just kind of selling it, you know, selling it out of their vehicle or walking around and doing hand to hand sells there in the parks as well.

So, we're starting to see it move from being in our smoke shops where it's, you know, at least not geared towards our kids. But, now, it's being taken out onto the street level to where, you know, my concern is, right now, it's being marketed towards the homeless in the parks and whatnot, being moved over to our youth in the

schools and whatnot since it is cheap for them to get and it doesn't show up on their drug testing through schools as well.

So, I'll let them touch on the medical aspects of it, but with that, I'll be open to any questions.

Thank you.

ACTING CHAIR PRYOR: Thank you.

Mr. Curry?

MR. CURRY: Thank you all, again, for having us.

Over traveling over the last probably two or three years speaking at multiple conferences, this seems to be the hot topic with EMS across the United States right now.

And, for the first time in our careers, we've had to look at not treating a protocol for treating a patient, treating first responders and able to protect ourselves.

Especially on the EMS side, the fire side with us not being able to carry weapons, that has been a big feat.

A lot of times with these cannabinoids, we're getting called for seizure activity, vomiting. And so, EMS will go in by ourselves without police because it's a general EMS call.

And, we get in there, we get ourselves into a situation, they become very violent with excited delirium. And, the next thing you know, we're in danger.

We've seen reports of this, we started using a drug called ketamine which is what they --

ACTING CHAIR PRYOR: What was that?

MR. CURRY: Ketamine which is what they sedate horses with in order to do castrations and those type things.

It's been a drug a long time and it's not been widely used until the last few years. It's the only sedative that's heavy enough, it's actually an LSD derivative, and it's actually something we can use to get these patients down to where we can control them.

As part of that documentation, we've seen as many as six to nine responders having to restrain somebody just in order to get the ketamine on board.

That places all of us at a great risk.

In saying that, it ties up resources, an already stressed EMS, police system, now you're having to have more responders. And then, when we go into the Zombie Park, we know typically what we're going into there so we take -- we go in by force.

We don't always have that availability. It happens in the richer community, the poorer community, it doesn't really matter. We're seeing this all over the city and the county of Lubbock no matter what the socioeconomical situation is at that point.

As part of the -- it is being sold as things as Scooby Snax. I mean, it's attractive to kids. It's got Scooby-Doo on it. I mean, why would you not want to do that?

And so, they're testing it and they

know that this drug cannot be tested. And so, they can't prove that you were on that. And so, a lot of kids are moving toward that.

On the socioeconomical side, you know, a lot of the people that we're seeing is aged about 13 to about 50. These are our normal working class. And so, now, they're no longer being productive participants of society and so that's costing their families a lot.

But, as far as on the -- what we're seeing is it's less expensive than marijuana to buy on the street and it's very easy to get.

You can go online and order it, have it shipped straight to your house in a lot of these situations.

I give a lot of credit to the Lubbock Police Department and to the Lubbock District Attorney's Office. They've done a great job trying to trim this down.

So, we typically have, in 2016, we used ketamine a 197 times. So, quite a few times for us in the city limits of Lubbock with only

250,000 people in it. That's a lot of ketamine in order to protect ourselves.

Since July of 2017, so the last just about five months, we've used -- we've cut that, it's been reduced by over half now. And so, the police, once again, the police department's done an outstanding job trying to break those situations down of how to, first of all, catch them and then how to prosecute them.

And, that's been a big thing because most of them are walking, you know, they're being charged and they're walking out the door in two hours and they're right back selling again.

So, that's been a huge big factor us, but they've done a great job and we've seen that reduction in ketamine use by 50 percent since July of this year. So, that's made huge progress.

I'd like to talk a little bit about the family effects. This has become very hard. A lot of times, these patients with excited delirium, they become very -- extremely violent.

Once again, we get called for a typical seizure call, a typical vomiting call. And so, we get there, we begin to take of them and we notice that mom's or a father or a child is beat up.

And, we start asking questions and then they become even more agitated and we come to find out what has happened.

At that time, typically, there's only two paramedics on an ambulance at a time. And so, that's left two of us to determine are we going to stay and defend ourselves or are we going to try to get family out and let them be until we get backup and then go back in.

And so, it's something we have to weigh as far as the safety.

We've had several instances of death due to this. I've got a video that I use for school education in this and we've started talking to high schools about this very regularly now.

And, in this video, two children or

two teens smoke Spice one after the other. The first one gets the euphoric high that he's wanting. The second one falls to the ground and begins to seize, eventually, he gets very hot temperature, blood pressure climbs, he herniates his bring and dies right there on the video.

And, I show that video as it impacted those children.

As part of that, those families have to make decisions a lot of times. Dr. Troutman can probably allude to this, but in the hospital setting, they're having to make that decision that my child is now brain dead. I have to make a decision, can I donate? Do I -- when do I need to pull the plug and no longer provide that long term care for them.

Some of those that aren't to that point maybe go into a long term care facility which costs astronomical amounts of money to the public. And, typically, these are not your insured patients and, therefore, it falls back on the taxpayer to take care of them long term with

a severe brain injuries, anoxic brain injuries, not able to function or even on a ventilator the rest of their lives.

Once again, I thank you very much for having us, and I'll be glad to take any questions.

ACTING CHAIR PRYOR: Thank you.

Dr. Troutman, I believe I mispronounced your first name, it's Gerad.

DR. TROUTMAN: Gerad.

ACTING CHAIR PRYOR: Gerad.

DR. TROUTMAN: It's okay, I get it all the time.

ACTING CHAIR PRYOR: But --

DR. TROUTMAN: Thank you.

Honorable Chair and the rest of the Sentencing Commission, thank you for having us here from Texas.

I want to discuss with you a crisis in our country that really needs to be stopped.

As an emergency medicine physician, I'm part of the front line in the trenches of healthcare seeing patients at their worst when

they need the most help.

I've taken care of murderers. I've taken care of police officers, elected officials, drug abusers, all walks of life every day come into our ER.

I've seen things I don't dare mention in a public context.

And, as emergency physicians governed by EMTALA, we see every patient, every time, 24/7 without regard to ability to pay.

Synthetic cannabinoids first surfaced in Lubbock, Texas about five years ago. We're a relatively safe, west Texas town of about a quarter of a million people. We have some drug use, we have some crime, but we're a far cry from America's large cities.

As an ER doctor, I've seen plenty of cases of drug abusers that use cocaine or heroin or methamphetamines. And, I can tend to tell you exactly what happens to the human body when these drugs are consumed.

We started seeing patients coming into

our ER after using what they were calling legal weed. That's what they were calling it out on the streets.

Different patients were reacting differently and that makes our job in medicine hard. Much of medicine is determining what is going on with the patient and then predicting what will happen next and then using our tools to help stop any of those next things that are happening that may be detrimental to the body.

This new legal weed was becoming a more common occurrence and everyone that presented in our ER and to EMS had these different reactions.

Some felt euphoric like they were often going for, some just felt bad, some had headaches, some had seizures. Some had fevers. Some had funny heart beats and some even die.

I remember specifically a few of these cases through the years.

One young girl we'll call Emily was brought in by her boyfriend. He had been smoking

legal weed for some time and he hadn't had any issue with it and asked his girlfriend to try it.

It was over-the-counter that he bought it, he didn't get it from dark alley. The girlfriend had never used any drugs before. So, she said, sure.

She smoked it, really didn't have any issue. They went to bed. Well, by the next morning, Emily wasn't responding right and so the boyfriend called 911.

So, EMS brought Emily into me. On quick exam, I had a 24-year-old fit young lady in front of me who couldn't move her right side. She was very weak on her left making noises by mouth but not forming normal sentences or normal words.

I know that we needed to get a CAT scan right away. And the CAT scan showed what I feared is, Emily had had a large stroke.

You know, I expect to see a stroke in a 70-year-old person, but not typically a 20-year-old young female that lay in front of me.

It was then that her boyfriend actually confessed, you know, the only thing that's been strange is we smoked some legal weed last night. And, we were seeing more of this and I knew right away that most like was the culprit.

You know, Emily will never recover from such a large stroke like that and I'm sure, today, she's under 24-hour care, somebody having to feed her and take care of her in a nursing home somewhere.

Patients continue to present to our ER after using this stuff which we now learned to call synthetic cannabinoids. Everyone who smoked it seemed to react differently.

We're heard that from some of the other testimony how it's kind of all over the place on how the human body reacts to this. Different batches just have different effects on people and even the same batch can have different effects on different people.

This makes our job in the ER incredibly difficult as we have difficulty in

anticipating what will happen next in a patient's body.

I also am the EMS Medical Director, the physician that sets medical policy for those who respond to 911 calls.

One of the biggest issues we have on 911 calls are when patients have used synthetic cannabinoids, where patients were acting almost superhuman, fighting against our police, our firemen, paramedics, often taking four, five, six of these providers to subdue a patient to get them into an ambulance.

This can harm our pre-hospital providers taking care of police or paramedics that have been punched by patients, folks that have been spit on and had to undergo extensive HIV testing and what have you.

So, we started using a medication called ketamine. This is an older drug that's resurfaced in recent time because it has been a relatively effective drug for patients that are acting almost superhuman on synthetic

cannabinoids.

It allows us to sedate the patient, but it doesn't completely take away their breathing drive which is, of course, important. We want the patient to continue to breathe.

This allows us to give the patient time for this poison to essentially get out of their body. You know, unfortunately, just like the body reacts differently, sometimes it may take hours for this to get out of the body, it may take weeks.

And, sometimes, now, as we see people that are using this chronically, the behavioral changes almost have seemed to stick, even those who have stopped, they're six months, a year out and they still have got some sort of mind altering issue with them.

My biggest issue with synthetic cannabinoids is the perception that many feel like it is legal or those who know that it isn't, they feel like the law is not that bad if they do use it or possess it.

So, they see it as relatively safe, not a big deal. It's a slap on the wrist at most.

Most of the users I've seen in the ER are not the typical person that would use a more typical drug such as cocaine or something like that. They would never touch that.

They've turned to this because it was easily accessible and even sometimes over-the-counter. This just gives that stigma that it must be safe.

We need to do something about the sale, manufacturing and use of those drugs and make it a serious crime. I think this deterrent would deter more of those from using it.

Thank you.

ACTING CHAIR PRYOR: Thank you.

It was referenced earlier to Scooby-Snax. And, I noticed in some photographs of Scooby-Snax that were presented to us that some were labeled Strawberry Smash or Green Apple.

Are they actually flavored?

MR. CURRY: Go ahead.

MR. BARBER: They'll have different scents to them, different --

ACTING CHAIR PRYOR: Scents?

MR. BARBER: Yes, and they may have a certain flavoring added on to them. But, they're -- they kind of -- they label to kind of market them toward certain groups of people.

So, like the last warrant around this stuff, they had one called Zero Gravity and it had a picture of an astronaut kind of floating in space, you know, to present a high.

They have one called Ripped that had like a cartoony banana that was all -- I mean, like a child-like cartoony drawing on there.

They had the Scooby-Snax is one of them. You know, they use these weird names on them or they'll, you know, they have a strawberry and blueberry and different types of flavorings, stuff like that as well.

They kind of like, I guess, the new -- it's an oil --

MR. CURRY: I'll say, yes, the vapor.

MR. BARBER: The vapors.

MR. CURRY: We've seen some of that, too. They'll put them in a olive press and press them down, use the oils and they're able to vape those.

Yes, we don't really know what vaping is doing yet because it's still, you know, absorbs into the alveolar sac and then they're not able to oxygenate and get gas exchange at that point. So, that's a whole other issue added on.

On top of that, you know, Flakka, it has been coming in through China a lot via Florida. We've got a little bit of it in Lubbock.

This is an LSD derivative, if you will, and a PCP mix. And, these people will not sedate with ketamine. And so, we have to continue -- then we have to move to paralytics, we have to paralyze them in the field and hopefully get a breathing tube in in a timely

manner so they can live.

That has been some of the newest stuff we've seen. And, I'm talking 90 pound females that are taking nine and ten first responders to restrain. And, one of them has even had a fracture of an arm because she just pulled so hard that kind of like an arm wrestler would can sometimes can break their own bones and that's what a lot of these patients are doing. And they won't sedate.

ACTING CHAIR PRYOR: Judge Breyer, do you have any questions?

COMMISSIONER BREYER: No.

ACTING CHAIR PRYOR: Thank you very much for your presentation this morning.

Before we finish up, though, before we adjourn the hearing, I want to -- I want publically to acknowledge the retirement of Dr. Lou Reedt. His last day working at the Commission is today, after 23 years of distinguished service to the Commission and to the public.

Lou previously served as the Acting Director of what had been the Commission's Office of Policy Analysis and for the last several years, as the Deputy Director of the Office of Research and Data.

It is fitting that Lou's last day at the Commission coincides with today's public hearing on synthetic drugs.

Lou has led the staff work on every amendment to the drug guidelines, big or small, prospective or retroactive for over two decades.

The list includes amendments relating to methamphetamine, ecstacy and steroids. But, the amendments most noteworthy to the public perhaps are to the -- are the 2007 Crack Minus Two amendment and its retroactivity, the Fair Sentencing Act of 2010 Guideline Amendment and its retroactivity and the 2014 Drugs Minus Two amendment and its retroactivity.

Now, of course, most recently, Lou has led our staff work on synthetic drugs leading up to today's hearing.

Lou also has been a principle staff contributor on numerous reports to Congress on drug offenses including three reports to Congress on crack cocaine and a fourth on the impact of the Fair Sentencing Act and one on MDMA offenses as well as reports to Congress on broader sentencing issues such as the 2003 report on downward departures as directed by the PROTECT Act, the 2006 and 2012 reports on the impact of United States v Booker on federal sentencing and the 2011 report on mandatory minimum penalties and the federal criminal justice system.

Lou's research and data has always been thorough and accurate and his advice to the Commission has always been thoughtful and helpful. Lou, we are grateful for your 23 years of exceptional service to the Commission and to the public. And, we now grant you compassionate release.

DR. REEDT: Thank you.

ACTING CHAIR PRYOR: Yes, another policy team that Lou led. We wish you all the

best in your retirement. Thank you. And that -

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(Applause.)

ACTING CHAIR PRYOR: And that concludes today's hearing. We thank our last panelists, the witnesses for their oral presentations and for their written submissions.

And we are adjourned.

(Whereupon, the above-entitled matter went off the record at 11:59 a.m.)