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THE OVERDOSE CRISIS: INTERAGENCY PROPOSAL TO
COMBAT ILLICIT FENTANYL-RELATED SUBSTANCES

THURSDAY, DECEMBER 2, 2021

House of Representatives,

Subcommittee on Health,

Committee on Energy and Commerce,

Washington, D.C.

The subcommittee met, pursuant to call, at 10:31 a.m., in Room 2123, Rayburn House Office Building, Hon. Anna G. Eshoo [chairwoman of the subcommittee] presiding.

Present: Eshoo, Butterfield, Matsui, Castor, Sarbanes, Welch, Schrader, Cardenas, Ruiz, Dingell, Kuster, Kelly, Barragan, Blunt Rochester, Craig, Schrier, Trahan, Fletcher, Pallone (ex officio), Guthrie, Upton, Griffith, Bilirakis, Long, Bucshon, Hudson, Carter, Dunn, Curtis, Crenshaw, Joyce, and Rodgers (ex officio).

Also Present: Representatives Schakowsky, and McKinley.

Staff Present: Lydia Abma, Health Fellow; Tania Calle, Health Fellow; Waverly Gordon, Deputy Staff Director and General Counsel; Tiffany Guarascio, Staff Director; Fabrizio Herrera, Staff Assistant; Zach Kahan, Deputy Director, Outreach and Member

Service; Mackenzie Kuhl, Press Assistant; Meghan Mullon, Policy Analyst; Juan Negrete, Junior Professional Staff Member; Kaitlyn Peel, Digital Director; Asad Ramzanali, Legislative Director; Tim Robinson, Chief Counsel; Chloe Rodriguez, Clerk; Kylea Rogers, Staff Assistant; Andrew Souvall, Director of Communications, Outreach and Member Services; Kimberlee Trzeciak, Chief Health Advisor; C.J. Young, Professional Staff Member; Alec Aramanda, Minority Professional Staff Member, Health; Sarah Burke, Minority Deputy Staff Director; Seth Gold, Minority Professional Staff Member, Health; Grace Graham, Minority Chief Counsel, Health; Nate Hodson, Minority Staff Director; Peter Kielty, Minority General Counsel; Emily King, Minority Member Services Director; Bihan Koohmaraie, Minority Chief Counsel, Oversight & Investigations Chief Counsel; Clare Paoletta, Minority Policy Analyst, Health; Kristen Shatynski, Minority Professional Staff Member, Health; Olivia Shields, Minority Communications Director; and Michael Taggart, Minority Policy Director.

Ms. Eshoo. Good morning, everybody. The Subcommittee on Health will now come to order. Due to COVID-19, today's hearing is being held remotely as well as in person. For members and witnesses taking part in person, we are following the guidance of the CDC, and the Office of the Attending Physician, so please wear a mask when you are not speaking. For members and witnesses taking part remotely, microphones will be set on mute to eliminate background noise. Members and witnesses, you will need to unmute your microphone when you wish to speak.

Since members are participating from different locations at today's hearing, recognition of members for questions will be in the order of subcommittee seniority. Documents for the record should be sent to Meghan Mullon at the email address we have provided to your staff. All documents will be entered into the record at the conclusion of our hearing. The chair now recognizes herself for 5 minutes for an opening statement.

As our country has grappled with the public health crisis caused by a novel virus for nearly 2 years now, we have also faced a more familiar threat in the form of drug addiction. More than 100,00 Americans have died. Let me repeat that. More than 100,000 Americans have died from drug overdoses since the COVID-19 pandemic began, a grim record that shows no sign of abating.

The fastest-growing cause of overdose deaths has been synthetic opioids, including fentanyl. Since 2018, all fentanyl-related substances that are not already scheduling have been temporarily listed under Schedule 1 of the Controlled Substance Act, and the current extension will expire at the end of -- no, I think the date -- at the end of January. The continuing resolution introduced this morning extends the deadline to February 18. Despite this temporary scheduling, deaths due to fentanyl-related

overdoses have continued to rise even as deaths caused by other drugs have fallen.

Our subcommittee hearing today is to learn from the administration its recommendations to Congress for permanent scheduling of all fentanyl-related substances. The interagency proposal calls for permanently scheduling these drugs under Schedule 1 but with an expedited process to reschedule those that are later found not to be dangerous enough to warrant such regulation.

Over 100 civil rights groups have expressed concerns about class-wide scheduling because it expands the number of drugs subject to mandatory minimum sentences that contribute to the disproportionate incarceration of racial minorities. To address this concern, mandatory minimums would not apply in most cases involving fentanyl-related substances unless there is death or serious bodily harm. And if a substance is later removed from Schedule 1, incarcerated individuals could have their sentences reduced or vacated.

The proposal would make it easier for researchers to get permission from the Federal Government to study all Schedule 1 substances. The current restrictions deter many researchers from studying these drugs, and removing some of these barriers will help us better understand how to treat addiction.

Today, we will hear from some of the agencies that developed these recommendations, including the FDA, the National Institute on Drug Abuse, the Drug Enforcement Administration, and the Office of National Drug Control Policy, and we look forward to their insights on how the administration's proposals will help address the overdose epidemic.

I want all members to know that we invited the Department of Justice, the DOJ, to testify, but they chose not to appear at today's hearing. Our staff began conversations with the DOJ about this hearing in September, last September, and I formally invited

them to send a witness on November 18. DOJ's refusal to testify, I find to be troubling, and they offered no legitimate reason. They just declined. Their perspective on their own recommendations to Congress would have been valuable for us to hear.

So now the chair is pleased to recognize the distinguished ranking member of our subcommittee, Mr. Guthrie, for his opening statement.

Mr. Guthrie. Thank you, Chair Eshoo, for holding this important hearing, and thanks to all of our witnesses for being here today.

Today, we are discussing how to permanently combat the trafficking of illicit fentanyl-related substances. This committee has a bipartisan history of addressing the growing opioid epidemic. For example, the SUPPORT for Patients and Communities Act include in my bill the Comprehensive Opioid Recovery Centers Act, which authorizes the creation of comprehensive opioid recovery centers throughout the Nation. These centers provide evidence-based comprehensive care with those with substance abuse disorders.

However, I am frustrated, and I am pleased to see that we are going to move forward with scheduling through February 18, but I am really frustrated that we failed to come up with and join together to permanently schedule fentanyl analogs. We lost 100,000 Americans last year to drug overdoses. In my home State of Kentucky, overdose deaths increased by 54 percent between spring 2020 and spring 2021. The Kentucky Office of Drug Control Policy described the trend as one of the most critical public health and safety issues facing Kentucky.

Additionally, the agency attributed most of these deaths to the illicit use of fentanyl and fentanyl analogs, which their 2020 overdose fatality report noted was responsible for over 70 percent of all of the Commonwealth's drug overdoses in 2020.

But these aren't just numbers on a page. There are mothers, fathers, brothers,

sisters, friends, and children. In March of this year, a Kentucky mother purchased drugs laced with fentanyl, and not too long after, found her 2-year-old son dead after he reached into her purse while she was napping and ingested the deadly poison. These tragedies have unfortunately become too familiar to not just Kentuckians, but to thousands of Americans across the country.

Healthcare closures have also caused disruptions or lengthy delays in care for individuals who are seeking substance use disorder treatment. These delays have also affected those seeking first-time care for substance use disorder and have tragically led to a sharp increase in overdoses.

I worry about further disruptions to care due to workforce shortages exacerbated by Federal vaccine mandates. CDC found in a recent survey that 30 percent of health workers in hospitals are unvaccinated. I oppose this government overreach on our healthcare heroes, although I am vaccinated and encourage people to do so if they so choose.

Even worse, President Biden's border crisis has essentially made Kentucky and every other State a border State. Only 2 milligrams of fentanyl could be a lethal dose. And the U.S. Customs and Border Protection has reported almost 4,000 pounds of fentanyl seized at the southern border. Drug Enforcement Administration's own leadership cited statistics showing that the agency seized enough fentanyl this past year alone to give every American a lethal dose.

The Biden administration's failure to address this problem at our southern border is driving increases in drug overdoses. I have been urging my colleagues to permanently schedule fentanyl analogs by supporting the Federal Initiative to Guarantee Health by Targeting fentanyl Act. And although the administration recently issued a plan to permanently schedule these substances, the proposal misses the mark by failing to

impose mandatory minimums on fentanyl analog traffickers. By excluding mandatory minimum for trafficking fentanyl analogs, the proposal effectively incentivizes the cartels to continue to develop more variation of fentanyl and ship these deadly substances to our own backyards. Given that fentanyl and its analogs have contributed to the highest levels of overdose rates this country has ever seen, excluding them from the mandatory minimum is disturbing.

It is unfortunate that the Department of Defense -- the Department of Justice can't be here today to explain this policy. Did the DOJ refuse to show up to today's hearing because they are unable to justify the policies in this proposal? Why didn't this administration send their top Federal law enforcement agency to share their plans with the American people on how they will get these deadly poisons off our street?

I appreciate the chair's strong remarks to that because it is important and disturbing that they wouldn't be here. It is their job. I know sometimes these hearings aren't convenient for people to appear, but it is our job for oversight, and it is their job to be here.

I will continue to press permanently scheduling fentanyl analogs and giving law enforcement the resources needed to fight back against the illicit trafficking of fentanyl and fentanyl-related substances across the United States that are sadly taking the lives of thousands of Americans.

Thank you. Thank you, Madam Chair, and I yield back.

Ms. Eshoo. The gentleman yields back.

The chair is now pleased to recognize the chairman of the full committee, Mr. Pallone, for your 5 minutes for an opening statement.

The Chairman. Thank you, Chairwoman Eshoo.

Today, we continue this committee's work of combating the ongoing drug

overdose crisis. This crisis is a tragedy, taking more than 100,000 Americans far too soon during the first 12 months of the COVID-19 pandemic. For years, we have worked to combat this crisis. Earlier this year as part of the American Rescue Plan, we included $3 billion in funding for the mental health and substance use block grant programs at the Substance Abuse and Mental Health Services Administration. And this funding was the largest aggregate amount of funding for these programs, and it goes to critical programs and services for people experiencing substance use disorder.

The American Rescue Plan builds upon the work we have done, but we obviously must do more. Today, we are, once again, discussing solutions to the overdose issue and what more Congress can do to end this crisis. Synthetic opioids such as fentanyl and fentanyl analogs have been a significant driver of overdose deaths in the United States. Last year, the Centers for Disease Control and Prevention estimated that more than half of overdose deaths involving synthetic opioids and drugs mixed with synthetic opioids, primarily illicit fentanyl. The availability of illicit fentanyl in the United States has dramatically increased, and manufacturers have been able to evade regulations by rapidly manufacturing new versions fentanyl substances that aren't subject to control.

Today, fentanyl-related substances are temporarily placed in Schedule 1 of the Controlled Substances Act, which is the strictest category of regulation. Schedule 1 is reserved for drugs that have no accepted medical use, a high potential for abuse, or lack of accepted safety. Schedule 1 also prohibits the manufacturing, distribution, or dispensing of these substances unless given explicit approval to do so.

The current temporary scheduling order subjecting fentanyl-related substances to these restrictions is set to expire on January 28 of 2022. However, the CR we will consider this week, and probably today, will provide for an extension through February 18 of next year. And it is critical that Congress and this committee work together in a

bipartisan fashion with the administration to put in place a long-term solution.

In September, the Biden administration released recommendations to address illicit fentanyl-related substances prepared by the Office of National Drug Control Policy, the Department of Health and Human Services, and the Department of Justice, and I appreciate the witnesses for joining us today. The administration's proposal would create a class-wide definition of fentanyl-related substances and permanently place them as Schedule 1. It would also create a mechanism to expedite rescheduling or descheduling of substances as needed. And I am pleased that the proposal also includes provisions to streamline registration requirements for all Schedule 1 substances. Aligning Schedule 1 registration requirements more closely with Schedule 2 requirements will help expedite registration for researchers who want to study Schedule 1 substances and will hopefully help to expand further research in this space and development of future treatments.

I look forward to learning more about the details of the administration's proposal, and why Congress should pass legislation to reflect the recommendations. As we discuss this proposal, it is also important to remember that this is a set of recommendations. This committee is responsible for crafting the actual legislation that will help dramatically improve the lives of many Americans. There are many ideas and proposals to meet this goal, including strategies to strengthen prevention, treatment, harm reduction, and recovery services. There is no idea too big or too small to get ahead of this crisis, and we must work together to solve it.

And, finally, I wanted to say that I am pleased that DEA is represented here by its Principal Deputy Administrator, and I look forward to also working directly with DOJ on the administration's proposal so this committee can better understand the intent and rationale behind their policy recommendations related to enforcement.

So I look forward to hearing from all our witnesses, and Madam Chair, I know that this is something that you are very concerned about and have been for some time. And thank you for having this important hearing today. I yield back.

Ms. Eshoo. The chairman yields back. The chair is now pleased to recognize Congresswoman Cathy McMorris Rodgers. She is the distinguished ranking member of our full committee for her 5 minutes for an openings statement.

Mrs. Rodgers. Thank you, Madam Chair.

Fentanyl and fentanyl-related substances are killing a record number of Americans. Making sure that these deadly poisons are permanently made illegal requires urgent action. Lives are on the line. An unthinkable amount of fentanyl and its analogs are coming across our border, enough to kill every American seven times over. According to CDC's National Center for Health Statistics, there were over 100,000 drug overdoses in the United States from April 2020 to 2021. In my home State of Washington, the overdose death rate increased by more than 36 percent. It is higher than the national average, all because fentanyl and its many analogs. Here is the recent headline in the Spokesman-Review: "Deaths and killings rise in Spokane." The report reflects increase in fentanyl overdoses.

I wanted to share a story about someone from my community where in Spokane, the illicit drug market is completely flooded with fentanyl. Alan had battled addiction and despair since he was a child. He recently had lost his job, relapsed, and, unfortunately, overdosed on heroin. The paramedics administered Narcan to save his life, and he woke up in an ambulance. He later learned that the heroin he consumed was laced with fentanyl. He was lucky. He survived. And each time Alan uses, he is playing a game of Russian roulette with his life, because fentanyl and its analogs are everywhere.

As of this year, the DEA has seized a record number, 9.5 million fake prescription pills containing lethal amounts of fentanyl. More counterfeit pills have been seized so far in 2021 than the previous 2 years combined with two out of every five pills containing a potentially lethal dose of fentanyl. This is not your typical street drug. This is a weapons-grade poison that is killing our children.

I learned another story about a young woman in my district named Kayla. She and her friend split what they thought was a Percocet tablet. That one pill, which was laced with fentanyl, immediately killed them both. They had no chance.

For people like Alan and Kayla, Republicans have been trying to permanently place fentanyl-related substances in Schedule 1. We are hearing from an army of parents every day, parents who deserve justice because they have lost a child, and they don't want anyone else to experience their pain.

The Biden administration agrees that we should permanently schedule fentanyl-related substances in Schedule 1. The Biden administration recommends also support more research into innovation and detect dangerous drugs like fentanyl and treat those with substance use disorders. That is where we agree.

Unfortunately, the administration is also trying to treat these deadly poisons differently from fentanyl and other currently scheduled fentanyl analogs. The administration is proposing to exempt the entire class from trafficking mandatory minimums. This would prevent our law enforcement from finding and putting away drug traffickers who are bringing these chemical weapons across the border.

For the parents we are fighting for, it would mean criminals who killed their kids who keep trafficking these lethal substances with lower repercussions. Surely, there is bipartisan support to deliver justice for these families. We should be working together to punish those who make, import, and distribute these poisons to our children, and help

those with substance abuse disorders with treatment and recovery. Congress must work together on the SUPPORT for Patients and Communities Act.

In addition to permanently scheduling fentanyl analogs, I stand ready to work together again to reauthorize key programs at the Substance Abuse and Mental Health Services Administration that expire next year to help get treatment for those who need it. We need to take urgent action on fentanyl analogs. It is too deadly a substance to be weak on traffickers, and to those who sell it to our children in our communities.

Even if Congress passes the CR later on today, after February 18, fentanyl-related substances will be street legal. I remain deeply concerned that we will not take action in time, tying law enforcement's hands in their battle to keep this poison out of our communities and simply kick the can another few months. Congress needs to make permanent the fentanyl analogs ban immediately, along with existing criminal penalties. Parents, communities, and our constituents need it. With that, I yield back.

Ms. Eshoo. The gentlewoman yields back.

I would like to advise members that pursuant to committee rules, all members' written opening statements shall be made part of the record.

I now would like to introduce our witnesses. Mr. Kemp Chester is the Assistant Director of the Office of National Drug Control Policy in the Executive Office of the President. Welcome to you, and thank you for being with us today.

Dr. Nora Volkow. She is the Director of the National Institute on Drug Abuse at the National Institutes of Health. We can say welcome back. You have graced the witness table several times before, and we welcome you back.

Dr. Douglas Throckmorton is the Deputy Director for Regulatory Programs in the Center for Drug Evaluation and Research at the FDA. Welcome to you, and thank you for being with us.

And Mr. Louis Milione is the Principal Deputy Administrator of the Drug Enforcement Administration, the DEA. Welcome to you, and thank you for being here today.

We look forward to the testimonies that you are going to provide to us. You are probably familiar with the light system. It isn't anything complex. You have 1 minute remaining when the yellow light comes on, and I think everyone knows what red means.

So, Mr. Chester, you are now recognized for your 5 minutes of testimony, and thank you again for being here with us today for this very important hearing.

STATEMENTS OF KEMP L. CHESTER, ASSISTANT DIRECTOR, EXECUTIVE OFFICE OF THE PRESIDENT, OFFICE OF NATIONAL DRUG CONTROL POLICY; NORA D. VOLKOW, M.D., DIRECTOR, NATIONAL INSTITUTE ON DRUG ABUSE, NATIONAL INSTITUTES OF HEALTH; DOUGLAS THROCKMORTON, M.D., DEPUTY DIRECTOR FOR REGULATORY PROGRAMS, CENTER FOR DRUG EVALUATION AND RESEARCH, U.S. FOOD AND DRUG ADMINISTRATION; AND LOUIS J. MILIONE, PRINCIPAL DEPUTY ADMINISTRATOR, U.S. DRUG ENFORCEMENT AGENCY.

STATEMENT OF KEMP L. CHESTER

Mr. Chester. Chairwoman Eshoo, Ranking Member Guthrie, members of the subcommittee, thank you for inviting me to testify today.

The Biden years administration approaches America's overdose epidemic with the urgency it demands, through evidence-based drug policy that effectively addresses both the public health dimension of the problem, as well as the dynamic nature of the drug trafficking environment facing the United States and the world.

At present, one of the most complex and consequential challenges we face is illicitly manufactured fentanyl, fentanyl analogs, and fentanyl-related substances, or FRS. They confound our efforts to reduce opioid-related overdoses and deaths, have pervaded the Nation's illicit drug supply, are found throughout country, and are the main driver of the increase in drug poisoning deaths in the United States.

In 2020 alone, overdose deaths involving synthetic opioids, primarily illicit fentanyl and its analogs, increased by 55 percent. New and emerging FRS are being manufactured faster than the United States can schedule them individually, necessitating

the permanent class-wide scheduling of FRS as a whole. Recent Customs and Border Protection data show that it may be possible to synthesize as many as 4,800 fentanyl analogs with relatively simple modifications to the base fentanyl molecule.

Time is of the essence. And although scheduling is not sufficient in itself to solve this problem, it is absolutely necessary to control substances yet to be made, and yet to be made available in America's communities. We must deter the creation of these new substances, and disrupt their flow into the United States in order to allow our historic investments and public health interventions to take hold and make tangible progress.

For the past several months, the Office of National Drug Control Policy, the Department of Justice, and the Department of Health and Human Services met regularly to develop recommendations for a comprehensive consensus approach that addresses the complex issues surrounding the scheduling of FRS. This process involved input from the Congress, public health officials, law enforcement partners, and stakeholder groups.

These recommendations would permanently schedule these dangerous substances as a class, while ensuring that access for scientific research is not burdensome, and civil rights protections are safeguarded. This is a delicate balance, and we have sought to provide a responsible and comprehensive approach.

The administration recommends the following: First, permanently schedule all unscheduled FRS into Schedule 1 in accordance with the Controlled Substances Act of the CSA; second, for these class scheduled FRS, exclude quantity-based mandatory minimum penalties normally associated with domestic trafficking of Schedule 1 substances. This exemption does not apply, however, where there is a direct link to death or serious bodily injury; third, create a streamlined process overseen by HHS to remove or reschedule any FRS found not to have a high potential for abuse as defined in the CSA; fourth, ensure a Federal court is able to vacate or reduce the sentence of an individual convicted of an

offense involving an FRS that is subsequently removed or rescheduled from Schedule 1; fifth, establish a simplified process to align research registration for all Schedule 1 substances, including FRS, more closely with the research registration process for Schedule 2 substances; and, finally, direct the Government Accountability Office to analyze the implementation of permanent class scheduling of FRS, including its impact on research, civil rights, and the illicit manufacturing and trafficking of these dangerous substances.

These recommendations follow the approach outlined in the administration's first year drug policy priorities, which include expanding access to evidence-based prevention, treatment, harm reduction, and recovery support services, as well as reducing the supply of illicit drugs.

The foundation of these recommendations rests with making our communities healthier and safer without causing unintended harm. They are a critical part of our comprehensive effort to reduce drug use and its negative consequences throughout the Nation.

On behalf of Dr. Gupta and the men and women of the Office of National Drug Control Policy, I would like to thank you and your congressional colleagues for your leadership, and thank our Federal partners as well for their close elaboration on this critical issue. I thank you for your time, and I look forward to your questions.

[The prepared statement of Mr. Chester follows:]

******** COMMITTEE INSERT ********

Ms. Eshoo. Thank you very much.

Dr. Volkow, you have 5 minutes for your testimony, and we once again welcome you here today.

STATEMENT OF NORA D. VOLKOW, M.D.

Dr. Volkow. Good morning. Chairwoman Eshoo, Ranking Member Guthrie, and members of the subcommittee, thank you for inviting me to speak with you today.

Illicitly manufactured fentanyl and fentanyl-related substances are driving the steep rise in overdose deaths in the United States. The latest data show overdose deaths exceeded 100,000 in a year, a staggering figure, and the highest number ever recorded in a 12-month period in the United States. Overdose deaths involving synthetic opioids increased by 49 percent during that period. Therefore, it is imperative that we reduce trafficking and manufacture of these dangerous substances. However, this should not be done at the expense of criminalizing people who use drugs, an approach that we know does little to deter drug use or alleviate substance use disorders. Instead, an evidence-based approach that prioritizes prevention and treatment of substance use disorders is needed to address the opioid and overdose crisis.

In this regard, research on fentanyl-related substances is essential to develop treatments for opioid addiction and overdose, particularly in light of reports that current medications may not be as effective against fentanyl. However, obtaining a DEA registration to study fentanyl-related substances and other Schedule 1 drugs presents challenges to researchers. Even experienced researchers report that obtaining or modifying a DEA registration can take many months. The application process is often

redundant with the reviews needed to obtain a Federal grant or an FDA investigational new drug authorization.

Establishing the security infrastructure to conduct Schedule 1 research, which is expensive, may need to be duplicated for each registrant working within a single department. Researchers have also reported a lack of clarity on the registration requirements on variability in their interpretation. These challenges can slow research progress and dissuade investigators from working with Schedule 1 substances. That is why the administration's proposals to permanently schedule fentanyl-related substances includes a process for rapidly removing those with no or low abuse potential from the scheduling.

This is critical because a class-wide scheduling, which is based on chemical structure alone, bypasses the usual substance-by-substance analysis of the compounds abuse potential. These will result in the permanent placements of thousands of compounds into Schedule 1, potentially including substances with little or no addictive potential, and those that hold promise for treating fentanyl overdoses, opioid use disorder, pain, and other conditions.

Equally important is facilitating research on the substances that remain in Schedule 1. The administration proposes an alternative registration process for Schedule 1 research funded by HHS or the VA, or conducted under an FDA IND, but more closely aligns with the process for Schedule 2 substances, such as methamphetamine and cocaine. It will remove duplicative practical reviews, expedite the process for modifying current registrations, and still prevent the version for maintaining the security and inventory controls currently in place. The proposal also addresses aspects of the law that researchers report to be confusing, burdensome, or inconsistently applied as well as to facilitate transparency in the registration and review procedures.

I am very grateful to our colleagues at ONDCP, HHS, and DOJ for their support of this important proposal, and to the committee for considering it. I am happy to answer any questions you may have.

[The prepared statement of Dr. Volkow follows:]

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Ms. Eshoo. Thank you very much, Doctor.

I now am pleased to recognize Dr. Douglas Throckmorton for your 5 minutes of testimony. Thank you again.

STATEMENT OF DOUGLAS THROCKMORTON, M.D.

Dr. Throckmorton. Chairwoman Eshoo, Ranking Member Guthrie, members of the subcommittee, I am Dr. Douglas Throckmorton, Deputy Director for Regulatory Programs at the Center for Drug Evaluation and Research at the Food and Drug Administration. Thank you for the opportunity to appear before you today to discuss the comprehensive approach to the scheduling of fentanyl-related substances developed with the Office of National Drug Control Policy, the Department of Justice, and the Department of Health and Human Services, as well as the important role the FDA plays in scheduling illicit substances that pose a danger to public health, while also supporting the development of needed new drug therapies.

As the committee has heard, new illicit synthetic drugs derived from fentanyl are coming into the U.S. and are being mixed with heroin and other drugs. The result has been a dramatic increase in opioid-related deaths in the U.S. in recent years.

While the DEA is the lead Federal agency responsible for regulating controlled substances and enforcing the Controlled Substances Act, HHS has a number of critical responsibilities under the Act, several of which have been delegated to the FDA. Given this, FDA and DEA have worked very closely together in the area of controlled substances, including opioids, including the work we are here to discuss today related to the appropriate level of control for the fentanyl-related substances that are flooding into our

country with tragic results.

DEA issued a temporary order in 2018, as has been mentioned, controlling the entire FRS class. Congress has since extended that order through January 28, 2022. In 2020, DEA asked HHS to make a scheduling recommendation for the entire FRS class. Following careful evaluation, the FDA concluded that such a recommendation was not possible for the FRS class for several reasons:

First, the class is vast in terms of the number of hypothetically covered substances; second, data on the pharmacological effects and epidemiological data about the harms and overdose deaths are available for fewer than 30 members of that FRS class; and third, among the individual FRS members that we have pharmacological data, FDA has identified examples of substances that do not activate the mu-opioid receptor. This activation is the primary pharmacology that would lead to opioid-related harms, such as those caused by fentanyl, Oxycodone, and Hydrocodone.

Instead, recognizing the significant public health risk posed by fentanyl-related substances, we have worked closely with our interagency colleagues on a legislative approach that would control the entire class while minimizing the impact of control on research and drug development by providing for a rapid decontrol or recontrol of individual members, as appropriate, when new data become available. This proposal would provide law enforcement with the tools they need to promptly respond to the traffic and manufacturing of illicit FRS substances. But because not all of them will demonstrate pharmacology that predicts a high risk of abuse and risks of injury, and in that way, do not warrant control as a dangerous Schedule 1 substance. And because we believe some members of the FRS class could have important therapeutic potential, the proposal includes a science-based mechanism to rapidly remove an individual compound from scheduling the most restrictive schedule into Schedule 1 if sufficient data emerge

that the substance does not share Fentanyl's dangerous pharmacological properties.

Under the streamlined approach for decontrol, HHS would determine if a substance should either be moved to a lower schedule or removed from scheduling altogether, again, focused on an assessment of its pharmacology. This work would focus on the substance's effect on the mu-opioid receptor, the receptor responsible for many of the dangerous effects of opioids, including sedation and respiratory depression.

We believe the proposed approach would appropriately balance the pressing need to address the public health risk posed by the illicit use of these substances, while also addressing the important need to support scientific research into these substances to develop new therapies, and to improve our scientific understanding.

We appreciate the combined work of the Federal partners to develop this proposal and the willingness of this committee to discuss it with us here today. FDA stands ready to do all we can to support this important work on this critical public health issue. I am happy to answer any questions I can. Thank you.

[The prepared statement of Dr. Throckmorton follows:]

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Ms. Eshoo. Thank you, Doctor.

And it is a pleasure to recognize Mr. Louis Milione now for your 5 minutes of testimony. Welcome, and thank you again.

STATEMENT OF LOUIS J. MILIONE, PRINCIPAL DEPUTY ADMINISTRATOR, U.S. DRUG ENFORCEMENT AGENCY

Mr. Milione. Thank you, Chairman Eshoo, Ranking Member Guthrie, and members of the committee. Thank you for inviting DEA to testify here today.

DEA's mission is to protect the public from the most significant drug threats harming our communities. I have had the privilege of serving as a DEA agent for over 20 years. I have worked in New York City and around the world investigating sophisticated criminal drug networks that were pushing different drugs into our community, into our country.

My DEA brothers and sisters and Administrator Milgram and I have never seen anything as dangerous as this fentanyl threat. Fentanyl is an existential threat to our country. Fentanyl is killing countless Americans every day in all our communities. It knows no geographic or economic bounds. As a synthetic drug, the supply and different variations of the drug are limitless.

Who is manufacturing it and pushing this deadly poison into our country? Mexican cartels working with criminal chemical companies in China; they are exploiting our opioid crisis by manufacturing massive quantities of fentanyl, flooding our country with it, and profiting from the devastation that they leave behind in our communities.

DEA's fentanyl seizures this year have reached an all-time high, largely because of

the temporary class-wide scheduling of fentanyl-related substances. We have already seized 13,000 pounds of fentanyl this year. That is enough fentanyl, as was mentioned earlier, to give every member of the United States population a potentially lethal dose.

What is extremely alarming is that Mexican cartels and other criminal networks are mixing fentanyl with other drugs like cocaine, meth, and heroin, and also marketing this fentanyl in a new form, fake prescription pills. These pills are filled with deadly fentanyl, and pushed on our population by these criminal networks. They are made and marketed to deceive users, often on social media platforms, making their target audience think that the fake pills are legitimate prescription medications, but they are not.

So far this year, DEA and our law enforcement partners have seized more than 15 million fake pills. Ten million of these pills were laced with fentanyl. DEA's lab testing confirmed that four out of 10 of these pills are laced with a potentially lethal dose.

As I said earlier, DEA's mission is to protect the public. We are laser-focused on this threat. In September, we issued our first public safety alert in 6 years, warning the public about fake pills laced with fentanyl. The prior public safety alert was also dealing with fentanyl. At the same time, we launched a public awareness campaign titled One Pill Can Kill, trying to get the message to anyone we could reach that just one of these fentanyl-filled fake pills can kill a user.

We also did a nationwide enforcement search focused on the fentanyl and counterfeit pill threat. Over a period of 6 to 8 weeks, we took action in all our DEA offices around the country. We seized millions of fake pills, thousands of pounds of fentanyl powder, dozens of guns, and arrested more than 800 drug traffickers. We will be relentless in the work that we have to do to protect the public.

The fentanyl threat, as I said earlier, is an existential threat to our country. Now, more than ever, it is critical that Congress permanently schedule fentanyl-related

substances as a class to enable DEA and our law enforcement partners to seize these substances before they enter the country, and as they are encountered in our communities.

DEA is also committed to expanding and enhancing research on controlled substances. This is a key pillar of DEA's commitment to fighting overdose deaths, and a critical part of DEA's mission to protect the public. We look forward to continued collaboration with the research community and our interagency partners to facilitate access to research and learn more about these substances.

We at the DEA are committed to doing anything that we can to protect the public from these dangerous drugs that are harming Americans and devastating our communities. We look forward to working with Congress and our interagency partners to address this threat and our Nation's overdose epidemic. I look forward to taking your questions. Thank you.

[The prepared statement of Mr. Milione follows:]

******** COMMITTEE INSERT ********

Ms. Eshoo. Thank you very much, Mr. Milione. That is compelling testimony.

We will now move to member questions, and I recognize myself for 5 minutes to do so.

To Dr. Throckmorton. Since the temporary class-wide scheduling of fentanyl-related substances began in 2018, overdose deaths, and it is contained in the testimony as well, have only risen. So tell us why the administration's proposal will succeed where the temporary scheduling hasn't.

Dr. Throckmorton. Thank you, Madam Chairwoman. No single solution exists for the problems that confront us around the opioids crisis, so I believe we have to acknowledge this is one important step among many that we need to take. One reason I believe this is a particularly important step is because of its focus on this class of substances, this class that is causing particular harm.

Temporary scheduling has been effective. It has helped prevent and controls these substances. Permanent scheduling will take that next step, then, and make it permanent to send a strong message that these substances are something that we take very seriously.

Ms. Eshoo. But even with the temporary scheduling, deaths have risen.

Dr. Throckmorton. The deaths have risen, I believe, as a consequence of other influence, other factors that have occurred in the system.

Ms. Eshoo. What are those?

Dr. Throckmorton. Well, there are other social influences. One is simply the economics of the misuse and abuse of opioids. We have transitioned from a time where prescription opioids, prescription pills were driving a substantial fraction of the overdose, overdose deaths that were experienced, to a place where this -- where the fentanyl and

the fentanyl-related substances are causing a much larger fraction of the overdose deaths.

Ms. Eshoo. I see.

Dr. Throckmorton. So this change in the complexion of the crisis leads to a need for us to focus particularly in this area.

Ms. Eshoo. Well, I wanted to ask Mr. Chester and Mr. Milione what role fentanyl-related substances play in the overdose epidemic relative to other opioids?

Mr. Milione. Sure. Thank you for the questions. DEA's main focus is protecting the public, targeting those that are causing the harm and helping those that are harmed. Without question, Mexican cartels are driving the substance into our country. They are driven by greed, they will stop at nothing, and they are flooding our communities with it. These substances are so deadly, as I said earlier, with the analysis that we have done that four out of 10 of the pills, and only a small amount, a miniscule amount, potentially will take the life of a user, so they are very deadly substances. The cartels are driving them in here, driven by greed, and will stop at nothing.

Ms. Eshoo. Dr. Volkow, the administration's proposal would make it easier to conduct research on all -- and you mentioned this in your testimony, on all Schedule 1 substances, not just fentanyl-related substances. What is the importance of including this broader category of drugs instead of just focusing on FRS? Turn your microphone on, please.

Dr. Volkow. Thanks very much for the question. And, indeed, to be able to do research is crucial for us to come up with solutions on how to address a problem, in this case, of opioid overdoses but other substance disorder problems that we face as a Nation.

For example, with the fentanyl overdoses, we are finding difficulty in reverting

some of those overdoses, and people die despite the fact that they are given Naloxone. So we need to investigate what are the pharmacological effects of fentanyl that are producing this, and for that, we need access to these drugs.

Ms. Eshoo. I see.

Dr. Volkow. And so being able to hold researchers to work with them is crucial and indispensable.

Ms. Eshoo. Let me go back to Mr. Milione. Thank you, Doctor.

Are these -- the FRS, does it -- do they come through the U.S. Postal system? Has DEA worked with any of the social media platforms relative to simply not carrying pharmaceuticals, pharmaceutical -- supposed pharmaceutical drugs? Tell us more about the reach across other sectors other than what you -- you know, the cartels that are highly responsible for moving this into our country.

Mr. Milione. Our focus at the DEA is on wherever the harm is being caused, and we have to work with our interagency partners. We will work with anyone that we can to try to address the threat and reduce that harm.

There is no question that the Mexican cartels, sourced with chemicals from China, are manufacturing massive amounts and flooding them throughout this country. We work with our State, local, and Federal partners consistently around the country. We will need to continue to do that.

Ms. Eshoo. Are they carried in the U.S. mail, though?

Mr. Milione. Trafficking organizations will use every single possible method to get them into the United States, and to move -- and the distribution networks in the United States will use any means necessary to distribute this poison.

Ms. Eshoo. I think you are saying yes.

Mr. Milione. Any conveyance that is possible, they will use.

Ms. Eshoo. Okay. Thank you.

The chair now is pleased to recognize Mr. Guthrie, our ranking member, for his 5 minutes of questions.

Mr. Guthrie. Thank you so much, and I appreciate all of y'all for being here.

I am still distressed, disappointed DOJ chose not to be here. But in September, I had an opportunity to host law enforcement roundtables. Kentucky's Attorney General, Daniel Cameron, was with us. Local officials, Federal officials came. I think DEA had representatives, and we had discussion of the crisis in our Commonwealth.

First, Dr. Gupta. I met with him the other day. Mr. Chester, I met with Dr. Gupta the other day and am encouraged by his enthusiasm he brings to the job, and I look forward to hopefully a very successful and supporting a way to fight this plague against us. But, Mr. Chester, I do want to ask you, the Biden's administration most recent proposal permanently schedules fentanyl analogs as Schedule 1 drugs, but does so without imposing mandatory minimums for trafficking these deadly substances. And there is some debate about what we should do with mandatory minimums, but eliminating or not scheduling, not applying the mandatory minimums through the scheduling of the analogs.

So does the Biden administration have data or other relevant research it can share with members of this committee that suggest excluding mandatory minimums from all fentanyl analogs will lead to less fentanyl and fentanyl-related substances on our streets?

Mr. Milione. Thank you for the question, Congressman. I would offer you a few things. Number one, the President opposes mandatory minimums, and the administration is committed to criminal justice reform that eliminates race and income-based disparities.

That having been said, in this particular proposal, we are talking about a narrow

class of substances that are causing harm in America's communities that are considered part of this proposal as part of an overall balanced and comprehensive approach that balances the safety of the American people, civil rights, and also researcher access.

In terms of criminal justice elements and mandatory minimums, I know the Department of Justice has submitted a written statement that addresses that, but I would defer to the Department of Justice on that.

Mr. Guthrie. Okay. When you say this deals with a narrow class of substances, this is one that as we are all talking about that is killing our people with the overdoses. It may be a narrow class, but it is a substantial plague upon our society. A lethal dose of fentanyl is 2 milligrams compared to 200 milligrams for a lethal dose of cocaine and methamphetamine.

Is there a reason why this proposal includes increasing a substance like fentanyl-related substances but keeps this -- but it keeps -- so the proposal keeps the mandatory minimums on, or allows them to stand on less potent drugs like cocaine. So why would they be the disparity of the one that is causing the overdoses versus the others? Why not address them all?

Mr. Milione. Right. And so, when we are talking about this particular class of substances, I think it is important to note we have a few things. Number one, we have fentanyl itself, the base fentanyl molecule. Then we have fentanyl analogs and an entire category of fentanyl related substances that have already been scheduled. So they have done the testing, they have already been classified, they have already been scheduled.

But as we talked about earlier, the universe of potential substances is about 4,800 that are chemically possible here, and so, we have an entire population of substances that have not yet been created, but have the potential to be created, and that is what we are talking about in terms of fentanyl-related substances in this particular class as a

whole.

But as I said, you know, when it comes to the criminal justice, and it comes to the mandatory minimums, I would have to defer to the Department of Justice.

Mr. Guthrie. So currently -- so fentanyl is scheduled, but fentanyl analogs, the reason they are being created is because they weren't scheduled, not permanently scheduled, is my opinion. They are trying to get around that. And so, by excluding these from the mandatory minimums, it seems arbitrary.

Mr. Milione. Right. So those fentanyl analogs that have been identified have been placed in Schedule 1, or in their proper place --

Mr. Guthrie. So they create a new one --

Mr. Milione. -- regime, right.

Mr. Guthrie. -- until we are willing on our side of the aisle -- or in Congress to make them.

Let me switch. I would like to go to Dr. -- Mr. Milione. In your testimony, you state that we must use every tool available to combat the opioid, and you note that DEA and your partners have seized 10 million pills laced with fentanyl but fail to mention how criminal penalties can be used to keep these drugs out of our communities. Does the Department of Justice believe mandatory minimums are a viable tool in the toolbox that we should use to keep criminals from selling these drugs in our communities? If not, why not, and what are the alternatives?

Mr. Milione. Thank you for the question. DEA, as a law enforcement agency, is focused on protecting the public from the greatest harms, the greatest drug threat. There is no question that fentanyl is that greatest threat. It is killing Americans every day at every corner within the United States.

Our focus, our laser focus, is on getting these fentanyl substances permanently

scheduled so that when we encounter them, we can stop them before they come into the country, and we can seize them and take them when we engage -- when we encounter them in our communities. We also need them permanently scheduled so that we can dismantle criminal networks that are distributing these drugs in our country.

Mr. Guthrie. But exempting them from the mandatory minimums, does that have an impact?

Mr. Milione. DEA is a law enforcement agency. We conduct our investigations. We work with our prosecutorial partners, and we allow the judges to follow the laws that Congress have enacted. So that is for the judges to determine.

Mr. Guthrie. Thank you much. I see my time -- I wish I had more time. My time has expired, and I yield back.

Ms. Eshoo. I think we all wish we had more time. There are so many questions that need to be asked.

The chair now recognizes the chairman of our full committee, Mr. Pallone, for his 5 minutes of questions.

The Chairman. Thank you, Chairwoman Eshoo.

I just wanted to ask each of you to focus on the Biden administration's FRS proposal. There are many that are opposed to classified scheduling of fentanyl-related substances in the proposal the administration has put forward to Congress. So what -- basically, what would each of you say to those who expressed concerns about why this proposal deserves their support? And what happens if the current emergency scheduling order for fentanyl-related substances expires? I mean, I would just like maybe each of you to spend a minute or so answering that question, if you will. I guess I will start with Mr. Milione.

Mr. Milione. Thank you. At DEA, we are focused on going after those that are

causing this terrible harm in the country and helping those that are harmed. Fentanyl, without a question, is the most significant drug threat that we are facing. It is much better to be proactive in dealing with this. These drugs are deadly. They are temporarily scheduled. We need to get them permanently scheduled so that when they are-- we can stop them from coming across the border into the United States. We can deal with the Mexican cartels that are pushing this into our country. And when we encounter these substances in our communities, we need the authority to be able to seize them --

The Chairman. But that is why --

Mr. Milione. -- to remove the poison out of this country.

The Chairman. But my question is, does that administration proposal accomplish that goal?

Mr. Milione. We believe that this administration -- the administration's proposal will help us protect the public safety and health.

The Chairman. Okay. Let me go to Dr. Throckmorton, same question. Because there are some that say, you know, that we shouldn't be, you know, doing this. They don't like the proposal, so that is why I am asking you.

Dr. Throckmorton. Thank you, sir. The FDA supports this proposal in its current form. We believe it achieves that important balance that is mentioned here today already, the balance between placing these products under appropriate control, recognizing their deadly potential, while also providing a rapid mechanism, science-based mechanism to support additional research, which, as Dr. Volkow has said, is necessary. We believe losing control would be an important loss to the public health efforts that we have all been making with regards to confronting the fentanyl crisis.

The Chairman. And you think the administration's proposal accomplishes that?

Dr. Throckmorton. I think it is -- in its entirety within control of the class with a possibility of rapid decontrol based on further science and research, it does achieve that goal, yes.

The Chairman. All right. And I will ask Dr. Volkow the same question, keeping in mind that, you know, we are getting those that say they are opposed to the administration's proposal and the class-wide scheduling.

Dr. Volkow. Yeah. And thanks for the question because, indeed, we have been getting a lot of concerns from scientists. And that is why we are very supportive of these new proposals that will actually allow us not only to address the challenges of doing research on fentanyl and fentanyl analogs, or related substances, but also other Schedule 1 substances.

So in its current form, it actually provides also a mechanism when it is found that some of these compounds may not have addiction potential and are therapeutically useful to remove them. And let me just give you an example of why this is so important that we do that.

Naloxone, which is the most effective intervention that we have to save lives, it reverses overdoses. That was Schedule 1, because its chemical structure is very similar of that of other opioid drugs, like Morphine. So being able to remove it now gives us a very powerful therapeutic, and the provision, as proposed, will allow us to do that. So it achieves protection, and it will help us accelerate research.

The Chairman. All right. Mr. Chester, the same thing. But the one thing no one has asked -- answered is what happens if the current emergency scheduling expires. So the same question, but maybe you can address that, too.

Mr. Chester. I will. Thank you, Congressman. So to answer that question, I would say that currently, particularly in the era of synthetic drug use, this is the most

dynamic drug trafficking and use environment that we have had in our history. I would say that these drugs are particularly deadly and because they are opioids, first use leads to chronic use very, very quickly, as well as them being deadly in their own right. I would say that drug traffickers are being able to create these drugs faster than they can be scheduled individually. And if we do not follow through on this proposal in some form, it will be profoundly dangerous to the American people to allow these drugs to be uncontrolled and essentially legal for sale and for purchase.

And so this proposition, along with the more comprehensive approach that the administration is taking that includes prevention, reducing barriers to treatment, harm reduction, as well as reducing the supply of illicit drugs in the United States, we believe is the absolute right approach for the environment that we face.

The Chairman. Thank you.

Thank you, Madam Chair.

Ms. Eshoo. The gentleman yields back.

The chair is pleased to recognize Mrs. McMorris Rodgers, Ranking Member of our full committee, for her 5 minutes of questions.

RPTR GIORDANO

EDTR CRYSTAL

[11:29 a.m.]

Mrs. Rodgers. Thank you, Madam Chair.

Dr. Volkow, we have received many letters from parents who have lost their children to fentanyl. The stories are heartbreaking. One pill, ordered through Snapchat, instead of waking up her son for school one morning, a mother found her son had passed away.

No parent wants their child to take illicit prescription drugs. If a pill is on the street, you should assume that it is not one made by the manufacturer in an FDA-inspected facility.

But I wanted to ask, are there ways to test pills for the presence of fentanyl? And is there research going on to find innovative ways to prevent and stop overdoses?

It is time that we did our part to permanently make these fentanyl-related substances illegal and Schedule I, but I think we are all desperate for some innovation to help arm parents to better protect and educate their children.

Dr. Volkow. Thanks very much for this question.

Again, this is another example why we need to do research. And, indeed, we are doing research that relates to try to understand how the fentanyl strip tests that allow you to actually measure if a drug that has been purchased contains fentanyl or not affect behavior of the users, and also, do they have the sensitivity to detect not just fentanyl or fentanyl-related substances.

We are also doing research to improve of the levels of sensitivity so that it is not only a yes/no test, but actually can give us an indication of the amount of drugs and whether other drugs are concomitantly mixed, because what we are seeing also is that

more and more people are dying from drug combinations.

So, indeed, that there is a lot of interest to understand how to optimally implement testing and what guidelines we can give people so that they can take the most advantage from it.

Mrs. Rodgers. Okay. Thank you.

Mr. Chester, Mr. Milione, I just wanted to ask, do you agree -- yeah, I think you have spoken to this a little bit -- but, for the record, do you agree that we cannot let fentanyl-related substances become unscheduled?

Mr. Chester. Yes, ma'am. We agree with that. And that is why we believe this proposal is the right approach.

Mrs. Rodgers. Okay.

Mr. Milione. Yeah. We agree with that, yes.

Mrs. Rodgers. Thank you.

Do you agree that fentanyl-related substances should be permanently placed in Schedule I?

Mr. Chester. They should be permanently placed in Schedule I until the research community can have access to them and determine whether there is any medical merit and where they should fall permanently in the scheduling regime.

Mr. Milione. I agree with Mr. Chester.

Mrs. Rodgers. Okay. Why is it helpful for these compounds to be placed in Schedule I?

Mr. Chester. To make them illegal for purchase and sale in the United States until the research community has the ability to determine just exactly whether they are active in the body and how dangerous they are.

Mr. Milione. So that we can protect the public and seize them, stop them from

coming in the country, stop them from killing so many Americans, and seizing them in our communities.

Mrs. Rodgers. Would you speak to how you believe this would deter the bringing in and the selling of fentanyl-related substances?

Mr. Chester. Yes, Congresswoman. And what I will do is I will kind of answer it in the opposite.

So what if they are not illegal?

Mrs. Rodgers. Okay.

Mr. Chester. Then the individuals are incentivized to create these novel substances, sell them on the internet or sell them on social media or bring them into the United States in order to do this.

And so, as I spoke to in my oral statement, we must deter the creation of these new substances before they can be created and introduced into our communities.

Many of these substances, in fact, you can argue the vast majority of them, are active in the body and potentially dangerous to Americans.

Mrs. Rodgers. Thank you.

Is there anything you want to add?

Mr. Milione. No, other than that our job at the DEA is to make our communities safer and to stop these drugs from coming into the United States, but also to investigate the groups that are trafficking in them. Having this scheduled gives us that ability and helps us make our country safer.

Mrs. Rodgers. Thank you.

It seems to me that exempting only certain fentanyl-related substances from mandatory minimums will encourage more trafficking in those substances. And I am worrying that we are playing politics with this issue. By insisting on pairing scheduling of

fentanyl-related substances with lessening the penalties on traffickers and importers of fentanyl-related substances, we are jeopardizing making these substances permanently illegal.

We need to act. We need to act now, permanently schedule this fentanyl-related substance, and hold traffickers accountable for those substances. It is a matter of life and death.

I yield back.

Ms. Eshoo. Thank you very much.

I don't quite understand the following, and that is the need to study fentanyl-related issues. We already know what fentanyl does.

So it is not clear to me. Everyone has stated how devastating fentanyl is and fentanyl-related substances, and yet you are not treating -- you state that, but you say the study has to continue in order to keep them or drop them from Schedule I.

What is it that we don't know about this drug and its related parts?

Mr. Chester. Madam Chairwoman, I will start, and then I will turn it over to the two doctors that I share the table with.

These substances have in common their relationship to the base fentanyl molecule, or the fentanyl skeleton, that we know its activity in the body. This involves substances that have modifications to that base fentanyl skeleton.

In some cases, these analogues have already been tested. They have been subjected to testing, and we understand their activity in the body. We are talking about a population of substances that have not yet been created and, therefore, not yet been identified and, therefore, the testing has not been able to take place.

However, they all share that same fentanyl skeleton and that same basic molecular identity. And so that is, from a policy perspective, that is how we set the four

corners of the substances that we are dealing with.

But I would defer to Dr. Volkow and Dr. Throckmorton as well.

Dr. Volkow. Yeah, and I think that you describe it very well, and it has to do with the notion that the chemical structure by itself does not necessarily predict what the pharmacological actions of that compound can be. And slight modifications, for example, can make the molecule very, very potent, or it can make it inactive. And that is why it is important to understand the unique characteristics of the thousands of molecules that can be derived that way.

Ms. Eshoo. You mean there could be a case where fentanyl is okay? Is that what you are saying?

Dr. Volkow. There could be a case where a chemical -- a drug that has a chemical structure similar to fentanyl could have potential therapeutic benefits and not be as toxic or addictive as the fentanyl molecule itself, yes.

Mr. Throckmorton. Madam Chairman, let me give you a very concrete example of exactly that.

So the DEA shares the data that they collect on members of the FRS class with the FDA. Our technical staffs talk to each other all of the time. And we have looked at a group of somewhere over 25 FRSes, and we have studied their pharmacology.

Among that group, there are members of that class, and one in particular, that has no activity to turn on the opioid receptor that we worry about here. In fact, it looks like an antagonist. It looks like it would be a blocker of the mu opioid receptor in the way Naloxone is a blocker of the mu opioid receptor.

So Dr. Volkow mentioned the concerns we have about reversing the overdose effects of fentanyl. This would be a substance that would have some potential for being a treatment for fentanyl. I am not saying I know that it is, but I am saying that is what

we are going to learn as we study these individual compounds.

We are going to understand if there are some that have no dangerous effects and instead have -- they could be antagonist. They could be new treatments for opioid use disorder. They could be new treatments for preventing overdose or reversing overdoses.

Those are the things that we need to make certain we don't lose even as we put this entire class under the control that it merits given the larger public health need.

Mr. Griffith. And, Madam Chair, if I might?

Mr. Chester, in his opening statement, said there were 4,800 potential -- based on math -- 4,800 potential analogues, and Dr. Throckmorton has just told us they have looked at 25. That is why you have to continue research.

Ms. Eshoo. Well, I thank the ranking member for yielding the time. I think I understand it a little better, but it is complicated.

The chair now is pleased to recognize the gentleman from North Carolina, Mr. Butterfield, for his 5 minutes of questions.

Mr. Butterfield. Thank you very much.

Ms. Eshoo. He is joining us virtually.

Good to see you.

Mr. Butterfield. Thank you very much. It is good to see you, Madam Chair. Thank you so very much for recognizing me this morning, and certainly thank you for your leadership on the committee.

And to the ranking member, I love the spirit of cooperation that I see between you and the chair.

And just thank you and your colleagues for all the work that you are doing. We have great challenges in front of us, and just thank you for your cooperation.

Madam Chair, as we consider legislation to address the opiate crisis, we must pay special attention to communities that have been historically marginalized. And I refer, of course, to communities of color.

Recent findings from the NIH found that, within a subset of counties disproportionately affected by the overdose epidemic, opioid overdose death rates from 2018 to 2019 level off across all of our racial groups with the exception of African Americans.

Isn't that strange?

Among African-American individuals, the opioid overdose death rate increased by some 40 percent. This is tragic, and we must take action to address this trend.

And as history has shown us, communities of color are also disproportionately punished by drug policies. A report published by the Sentencing Commission this past January found that in 2019 African-American individuals composed a greater proportion of fentanyl and fentanyl analogue offenders, of which over 50 percent faced a mandatory minimum penalty even though less than 8 percent were importers or high-level suppliers.

These staggering statistics are just absolutely a sobering reminder of the stakes held in our discussion today, and that is why it is important that we have a bipartisan approach to this problem.

And so, Mr. Chester, let me ask you, please. And thank you not only to Mr. Chester, but to all of our witnesses today.

But, Mr. Chester, the Biden administration has been clear in its intent to address the disproportionate impact that past drug policies have had on communities of color -- he said it in the campaign, he is saying it today -- from both a justice and a public health perspective.

How does the fentanyl-related substances proposal meet that goal?

Mr. Chester. Thank you, Congressman.

And for that very reason that has created the contours of this proposal. And so, while permanently scheduling this class of substances is what is done on the front end in the interest of public safety, we must also understand that we can't do unintended harm by doing that.

And so the very reason that you explained is the reason why this proposal looks the way it does, why it is comprehensive, and why we were able to bring together the Department of Justice and the Department of Health and Human Services to make sure that we make all of those considerations.

Mr. Butterfield. Let me now talk about criminal penalties. As a former judge, I have particular interest in this.

There are concerns among criminal justice and civil rights organizations that this proposal will lead to harsh criminal penalties, even with the inclusion of provisions excluding fentanyl-related substances from quantity-based mandatory minimums.

Now, do you agree with that assessment? And if not, can you tell me why?

Mr. Chester. Congressman, as I mentioned before, the President opposes mandatory minimums, and the Biden-Harris administration is committed to criminal justice reform by eliminating race- and income-based disparities in our criminal justice system. And that is one of the foundational elements that the administration has used to approach this incredibly complex issue.

When it comes to detailed criminal justice matters, I know the Department of Justice has submitted a statement for the record. But I would defer to the Department of Justice on those matters, sir.

Mr. Butterfield. Thank you.

And my final question, Mr. Chester. What guardrails are in place, or what

guardrails should be considered, to promote racial equity in drug enforcement efforts?

Mr. Chester. Congressman, I can only speak to the proposal that is here before us today. And guardrails is probably the exact right term. If we were just to simply schedule all these substances as a class, that is the bluntest instrument that we have.

Rather than do that, we ensured that we also not only considered research provisions, but the criminal justice aspects to it as well.

And so we were able to provide the tool that our law enforcement community needs in order to be able to protect the community, but at the same time make sure that we were not doing unintended harm. And guardrails is the exact right term for the approach that we used.

Mr. Butterfield. Thank you very much, Mr. Chester.

And I will conclude, Madam Chair, by repeating what you and others have said throughout this hearing. It is absolutely unacceptable that the Department of Justice is not participating in this conversation. Shame on them. I hope we can hear from them very soon.

I yield back.

Ms. Eshoo. Hear, hear, Mr. Butterfield. Thank you.

The chair is now pleased to recognize the gentleman from Michigan, former chairman of the full committee, Mr. Upton, for your 5 minutes of questions.

Mr. Upton. Well, thank you, Madam Chair.

And I join with everyone here voicing our disdain for the Department of Justice not appearing and knowing that they had a number of months to be prepared for this. It is really sad on an important issue like this.

I had the privilege of being selected by Kevin McCarthy to serve on the White House Commission on Combating Synthetic Opioid Trafficking, and we have had great

meetings. Another scheduled for this afternoon, in fact. And just a couple weeks ago, I was able to send one of my staffers on a commission trip to Mexico and the southern border.

That is why I am troubled about the administration's September recommendations on fentanyl-related substances. At a time when we are seeing the highest rates ever -- 100,000 folks, man, in 2020 -- it is so disturbing that the administration seems to be favoring weakening penalties for drug traffickers who are flooding every community with potent and deadly fentanyl analogues. And I don't hesitate to say that everybody here on this panel probably knows someone who was maybe part of that 100,000 in our families.

Mr. Chester, is there a concern that the Mexican drug cartels, who are large-scale manufacturers of these fentanyl analogues, are going to take advantage of the loophole by producing fentanyl analogues with arbitrarily lower mandatory minimums for trafficking while continuing to take advantage of our lack of proper enforcement at the southern border?

Mr. Chester. Thank you for the question, Congressman.

And I would say the first thing is that the men and women of Customs and Border Protection and our law enforcement partners who are at the southwest border do a tremendous job.

Mr. Upton. They do, absolutely.

Mr. Chester. They absolutely do.

Mr. Upton. They are overwhelmed, which is unfortunate.

Mr. Chester. And I would also tell you that one of the reasons we need this proposal is to do just what you described, and that is to deter the creation of these new substances by making them illegal.

And we make them illegal before they have even been tested. And we do that to ensure that drug traffickers know and understand that these are Schedule I substances. You cannot create a novel substance based upon the fentanyl skeleton and sell it in the United States with impunity. That is not going to happen.

And so I think it is critically important that not only Mexican drug traffickers, but anyone else with the potential to make these substances and push them into the United States understands that this entire universe of 4,800 substances is illegal.

Mr. Upton. Well, I know that every one of us wants to make sure that we do everything that we can to deter the creation of these new analogues. I mean, there is no question about that.

Mr. Milione, we have talked a little bit about numbers, 4,800 potential analogues. I guess the DEA has looked at some, a couple dozen.

Do any of them have a legitimate medical use?

Mr. Milione. Thank you for that question.

I would defer that question to Dr. Throckmorton or Dr. Volkow.

Mr. Upton. Okay. And let me just follow up with that, because I was going to ask them the same question.

For those that may have some legitimate medical use, are all of those in Schedule II, or are any of them in Schedule III or IV?

Dr. Throckmorton. So fentanyl has an approved medical use. It is a component in approved drugs that are on the market and available. It also has a high potential for abuse, and so it is in Schedule II.

There are no fentanyl-related substances otherwise in schedule other than in Schedule I.

Mr. Upton. Mr. Milione, an ONDCP press release from September of 2021

announced that the administration's recommendations to Congress on reducing illicit fentanyl-related substances states that, and I quote, "The Justice Department reported only eight cases with FRS charges from the time temporary class scheduling was adopted in 2018 through December of 2020, of which only a handful even included charges of quantity-driven mandatory minimums," end quote.

Given the extremely low prevalence of cases involving quantity-driven mandatory minimums and already established statutes to waive mandatory minimums like the safety valve for low-level drug offenders and the substantial assistance provision for providing prosecutorial or investigative help to the government, why did the administration release recommendations that would further hamper enforcement of those crimes?

Mr. Milione. Congressman, my colleagues at the DEA, myself, my whole career as a DEA agent, we are laser focused on protecting the public from these dangerous substances. It is a top priority to have all these deadly substances scheduled in a classwide way so that we can seize them at the border, investigate them in our country, and seize them when we encounter them in our communities.

Mr. Upton. Okay. My time has expired. Thank you, Madam Chair.

Ms. Eshoo. Thank you. The gentleman yields back.

Pleasure to recognize the gentlewoman from California, Ms. Matsui, for her 5 minutes of questions.

Ms. Matsui. Thank you very much, Madam Chair.

And I want to thank you for having this hearing.

And thank you for the witnesses for joining us today.

I, along with others, are concerned about the rise of street drugs in our districts, including counterfeit pills containing fentanyl. We have to work together on a comprehensive approach to combat this next wave of the opioid epidemic, and that

includes cutting off how these illicit fentanyl products are getting to our communities and helping those who are already addicted get the treatment that they need.

When Congress passed the Ryan Haight Act of 2008, our intent was to curb online sales of controlled substances while recognizing there is great value in legitimate prescribing via telemedicine. We worked to ensure that the law struck the right balance between safety and access.

Unfortunately, DEA restricted teleprescribing to patients located in-person, and this narrow interpretation has historically limited the number of patients who can access care.

Now, most recently, DEA has waived that in-person requirement during the COVID public health emergency to allow remote prescribing of MAT via telemedicine regardless of a patient's location.

Mr. Milione, to start off the question, I just need a yes or no. Has DEA tracked any increased use of teleprescribing of MAT since waiving the in-person requirement in response to COVID-19?

Mr. Milione. Congresswoman, DEA knows that medical-assisted treatment is critical to help those suffering with opioid use disorder.

Ms. Matsui. Could I get a yes or no to that, please?

Mr. Milione. We are committed to working --

Ms. Matsui. Okay. So has the waiver expanded access to substance use services and interventions during the pandemic?

Mr. Milione. I am sorry. Could you repeat the question?

Ms. Matsui. Has the waiver expanded access to substance use services and interventions during the pandemic?

Mr. Milione. Congresswoman, we are committed to working with our

interagency partners and have done so to expand access to treatment. We believe that that is critical, helping those that are harmed.

Ms. Matsui. Okay. So you are saying it has expanded access. Is that correct?

Mr. Milione. I am saying that we are committed to working with our interagency partners to expand access to treatment and working with the White House.

Dr. Volkow. If I can interject there, because we have been monitoring it from the research perspective, and the answer, yes, it has facilitated access to treatment, for example, of individuals in our communities. It has made it much more accessible for people that are in the justice setting, on parole, to have access to buprenorphine much more widely.

Ms. Matsui. Okay. Let me just ask this. Okay. The SUPPORT Act of 2018 required the DEA to complete a special registration process to allow more providers to prescribe MAT via telemedicine. I have authored legislation that would specifically authorize community mental health centers and community behavioral health organizations to use this process to register as eligible provider sites.

To my knowledge, DEA has yet to carry out that congressional directive.

Mr. Milione, when can Congress expect the DEA to complete its statutory requirements and issue the special registration rules in accordance with the law?

Mr. Milione. Congresswoman, as I said, we are committed to working with the interagency community to expand access to treatment. I am not familiar with the specific answer to that question, but I am happy to take that back and get back to you.

Ms. Matsui. Yes, would you please do that? Because this addiction crisis has gone on far too long, and it has always been clear to me that Congress and DEA must come together to meaningfully put an end to the opioid epidemic.

Now, I want to quickly shift focus to how the proposal before us today will impact

research eligibility.

Dr. Volkow, there has been some question regarding whether the streamlining for Schedule I research registration would be limited to Federal researchers.

Can you clarify who would be eligible to conduct Schedule I research under the provisions included in the administration's proposal? Would it include private researchers, or just federally funded researchers?

Dr. Volkow?

Ms. Eshoo. Excuse me. Use your microphone, please.

Dr. Volkow. Sorry.

Yes, it will, it will include private -- researchers funded by private foundations or private investors as long as they have an IND with the FDA. But if they do not, then it will not include them.

Ms. Matsui. Okay. So researchers are already able to conduct research on Schedule I. This change will allow them to use a new process for other Schedule I substances, such as marijuana?

Dr. Volkow. It will -- the proposal will basically apply for all Schedule I substances. So it will expedite research on THC as well as any other substance that is Schedule I.

Ms. Matsui. Okay. Thank you.

I am particularly interested in eroding existing barriers in Federal law that limit researchers at academic medical centers from studying Schedule I substances. So I am grateful that our research agencies are working to find effective solutions to help [inaudible] continue important work here.

Thank you very much, and I yield back.

Ms. Eshoo. Gentlewoman yields back.

The chair is pleased to recognize the gentleman from Virginia, Mr. Griffith, for your 5 minutes of questions.

Mr. Griffith. Thank you very much, Madam Chair. And I appreciate the questions of all my colleagues.

And this panel is great. Thank you all very much for being here.

Dr. Volkow, let me start with you. I believe that much more research on fentanyl analogues is necessary. Based on what we know now, how do these fentanyl-related substances compare to traditional fentanyl in terms of how they affect the body as well as their addictive properties?

Dr. Volkow. Thanks for the question.

There has not been as much research in fentanyl analogues, and it has to do with the complexities and difficulties of doing research on Schedule I substances. It takes longer. It is much more costly. It is cumbersome.

So that has deterred researchers. And I am optimistic that this proposal will make it easier so that we can get more talent and expand our knowledge.

Mr. Griffith. Well, I will tell you -- and I appreciate that -- and I will tell you, both Ms. Matsui, my colleague, and others, I have been working for years to try to get more research on Schedule I. And I have a bill that has already been introduced this Congress, House Resolution 2405, that does that. So I am glad to be in agreement with the administration on this issue.

I was looking this morning at a bill that addresses many of the administration's requests and concerns that I hope to be introducing soon. So I am big on that.

Dr. Throckmorton, if I can go to you.

And then, Dr. Volkow, I wouldn't put the mask back on yet. I am coming back to you.

You indicated in your testimony, both written and oral, and then in some of the questions, that there is at least one of the analogues that may have some potential. And could you provide me the name of that one?

In your written testimony, there was an "s" on there. It indicated there may have been more that didn't have problems. Were there others that were inert or didn't function the way most opioids do?

Dr. Throckmorton. Sure. Thank you for the question.

First, it is really important to understand that we have only looked at a relatively small number of these compounds.

Mr. Griffith. Twenty-five, right.

Dr. Throckmorton. And without being able to give you the exact number, we are sharing the information with the DEA, looking at them as much as we can. I have a group of scientists that are focused mostly on that.

Having said that, within that group there is more than one compound that does appear to have other effects than activating the mu opioid receptor. So whether it is this one compound that I mentioned that appears to have this antagonism effect or other compounds that have effects at other receptors -- there is another opioid receptor, for instance, and some compounds -- the major point, the point I want to make is that those exist.

The details are important to study, but fundamentally they illustrate why just putting these all into Schedule I is not sufficient. We have to do it along with the mechanism for removing these promising substances that have these other effects that are potentially less dangerous so that we don't miss an opportunity to identify a new reversal agent like Naloxone, or a new treatment for opioid use disorder. And this small number of compounds illustrate that.

Mr. Griffith. And I appreciate that.

And I want to get back to Dr. Volkow.

So based on your previous testimony and his testimony, what I am gathering the administration wants to do and what I want to do -- I want you to tell me if I am on the right path, that we are in agreement -- is put it all into Schedule I permanently, but then have research available even on the Schedule I substances so we can determine if we have got something that may be helpful, and then can come back and take it out later if it is inert, it doesn't do the mu opioid receptor, or if it has some medicinal value, then allow that to move forward with research as well.

Is that my understanding? Is that correct?

Dr. Volkow. I mean, you are asking a question in terms of the scheduling, and I think that that is much better sent to the Department of Justice.

Mr. Griffith. Who are not here, by the way. But go ahead.

Dr. Volkow. My view on this is that, as Dr. Throckmorton was saying, we have an opportunity of actually, by doing research, and not just coming with better overdose reversals and treatment for opioid use disorder, but another area that has been neglected is better treatments for pain.

So, as he mentioned, there is another opioid receptor, [inaudible] receptor, that can produce analgesia, but it is not in [inaudible] areas of the brain. So to the extent that we could have a compound that specifically binds to it, you could have an analgesic that is not addictive.

But this is why science becomes so relevant. And that is what we focus on, to try to make that knowledge accessible.

Mr. Griffith. And, unfortunately, my time is up. I have got lots of other questions, and this is a fabulous discussion. Thank you all very much.

Thank you, Madam Chair, for holding the hearing.

Ms. Eshoo. The gentleman yields back.

I think we all have many questions. And, to our witnesses, every member, I think, is going to be submitting written questions, detailed written questions to you, and look forward to your timely response to them.

The chair now has the pleasure of recognizing the gentlewoman from Florida, Ms. Castor, for her 5 minutes of questions.

Ms. Castor. Thank you, Madam Chair.

And thanks again to our terrific witnesses here today.

I really appreciate President Biden and the administration's forceful and comprehensive strategy to tackle the opioid crisis, especially this deadly fentanyl and the synthetic opioids flooding into the country.

Unfortunately, my community in the Tampa Bay area has not been immune. If you look back at the trends over the last 5 years, like other parts of the country, we have seen a dramatic increase in opioid deaths fueled by synthetic opioids.

And I really want to compliment the Tampa Police Department. They have an opioid task force where they have brought in, working with the DEA, FBI, ATF, and then a lot of our nonprofit partners, our research university at the University of South Florida. They are criminally pursuing and prosecuting the folks who are perpetuating the abuse, going after the dealers.

But what they have advised me is they cannot arrest their way out of this. They received a DOJ grant a few years ago. And after surveying everyone, they really wanted to put more into crisis intervention.

And you all know that President Biden and the Democrats in Congress earlier in the year passed the American Rescue Plan where we devoted historic amounts of new

money into crisis intervention, mental health, substance use disorder services.

I would like to know, Mr. Chester, are those moneys now getting out? Because we really need them on the street. My police department and nonprofit community, they say they need more crisis intervention services to save lives, get folks treatment, in addition to what they are doing on going after folks criminally.

What is the status of the American Rescue Plan dollars getting out to communities like mine?

Mr. Chester. Yes, Congresswoman. Thank you very much. And we will provide you an exact, accurate answer as to what the status of all those dollars are, because it would be irresponsible for me to say off the top of my head. So we will make you know for sure.

I will also tell you, though, that what you described in the Tampa area, in Hillsborough County, is an approach that is taking place nationwide, and it is the approach that the administration uses as well.

And so while you need to have a strong law enforcement component to what we need to do, we also need to prevent drug use before it starts and reduce barriers to treatment and incorporate harm reduction as a whole as a comprehensive approach. One single dimension of this is insufficient in and of itself to be able to do that.

And I appreciate you mentioning the American Rescue Plan. That was $4 billion for SAMHSA and HHS to expand mental health services and substance use disorder services, which also included another $30 million to support harm reduction interventions as well.

And I will get you the exact answer on where those dollars are. I would be glad to do that.

Ms. Castor. And then didn't ONDCP and Secretary Becerra from HHS, haven't

you all come together to do a deeper dive on how you support those collaborations? And tell us about that.

Mr. Chester. Yes, Congresswoman.

So, yes, ONDCP and HHS work incredibly closely, hand-in-hand, on all of the public health aspects of this. And I think it is important also to remember that the President's fiscal year 2022 budget, in and of itself, which includes HHS and all the Federal drug control programs, is $41 billion, $41 billion across the span of both supply and demand reduction applied to this very difficult problem. And it is about $670 million above the previous year's enacted levels.

A lot of that money goes to HHS, but a lot of it goes to several other places throughout the Federal Government in order to do many of the things that we are talking about here today, to not only reduce the supply of these drugs in our communities, but also the span of public health interventions that are necessary in order to reduce the pull of these drugs across our borders.

Ms. Castor. Thank you very much. I yield back.

Ms. Eshoo. Gentlewoman yields back.

The chair is pleased to recognize the gentleman from Florida, Mr. Bilirakis, for his 5 minutes of questions.

Mr. Bilirakis. Thank you, Madam Chair. I appreciate it. Thanks for holding this hearing.

I am saddened that the overdose epidemic continues to worsen across our Nation as deaths involving synthetic opioids continued to skyrocket over the past year. That includes my district, and specifically Pasco County, where 193 people have died from overdose since January, the vast majority involving fentanyl.

This crisis has led me to call for a roundtable in my district this month where I will

be consulting with local leaders, providers, and local law enforcement from Pasco, Pinellas, and Hillsborough counties. We must continue to be engaged on all levels of government to fight back against this scourge to our communities.

Again, Assistant Director Chester, in a previous hearing we have had in this committee, I questioned then Acting Director LaBelle about our relationship with China and the role it plays in preventing the entry and sale of fentanyl and its analogues. She mentioned that China is now channeling much of their fentanyl-related substances and its components through Mexico and thus across the border.

In fact, the Biden administration's own Justice Department, whose Deputy Attorney General, unfortunately, decided not to come here -- and, again, that is inexcusable. I agree with you, Madam Chair.

But, again, the Attorney General stated, and I quote, "Mexican criminal drug networks are mass producing illicit fentanyl and fentanyl-laced fake pills using chemicals sourced largely from China and are distributing these pills through U.S. criminal networks."

I don't think anybody will dispute that.

"These fake pills are designed to appear nearly identical to legitimate prescriptions, such as OxyContin, Percocet, Vicodin, Adderall, Xanax, and other medicines. Criminal drug networks are selling these pills through social media, e-commerce, the dark web, and existing distribution networks. As a result, these fake pills are widely available, unfortunately."

Now, that is a quote from the Assistant Attorney General.

If we have learned anything from the COVID pandemic, it is that we should be skeptical of China. The Trump administration was very tough on China and the border issues, as you know, and yet the Biden administration's proposal fails to address these

components.

The question, Mr. Chester. Can you provide an update on how the administration is engaging not only with Mexico, but with China directly on its role in proliferating this deadly substance? And can you tell me whether China has been consistently enforcing its laws in this area? And what mechanisms do we have to hold China accountable to its commitment to ban the export of fentanyl and its analogues?

Please, Mr. Chester.

Mr. Chester. Yes, Congressman. Thanks for the question.

You have in your question identified the two fundamental countries involved in the flow of these drugs into the United States, and that is China and Mexico.

China's role has changed over time. So there was a time, pre-2019, when China was the preponderant source of finished fentanyl and fentanyl analogues coming into the United States. And it was either routed through Mexico or, quite significantly, we talked about the Postal Service before, ordered on the interweb and shipped directly through express consignment like FedEx or UPS or through the Postal Service.

We approached the Chinese Government -- and this was actually a conversation between the Presidents in December of 2018 -- and asked the Chinese Government if they would do just what we are discussing today, and that is to schedule all fentanyl-related substances as a class.

They did that effective May of 2019, and it had a couple of impacts. The first one was we saw direct from China to the United States shipments of fentanyl and analogues go down to essentially zero. But that didn't solve the problem.

What happened was a lot of the fentanyl synthesis shifted to Mexico, with Mexican drug trafficking organizations, with the raw materials provided from China, and a lot of Chinese traffickers got into the precursor chemical business. So it shifted, the

locus of production shifted from China to Mexico, but then it was enabled by China.

Mr. Bilirakis. I would like to ask another question, if I may, Madam Chair. Is that all right? Thank you.

Mr. Chester. Yes, sir.

Mr. Bilirakis. Another concern I have is the availability of sales of fentanyl-laced drugs online, and you are getting to that.

One prominent study regarding the fake prescription pills states, and I quote, "fentanyl networks are among the world's first digital native drug networks. Global internet connectivity has opened a new era of drug distribution by facilitating direct-to-consumer transactions, rapid reaction to enforcement trends, and the delivery of retail rather than wholesale drug volumes through legal commercial delivery services."

Again, Mr. Chester, Assistant Director, and Deputy Administrator Milione -- if you will allow them to respond, Madam Chair -- given the dynamics of legal immunities available for the big tech companies to essentially incentivize them to bury their heads in the sand, how is the administration working with these companies, if at all, to prevent these illegal sales? And what is the level of transparency and information sharing between these companies and law enforcement agencies?

First, Director Chester, please.

Mr. Chester. Yes, Congressman. I will tell you that you have identified a key part of the problem, which is we have many vectors for these drugs to come into the United States and we have many platforms on which they can be sold, which include social media.

I would like to stay within the limits of the FRS scheduling right now. But we could get you an answer, a more specific answer, I would like to provide, on specific actions that the administration is taking. But what you identify obviously is a critical

component of this threat.

Mr. Bilirakis. Administrator Milione, if that is allowable, please? Oh, okay.

Ms. Eshoo. Finish answering the question briefly from the panel to Mr. Bilirakis.

Mr. Bilirakis. Mr. Milione, please?

Mr. Milione. DEA is focused on the largest threats to protect the public. I have said that throughout the hearing. There is no question --

Ms. Eshoo. You have.

Mr. Milione. What?

Ms. Eshoo. You have.

Mr. Milione. It is critical to our mission.

Ms. Eshoo. Consistently.

Mr. Milione. You mentioned earlier Mexico and China. Certainly Mexican cartels are flooding the country, working with Chinese chemical companies.

Ms. Eshoo. But you are not answering the direct question, though, with all due respect to you, sir, and that is, who are you working with? It has been testified that there are social media platforms and such. I think that is what the gentleman is asking.

Mr. Bilirakis. Absolutely.

Ms. Eshoo. I asked the same question. Who is DEA working with? Can you name any of the companies? Is there outreach? If there is, with whom? Have you been successful? If not, have they turned you down? Maybe the Congress needs to do something about that.

Mr. Milione. Where DEA is focused is wherever the threats are. So if the social media platforms and e-commerce platforms are being used, we will focus our investigative efforts there.

Ms. Eshoo. Will, or have, and shall?

Mr. Milione. We will continue every day to do that. We will continue every day to do that. We have been doing that.

Ms. Eshoo. So you are doing it.

Mr. Milione. We are focused on wherever the threat is. And if social media platforms are being used, or e-commerce platforms are being used, or Mexican cartels are flooding the country --

Mr. Bilirakis. But they are being used. Is that correct?

Mr. Milione. There is no doubt that social media companies should do more to prevent their platforms from pushing this poison into our homes.

Mr. Bilirakis. Thank you for following up, Madam Chair. I appreciate it.

Dr. Throckmorton. Madam Chairman, can I just say that the FDA does have an active, ongoing set of efforts in this space we would be happy to talk to you about. We agree it is a very serious threat.

We take counterfeit drug sales, especially online drug sales, very seriously and have taken actions, including discussions since 2018 with some of the internet providers and some of the groups that control access to the internet, the internet service providers and the like it, for instance. Happy to talk with you more.

Ms. Eshoo. Thank you, Doctor.

The gentleman from Florida yields back.

A pleasure to recognize the gentleman from Maryland, Mr. Sarbanes, for his 5 minutes of questions.

Mr. Sarbanes. Good morning, Madam Chair. Thanks very much for this hearing. Appreciate it.

Obviously this is a very delicate and pretty complicated topic, this one of scheduling fentanyl, because there are a lot of obstacles to navigate or issues to address.

Maryland hasn't escaped the scourge of this pandemic that we are seeing, or epidemic really, of opioid-related deaths. And my constituents obviously are as interested as anyone in how we are going to address this and strike the right balance here. And I know that is the effort that has been undertaken. Now the Biden administration is coming with a proposal that attempts to do that.

I would like to get a little bit back into the weeds on this. So given the significance of the scheduling, the recommendation for permanent classwide scheduling of fentanyl-related substances, I would like to hear a little bit more about that process.

So, Dr. Throckmorton, can you lay out for us plainly -- I mean, you have done this a little bit, I would like you to come back to it -- what the scientific or medical evidence is that is needed to remove or reschedule a substance?

Dr. Throckmorton. Thank you, Congressman.

There are two parts, two possible answers to that question, so I just want to clarify. Are you asking about the FRS class proposal that the administration is putting forward, or are you talking about the more general approach that has been historically used to remove a substance or change a scheduling?

Mr. Sarbanes. I am speaking now sort of more generally. What are the kind of scientific reference points that we use when we are removing or scheduling or rescheduling a substance for that matter?

Dr. Throckmorton. So the general process involves eight factors that are laid out in statute, and we are obliged, we, the FDA, are obliged to look at each one of those factors. And they include things from the pharmacology, the available information about public health, injury, deaths, any accepted medical uses the product might have. We look at all of those eight factors and then provide a recommendation to HHS.

In this case, we would have to conclude that the available data suggests that the

compound has no abuse potential based on those full eight factors, which is a considerable amount of data that are needed to be developed.

Mr. Sarbanes. So you have anticipated, you anticipate a little bit the next question I was going to ask, because under the expedited process -- and you were alluding to this, I guess -- to reschedule or deschedule a fentanyl-related substance, HHS would only consider one of these eight factors that you are mentioning.

And I am curious, or can you elucidate a little bit more how the interagency working group determined which factors would be required to be considered when removing a substance from the schedules? Just draw that comparison, if you could.

Dr. Throckmorton. Yeah. Thank you, Congressman. That is a really great question.

First, the focus on the one factor, which is the factor related to the pharmacology, comes from the focus of the FRS class legislation as a whole.

So the idea of placing something in the FRS class and putting it into Schedule I reflects this pharmacology that the drug causes and effect on the mu opioid receptor, that its effects are pharmacologically like what we see with fentanyl and hydrocodone and oxycodone and other lethal things.

What we believe as an interagency group is that, if we are satisfied that, in fact, that pharmacology is not present for one particular compound based on all of the available data, not just that factor, then that compound belongs in other places in the schedule. It may still have abuse potential, but we don't yet have all the information.

But it is not a substance that has the high risk of abuse and misuse like oxycodone, like fentanyl. And so it belongs in a lower part of the schedule, Schedule III, or decontrolled entirely.

And so it is not that we are ignoring any data. We would look at all of the

available data. It is that we are focusing on the same part of the compound's effects that led to it being placed into Schedule I in the first place.

Mr. Sarbanes. Thank you. It is pretty complicated stuff. I appreciate those answers. I think that will be helpful to us in understanding these various proposals that are coming forward and trying to do something responsible from a legislative standpoint.

With that, Madam Chair, I will yield my time back.

Ms. Eshoo. The gentleman yields back.

The chair is pleased to recognize the gentleman from Indiana, Dr. Bucshon, for your 5 minutes of questions.

Mr. Bucshon. Thank you. I want to thank the chair and the ranking member for holding this very important hearing on drug overdose and fentanyl-related substances.

I do want to mention, though, without demand there is no supply. And I think for many years we have not addressed what the factors are in our country that are creating such a demand for these substances, and we should maybe do that.

Members of the committee have had a long history of working to help combat substance abuse of opioids, and I believe the country is making some great strides in those efforts.

Specifically related to fentanyl and its analogues, I don't particularly get the connection in the proposal from the administration to the larger discussion on mandatory minimums and racial disparities in sentencing for drug-related offenses. And specifically related to fentanyl and analogues, I disagree with the administration.

Unfortunately, the pandemic has created the perfect storm and sent our country backwards in many ways in this battle against drugs. One of the contributors -- and I am a doctor, so this could -- is we halted elective surgeries and other procedures that allowed

patients to have access to medical care, which many people were left in pain, bad knees, bad hips, other things.

And, while I understand the reasoning for a short while, many States waited too long, honestly, to reinstitute these type of treatments. And there are States now, New York State, for example, has done this, because of the Omicron variant before we even had a case in the U.S., and I think it is problematic. And when someone is in pain and can't get the relief they need through medical procedures, it is much more likely for them to turn to opioids to manage their pain, which can obviously lead to abuse.

And as has been described, a lot of the prescription drugs that have been prescribed, that is decreasing the use, and this illicit is getting higher, but it is still an issue.

So, Dr. Throckmorton, what can Congress and the FDA do better to promote nonopioid treatments? And is the FDA currently prioritizing review of devices and other opioid alternatives that patients can use to better control their pain?

Dr. Throckmorton. Thank you, Doctor.

Short answer to your second question, absolutely yes. We are doing anything we can to prioritize the development of safe alternatives to opioids, whether it is devices or drugs.

We recognize that there are two forms to those alternatives to the drugs. They could be drugs that look like opioids but that do not have the addiction and overdose potential that many of our current opioids do. That is an area of strong importance for us.

Mr. Bucshon. Yeah. Can I just say this? And that is why it is important to have a strong procedure in place if we are going to schedule these as a class to make sure that, if we find one of those, that we can get that back to Schedule II so patients have

access, correct?

Dr. Throckmorton. Could not agree more with you. And NIDA and we talk regularly about those kinds of products and how we can bring them forward.

The second class of products is obviously the ones that are nonopioids but are effective at treating severe pain. We have to acknowledge that we don't have a broad armamentarium there. We have other medicines that treat pain that is less severe.

But opioids are uniquely effective in certain places. And so we need to do everything we can to understand that science better and identify nonopioid alternatives that will work for those really severe pains, end-of-life pain and things like that.

Again, those are the highest priority for us as a center. We have breakthrough designation that we stand ready to extend, priority review. We have other mechanisms. Basically we will do anything we can to help.

Mr. Bucshon. And we in Congress have also created a separate payment structure for a period of time, as you know, for these nonopioid alternatives to encourage their use, because the reality is opioids are cheap.

And so if you have a more expensive nonopioid product that, for example, under a diagnostic-related group at a hospital, a DRG, those may not be used if they are going to cost the facility more money because the opioids are so cheap.

So we have worked on that part of it also to make sure there is reimbursement encouragement to use nonopioid alternatives.

Mr. Chester, so we have talked about the illicit drugs in Mexico. How are they getting into the country? They are in Mexico. They are being created. How are they getting here?

Mr. Chester. Yeah. Congressman.

Mr. Bucshon. And be short, because I have got a follow-up.

Mr. Chester. Yep. Principally across the southwest border.

Mr. Bucshon. Okay. So if we were to work to secure the border better, would that help?

Mr. Chester. There are multiple vectors by which they come in, both the southwest border, which is the short answer, but also through the mail system and also through other --

Mr. Bucshon. We did some changes in the mail system to allow the FDA -- to allow the DEA, I think. You mail a crate of a thousand little boxes, right?

Mr. Chester. Right.

Mr. Bucshon. And each one of them has drugs in it. We allowed them not to have to open up every one of those. I think we did that a number of years ago.

Mr. Chester. The most effective thing we can do is our relationship with Mexico to help deter the production of the drugs themselves.

Mr. Bucshon. And not to criticize any other government, but do you realize that, as you know, the cartels, the amount of money involved, it is very difficult to get public officials across our southern border to engage in this process, both because they worry about their own personal security and, honestly, because there is just so much money.

I yield back.

Mr. Chester. Yes, sir.

Ms. Eshoo. The gentleman yields back.

The chair is pleased to recognize the gentleman from Vermont, Mr. Welch, for his 5 minutes of questions.

Mr. Welch. Thank you very much, Madam Chair.

I mean, this opioid crisis is just so horrifying for so many Americans. And my colleague, Mrs. McMorris Rodgers, describes those who succumbed to the opioid crisis.

It is a death of despair.

And there are really two things about it. We are not talking about the dealers, but we are talking about many of the good Americans who find themselves in the grip.

One is that we need treatment more than we need prosecution of those folks, my view.

And, secondly, although it is not the topic of this hearing, we need to rebuild our communities, because people who are alone and lonely, who are dealing with COVID and don't have any support systems, they often make a mistake thinking an opioid might be that support system that they want.

The second thing, though, that is very disturbing is that, where we do have an overreliance on the criminal justice system rather than treatment, there is real disparate treatment within the criminal justice system, with Black and Brown Americans being much more highly prosecuted.

Just as an example, in Vermont the odds of a person of color being prosecuted are significantly higher, maybe 14 times as high. So it is another reason why the over, my view, overreliance on prosecution versus treatment for the users, not the dealers, is something that we, I think, have to be mindful of.

Let me ask Mr. Milione -- thank you for your work, by the way -- how do we ensure that we are taking the right steps in the criminal justice system, on the one hand, to address the public health crisis, while simultaneously ensuring that we are not exacerbating an already problematic criminal justice system that does have disproportionate impact on people of color?

RPTR MERTENS

EDTR ROSEN

[12:28 p.m.]

Mr. Milione. Thank you, Congressman. At the DEA, we are very concerned about those that are inflicting the harm in our communities, and obviously, with something as deadly as fentanyl, that is our primary concern. That is where we are focused on the most significant drug threats. But we are also interested in helping those that are harmed, and that is why we support expanded access to treatment and will work with our interagency partners to do that.

Our focus are on the biggest drug threats that -- right now, that is fentanyl, and a close second is methamphetamine, and the Mexican cartels that are flooding our country and distributing it throughout all communities across the country.

Mr. Welch. You know, on that topic, a lot of us here have seen the benefit of telemedicine, and that is a tool that can be helpful to provide treatment to the individuals, not the ones you are going after in the Mexican cartel. And it is really true for those of us who represent rural districts. There are many temporary flexibilities in place right now to allow telemedicine that could benefit from being permanent, and I want to ask about the telehealth ability to prescribe.

Earlier this year, the ONDCP indicated that a rule might be coming regarding telemedicine and special registration. And how do you see DEA's progress here, and what might be the status of this rule to ensure that patients are getting the care that they need?

Mr. Milione. Well, as I said, we are focused on doing whatever we can to help those that are harmed. I know that we are working with our interagency partners on anything consistent with the Controlled Substances Act. I would have to get back to you

with some specifics about that.

Mr. Welch. All right. Well, your role in that is really important because you have got a dual responsibility, you know. We look to you for really hard and effective law enforcement, but on the other hand, you are making that distinction between where to focus your resources and where to facilitate treatment for people that we want to help, so I thank you for that, and I thank all the witnesses. I yield back.

Ms. Eshoo. The gentleman yields back.

A pleasure to recognize the gentleman from Florida, Mr. Dunn, for his -- for your 5 minutes of questions, sir.

Mr. Dunn. Thank you very much, Madam Chair and Ranking Member Guthrie, for hosting this hearing today to discuss the enormously important issue of proper scheduling of fentanyl analogs.

I fully support the permanent scheduling of fentanyl analogs as Schedule 1 substances, and I am proud to co-sponsor the Fight fentanyl Act introduced by my colleagues, Congressmen Chabot and Latta. I also support strong punishments for those who are responsible for producing and distributing fentanyl analogs on our streets.

You know, the cartels are producing synthetic opioids, and they are pouring over our southern border, and they are assisted by Chinese chemical companies who are sourcing their precursors. Lax punishment for those found trafficking in these substances will only incentivize the spread of these deadly substances in our communities. I think the Biden administration proposal gets one thing absolutely right, and that is, the permanent scheduling of the fentanyl analogs. I think it fails in its shortsighted decision to exclude fentanyl analogs from mandatory minimum sentencing requirements.

You know, the fentanyl analogs are literally, as has been said already today,

poison on our streets. In a single drug bust in my district, Marion County, earlier this year seized 2 ounces -- I am sorry -- 2 pounds of fentanyl. 2 pounds of fentanyl, pure fentanyl, is potentially enough to kill 80 million people. We are talking about wiping out cities here.

When it is prescribed as a medication -- I am a doctor as well -- in a healthcare setting, we administer this in microgram doses. That is one-millionth of a gram.

Excluding one of these deadliest drugs in the world from the mandatory sentencing is simply irresponsible, in my mind, and it will surely shift the illicit drug market towards moving more of these analogs through our communities. I think now is not the time, and these are not the charges to encourage prosecutorial leniency. The proposal we are reviewing today will empower organized fentanyl producers, mostly Mexican cartels who are getting their precursors from chemical companies in China. It will just empower them.

So, Mr. Milione, a quick question. In the DEA's 2020 intelligence report, they determined that China was the number one source of producing these precursors. Is that still true?

Mr. Milione. Yes.

Mr. Dunn. Excellent. Good. That is a factoid we can work with. Dr. Throckmorton, is the DEA -- this is interesting to me just as a science end of this thing -- to confidentiality identify the sources, the origins, if you will, of fentanyl analogs and fentanyl when you seize drugs?

Dr. Throckmorton. I think I would defer to the DEA on their detection and deciding where these things came from.

Mr. Dunn. Very good.

Mr. Milione.

Mr. Milione. Can you repeat the question?

Mr. Dunn. Yeah. So if it is -- you can -- can you confidentiality determine the origin of a compound, an analog, a fentanyl analog when you seize it? Is there enough chemical analysis that you know the telltale signatures of where it came from?

Mr. Milione. In DEA's labs, we have a significant profiling program that looks at all of that.

Mr. Dunn. I am pleased. Thanks so much. Mr. Milione, again, has the administration dedicated enough resources to our southern border to adequately empower you to reduce the fentanyl trafficking and analog trafficking across our southern border?

Mr. Milione. We are very concerned with the threat of fentanyl. We are very concerned with what is going on in Mexico. Every day, agents on the southwest border and throughout country are investigating these criminal drug networks.

Mr. Dunn. Are there any particular tools you would like us to provide?

Mr. Milione. Congressman, we can always use more resources. This is a very, very difficult, challenging problem, and we can always use more resources.

Mr. Dunn. Thank you so much. Let me say that I am -- I will vote for this bill. I am glad we are doing it, but I am disappointed that there is no mention made of the problem we have of sourcing all of these drugs across our southern border.

With that, Madam Chair, I yield back.

Ms. Eshoo. Dr. Dunn yields back.

The chair is pleased to recognize the gentleman from California, Mr. Cardenas, for his 5 minutes of questions.

Mr. Cardenas. Thank you very much, Madam Chairwoman, and also Ranking Member Guthrie. We really appreciate this opportunity for us to discuss this very, very

critical and important issue.

When it comes to overdose deaths, they are rising, and it is clear we must do what we can to act to control the distribution, sale, and use of fentanyl-related substances. To do this successfully, Congress must address rising overdoses as the public health crisis that it is rather than a problem of not enough enforcement. Because of this, I am concerned that class-wide scheduling takes the approach of guilty until proven innocent. We would be criminalizing compounds which haven't even been discovered yet. This approach applies harsh Federal penalties and restrictions even if a compound turns out to be non-harmful. It could be helpful, as a matter of fact. For example, fentanyl and fentanyl-related substances are in a category of compounds which also includes medication for pain, diarrhea, Parkinson's disease, depression, anxiety, and dementia.

I would like to submit for the record this paper titled "Potential Unintended Consequences of Class-Wide Drug Scheduling Based on Chemical Structure, a Cautionary Tale for fentanyl-Related Compounds." It was published in the Journal of Drug and Alcohol Dependence by Dr. Sandra Comer, who is a Professor at Columbia University and testified earlier this year before Congress on this very topic. She warns that, quote, "class-wide banning based on chemical structure is likely to have unintended consequences, including severely limiting biomedical research, and in the long term, adversely impacting public health," end quote.

Dr. Volkow, I think we all agree that the current scheduling classifications system has made it very difficult to scientists to research the effects of scheduled compounds which may have medicinal properties. For example, we know that compounds in marijuana have legitimate and beneficial medical uses, despite it being Schedule 1. So I am encouraged to see that efforts are being made to allow researchers to study the effects of various compounds in this proposal.

However, I am concerned with the idea of treating entire categories of compounds as a Schedule 1 for enforcement purposes but differently for research purposes. I think this puts the entire scheduling system into question. Question one -- schedule one compounds are, by definition, compounds with no medical use and a high potential for abuse. I will say that again. Schedule 1 compounds are, by definition, compounds with no medical use and a high potential for abuse.

In this specific situation, if we don't have the data to support fentanyl-related substances as Schedule 1, why is it being recommended to classify an entire category as such, and also, including compounds which haven't even been discovered yet?

[The information follows:]

******** COMMITTEE INSERT ********

Dr. Volkow. In general, certainly, I would be also very much worried about just taking chemical structure as a way of scheduling, but I also recognize that we are really in an emergency situation. It is not business as usual. And we have never seen so many people dying from overdoses ever, and fentanyl is one of the drivers as well as fentanyl-related compounds. They are highly, highly profitable. They are not going to go away. And we need to actually do everything that we can to make it harder for the manufacturer and dealers to do it.

At the same time, we need to also be very conscious that the way we are going to be addressing the crisis, as said by the other agencies, is not one intervention. We need to actually provide prevention, treatment, recovery. And that requires research, and that is why I am so -- I am very supportive of these provisions because it will give us an opportunity to make research simpler and faster on these Schedule 1 compounds. So we are in no ideal world. We are in an emergency situation.

Mr. Cardenas. Yes. It definitely is an emergency situation. I also would like to add to what my colleagues have mentioned about our disappointment that Department of Justice is not here. I hoped that we would have been able to hear from the Justice Department on these issues as they played a key role in developing and potentially enforcing this proposal. I appreciate the feedback of all of the witnesses who are here today.

Being the DOJ is not here, I want to ask a question to the DEA and also ONDCP. The bottom line is, why is it being recommended we continue the same strategy of criminalizing compounds which clearly isn't working so far?

Mr. Milione. I will take that. Thank you for the question. Fentanyl is killing hundreds of people every single day in every community across this country. Tens of

thousands are dying every year. These are incredibly dangerous substances. Mexican cartels are flooding the country with these substances, working with chemical companies in China, and they are profiting off the opioid crisis in our country.

So our focus is on those that are harming the country and investigating them and bringing them to justice, but also, it is critical for us to have these drugs scheduled so that we can prevent them from coming in and harming our public citizens in our country, and also seizing it when we encounter it as well as dismantling the groups that are profiting off this.

Mr. Cardenas. Thank you. My time has expired. I yield back.

Ms. Eshoo. The gentleman yields back.

The chair now recognizes the gentleman from Georgia, Mr. Carter, for your 5 minutes of questions.

Mr. Carter. Thank you, Madam Chair, and thank all of you for being here. I am so glad that we are having this hearing, and I appreciate you calling this hearing, Madam Chair, but I am frustrated. I am very frustrated. I mean, here we are at this hearing, and we have a border where fentanyl is pouring across the border, pouring across the border. Enough fentanyl was seized during the month of September to kill 2.1 billion people. Enough fentanyl has been seized at that border this year to kill every American three times over. And yet, do we have a representative from the Department of Justice? Do we have a representative from the Department of Homeland Security? No. It is ridiculous, ridiculous that we are doing this.

You know, drug traffickers are murderers, period. Drug traffickers are murderers. Ask any of 100,000 family members -- the family members of 100,000 people who died this past year as a result of drug overdoses. Ask them, and they will tell you. They are murderers. Until we resolve the situation at our southern border,

anything we do is ridiculous. This has got to be addressed. And, again, if we have to subpoena the Department of Justice, subpoena Homeland Security, get them here and answer these questions.

I want to ask you, Mr. Chester, and I will ask Mr. Milione in a second. If ever there was a time, if ever there was a time to debate reforming mandatory minimum laws, do you believe it should be now with the unmatched lethality of fentanyl-related substances which are even more lethal than fentanyl itself?

Mr. Chester. Thank you for your question, Congressman, and I want to talk to you from a policy perspective. I am not an attorney, and I am not part of Department of Justice, but I do want to answer your question directly.

And the first one, the first element of that is this: What is not included in that exception are fentanyl analogs that have already been identified and are already placed in the scheduling regime of which there have been close to 30 that have been seized and identified by CBP and maybe another handful by our Canadian partners that we deal with. So that is valeryl fentanyls, sufentanyl, methoxyacetylfentanyl. Those have already been identified. Those are in the schedule regime. That is a Schedule 1 drug. This provision does not apply. It also does not apply for those substances in which there is a case of death or serious bodily injury. That also does not apply. So what you have is kind of this very narrow universe of substances that have not yet been identified that this exception applies, and so I want to make sure that we are absolutely clear on that particular provision.

To the previous statement about the mechanism by which we gather these up, it is true that these substances have not been tested in vitro or in vivo. That is true. But it is also true, as you state, that this class of fentanyl substances is remarkably dangerous from the ones that we have detected and potentially dangerous for the ones that we

have yet to detect and yet to be able to put to testing, and that is why this is important.

Mr. Carter. And, you know, I dealt with this when I was in the Georgia State Legislature. Being a pharmacist, I often carried the update of the pharmacy rules in Georgia. And every year, we would identify the dangerous drugs and include them on there, and every year they would change them, just technically, and we would be behind. We were behind before we even started.

Mr. Milione, I am going to ask you the same question. Do you need me to repeat it?

Mr. Milione. No. Thank you. We are focused every day, obviously, on the threat that we are facing with these drugs. This is an existential threat to the country. The fentanyl substances are coming in. What is critical for us is the class-wide scheduling so that we can seize them before they come in, and seize them when we encounter them.

As a law enforcement agency, we will continue to investigate those groups that are harming our communities, and we will do everything we can to get help for those that are being harmed. Prosecutors make decisions about charging. Judges follow the law. They will sentence. We will continue to investigate and protect the public with all the tools that we have.

Mr. Carter. Let me ask you something. Isn't it true -- I will ask you, Mr. Milione. I am sorry.

Mr. Milione. That is all right.

Mr. Carter. Isn't it true that the fentanyl and the fentanyl variants are so potent that even at low doses, they can be dangerous, even so much so that the DEA agents are warned about touching them?

Mr. Milione. Fentanyl is an incredibly dangerous substance. Two milligrams, a

few grains of salt, is a potentially lethal dose. That is why we have put out a public safety alert to warn about the pills that are laced with fentanyl. Four out of ten of those pills are --

Mr. Carter. That you can get over the internet. That is the ones you are talking about?

Mr. Milione. That is correct.

Mr. Carter. Absolutely.

Madam Chair, I cannot believe the Department of Justice and the Department of Homeland Security are not here. We should subpoena them and make them come here.

Thank you, Madam Chair, and I yield back.

Ms. Eshoo. The gentleman yields back.

I think when an agency declines to come and testify, they injure their own case. This is -- you know, this is a -- this is the people's House, and we are examining, with every legitimacy, the administration's proposal, and it is an agency that is key in this. So I think that they have hurt themselves by the choices they have made, and I think it is regrettable, and it is troubling to me. I think we all feel the same way about it.

Okay. The chair now recognizes the gentleman from California, Dr. Ruiz, for your 5 minutes of questions.

Mr. Ruiz. Thank you very much, and thank you for this hearing. I am saddened that we are here, yet again, to discuss this crisis that continues to sweep our Nation, affecting each and every one of our communities. As a physician, I treated far too many patients with substance abuse disorder in the emergency department, many fighting for their lives.

Just this week, I heard from one of my constituents, Jennifer, from Bermuda

Dunes in my district in California, who tragically lost her son last year. Steven Loza was just 18 years old and had recently graduated from high school when he died of fentanyl poisoning. He should have had his whole life ahead of him. Unfortunately, this case is not unique. These tragedies cannot continue. We must continue fighting for Jennifer, Steven, and the families across the country who have been afflicted by this crisis and enact policies that help prevent more suffering and unnecessary loss of life.

Earlier this year, the Biden-Harris administration's Office of National Drug Control Policy released their drug policy priorities which included various bold approaches to reduce overdose deaths. I applaud this proactive approach. This overdose epidemic is one of the most important public health issues of our time and requires urgency.

Mr. Chester, I am interested in hearing about the administration progress on these priorities, and more specifically, what major actions has the administration taken to increase access to evidence-based treatment services since releasing its policies priorities.

Mr. Chester. Thank you, Congressman. So I would like to bring you up to date on a few things. So at the administration level, the American Rescue Plan invested nearly $4 billion, and that was to allow HHS and SAMHSA resources to expand vital mental health and substance use disorder services. The funding also included $30 million specifically for harm reduction, and we know how important that is in saving lives and preventing overdoses.

The President's fiscal year 2022 budget, $41 billion across the National Drug Control program, but that is both demand reduction and supply reduction as well, and that is about $670 million above the fiscal year 2022 enacted. We have also designated six new counties as part of the HYTA program, the highly successful HYTA program. We have also funded the nationwide expansion of the overdose response strategy for the HYTA, which is not only law enforcement, but also brings together critical public health

interventions in our communities as well. We met with more than 300 State, local, and Tribal leaders from all 50 States and territories to talk about how they could use opioid litigation settlement dollars and focus them in the right place for substance use disorders.

Mr. Dunn. Mr. Chester, since you mentioned Tribes, we know that many -- like in many other areas of healthcare, there is marked disparities in access to substance abuse treatment for underserved communities of color, rural communities, and Tribes. So what steps has the Biden-Harris administration taken, or is planning to take to close these disparities to access to treatment?

Mr. Chester. Yes, Congressman. I would offer you two things: The first one is there is never a time that we talk about a particular policy that we don't mention State, local, and Tribal as well. And we understand the unique aspects and the unique needs of the Tribal community, and the fact that substance use disorder has fallen on our Tribal communities in an outsized fashion.

Two things that I can offer. One of them is, and this was HHS released practice guidelines for the administration of buprenorphine for treating OUD. We know that there has been an expansion in the provision of buprenorphine over the COVID pandemic, and that has been incredibly useful in getting more people into treatment.

And the other thing, we are very proud of the fact that the DEA, in working with ONDCP, lifted a decade-long moratorium on opioid treatment programs that have a mobile component that is critically important for rural and Tribal communities to be able to extend treatment in areas that are traditionally underserved. And so that is two examples of things that we are very proud of that we have done just within the last 10 or 11 months.

Mr. Ruiz. Thank you. And are these efforts also conducted and these outreach educational efforts also conducted in Spanish?

Mr. Chester. I can get you the absolute answer on that, but what I can tell you is I just -- let me just talk about the drug-free communities program for a second. Because the drug-free communities program is entirely local, their motto -- and they are managed through the Office of National Drug Control Policy, their motto is local problems require local solutions, and that is one that I would be glad to provide you some more information on that, and it being culturally and linguistically focused because we are very proud of that program and announced $13.2 million in funds just over this past year.

Mr. Ruiz. Thank you. I yield back.

Ms. Eshoo. The gentleman's time has expired.

The chair is pleased to recognize the gentleman from Pennsylvania, Dr. Joyce, for 5 minutes.

Mr. Joyce. Thank you, Chair Eshoo and Ranking Member Guthrie, for convening this hearing on what we all recognize is a grave and important matter. We are aware that the expiration date for the current emergency class-wide scheduling order for fentanyl-related substances is coming up next January, or now will be likely punted until February. Congress cannot, I repeat, Congress cannot allow this life-saving order to expire and, rather, finally needs to pass legislation to permanently schedule fentanyl-related substances to empower our brave law enforcement officers to get these deadly drugs off the streets, and to bring the traffickers and the dealers of these poisons to justice.

In the face of this escalating crisis, I share with Chair Eshoo and Ranking Member Guthrie's concerns that the DOJ hasn't even allowed themselves to be present at this important hearing. Drug overdoses are killing more Americans than ever before, and nearly two-thirds of these deaths are the fault of synthetic opioids, like fentanyl, and fentanyl-related substances.

My district in Pennsylvania has been hit hard by this crisis over the last 2 years. Every single one of the ten counties that I represent has experienced increase -- increases in the overdose death rates from 2019 to 2020, over 30 percent in each and every one of those 10 counties. While I am pleased to see the Biden administration finally releases a plan to permanently schedule these substances, I worry that this plan is misguided, and that the changes of the proposed mandatory minimum sentences for these drugs specifically will have the reverse impact and encourage the traffickers, the traffickers that you talked about to us today, to continue to bring these substances into our communities and kill our families and our friends.

My first question is for you, Mr. Milione. Is it reasonable to believe that class-wide scheduling would not expand the application of mandatory minimum sentences, as some might suggest?

Mr. Milione. Thank you, Congressman. Our job at the DEA is to make sure that we are making our communities safer, and that includes conducting the investigations into those groups that are flooding our country with fentanyl. As I said before, fentanyl is an incredibly dangerous substance. What is critical is that those drugs are classified permanently so that we can stop those drugs from coming into the country and seize them and dismantle the networks that we are investigating.

Mr. Joyce. My next question is for Dr. Throckmorton. As a physician, I followed with interest the discussion about streamlining the process to remove fentanyl-related substances from Schedule 1 based on just one factor, not all eight. Does that mean a fentanyl-related substance could be removed from Schedule 1 even if there is no medical use?

Dr. Throckmorton. The short answer is yes, under the current proposal. It would remain in Schedule 3, presumably, if the pharmacology anticipated that it would

have low amount of potential for abuse, but it would still be controlled under other various aspects of drug development. My agency has a series of controls that we have over drugs that are understudied -- as new drugs for us, investigational review boards would continue to be watching them, for instance.

But the short answer is yes. Under the current proposal, the focus is on the pharmacology that we anticipate would cause greatest harm, identifying that pharmacology, and if it exists, that compound stays in Schedule 1. It should not leave the tightest possible controls.

Mr. Joyce. I agree with that. It should not leave the tightest possible controls.

Mr. Milione, I think you said some important issues to us. You stated that these cartels are permeating our southern border. They are flooding every community with fentanyl-related substances, driven by greed, your terms, and stopping at nothing, your terms, and I agree.

But my question is for you, Mr. Chester. Is it not incredibly dangerous to leave the door open for hypothetical future compounds? Why not fix the threat today? Wouldn't it be prudent to be on course if there are research exemptions to address those as the research guides us?

Mr. Chester. Yes. I appreciate your question, Doctor, and I agree with your characterization of the threat, but not that we are leaving the door open. I mean, the fundamental element of this particular proposal is to gather these substances up and bring them under control, substances not even yet created. And I think that is the important aspect of this is that we are permanently scheduling these substances as Schedule 1 until the research community has the ability to access them and determine their proper place in the scheduling regime.

Mr. Joyce. I thank you all for being here today. I thank Chair Eshoo and

Ranking Member Guthrie. This is informative, and this is an important hearing to have. Again, I want to state my grave concerns that the Department of Justice refused to participate in this hearing today. Thank you, and I yield.

Ms. Eshoo. Thank you, Doctor. Always a gentleman.

The chair is happy to recognize the gentlewoman from Michigan, Mrs. Dingell, for her 5 minutes of questions.

Mrs. Dingell. Thank you, Madam Chair. I would also like to thank our witnesses for being here today and just telling you how important this hearing is. Most of you know I lost my sister to an opioid drug overdose, but in the last year, I also lost a family member from fentanyl. And we all talk about the southern border, but people don't talk about the fact that the Canadian border is also a very dangerous source, and law enforcement at the time told me about how deadly this is that is coming in, and most of the people that are buying it have no idea what is about to happen to them, and that is why it is so important to continue this discussion.

These witnesses from the Justice Department should be here. I do believe these people are murderers [inaudible] which we need to take that on. But it would be good to hear about additional policies that the Biden administration is proposing for addressing the opioid crisis. We all recognize that multi-faceted problems require multi-faceted solutions with over 100,000 deaths in only a year period in this country, and almost 3,000 just in Michigan. It is important we consider all possible strategies to combat the crisis.

Mr. Chester, could you briefly summarize other avenues that the Biden administration is pursuing to reduce overdose deaths, particularly those around prevention, treatment, harm reduction, and recovery services?

Mr. Chester. Yes, Congresswoman. Thank you very much. The first thing is, you mentioned it, prevention, and that is preventing drug use before it starts. The

second one is reducing barriers and access to treatment leading to long-term recovery. And some of those we talked about earlier, particularly extending into underserved populations, reducing financial and other barriers to accessing treatment. But the third thing is harm reduction. And I think it is critically important that we remember that harm reduction is a critical part of ensuring that individuals are not losing their lives to overdose. And that is not only syringe service programs, fentanyl test strips, which I know that have been spoken about a lot in the press lately, but also access to Naloxone. Naloxone is critically important as a harm reduction intervention to make sure that we can ensure that Americans do not lose their lives to opioid overdose. Thank you.

Mrs. Dingell. Let me build on that, Mr. Chester. A number of States have adopted co-prescribing programs when a doctor pairs an opioid prescription with a prescription of the overdose reversal drug, like Naloxone. I can't talk today. Mr. Chester, what role can increased utilization of co-prescribing programs play in assisting with response to the opioid crisis?

Mr. Chester. Thank you for the question, Congresswoman, and I know Congressman Sarbanes is also a supporter of co-prescribing. What I can tell you is, and specifically about ONDCP's role is, we look across the span of possible policies, possible interventions, and those that could be extended across the country that could be useful in co-prescribing is one of those things that we have looked at and that we will [inaudible].

Dr. Volkow. If I may interject. I am sorry. I apologize. But I also think that the importance of science in counting the fentanyl crisis should be highlighted because the reality is being we are faced with a drug that we don't have so much information to optimally reverse overdoses or to optimally treatment. So, therefore, the importance, again, of doing clinical research that will allow us to implement policies that are more

likely to be effective.

Mrs. Dingell. I think that's very important, and you -- I think it was you who spoke earlier about one of my biggest bugaboos is that we do not have pain relievers that are not addictive. We need to be investing in more pain reduction medicines. I mean, it is a combination of reasons why people are using these drugs.

And I do want to say that my colleague, Congressman French Hill, and I are leading legislation, Preventing Overdoses and Saving Lives Act, to provide State grants to encourage uptakes of these programs which have proven effective in helping address the opioid crisis.

I was going to ask you all more questions, but I have 30 seconds left, so I won't. I will yield back, Madam Chair, but I will have additional questions for the panel, especially on what they think we should be considering in the policies to reduce overdose deaths. Thank you, and I yield back my time.

Ms. Eshoo. The gentlewoman yields back.

I think all members are going to be heard from in terms of detailed questions to our witnesses because there is so much to -- more to be learned and questions answered, so we will be doing deep dives on that.

The chair is pleased to recognize the gentleman from Texas, Mr. Crenshaw, for 5 minutes.

Mr. Crenshaw. Thank you, Madam Chair. Thank you all for being here. It is an important topic, and I think it has a lot of potential for bipartisan agreement and policymaking.

I want to start -- I want to try and understand the mandatory minimum policy by the administration and understand what the intent is, and maybe get at what some of the repercussions are. So the administration -- Mr. Chester, this is for you. The

administration supports mandatory minimums for cases where death or serious bodily injury can be directly linked to the fentanyl analog that was trafficked. I understand where we are going with this. You don't want to put people in jail just because they are a drug addict, but you do want to put the drug dealers in jail.

Now, the problem is, why support this standard rather than a standard that would get at the serious trafficking cases, because these are notoriously hard to prove, for prosecutors to prove that this overdose was directly linked via intent and the substance to this dealer. They are having a very hard time prosecuting that.

Mr. Chester. Thank you for your question, Congressman. I will give you the policy aspect of it, but I would like to defer to the Department of Justice. And I know that they have submitted a statement for the record on this particular. I am kind of the arcana of it as well, but I will tell you, you asked the question, where we were coming from on this, and so I want to make sure that we are clear.

I would make a different distinction than the one that you made between the trafficker, and actually, the user and make a distinction, actually, among -- upon the substance itself. And so you mentioned fentanyl analogs. Those fentanyl analogs that have been identified and have been tested, those are Schedule 1. They have been placed in the scheduling regime. That is not what we are talking about.

What we are talking about is we have gathered up an entire class of substances, uncreated, that within that class of substance, there may be substances that either have medical merit, or are not the least bit harmful. They are not any more harmful than water.

So the question is, what do you do with those particular cases where an individual has been convicted of a substance that is only within Schedule 1 by virtue of its class scheduling? That is why that particular guardrail was put in.

Mr. Crenshaw. Okay. And maybe if DOJ was here, we would ask them what we could do to make it easier to prosecute drug dealers with bad intent that are dealing fentanyl that is killing people. I mean, I am just going to simplify what we are trying to get at, and this seems to get in the way of it.

On a separate note, the administration talks about harm reduction as a method to deal with this crisis. San Francisco, Philadelphia, New York City, they are promoting harm reduction programs. They had great success in mitigating opioid abuse, more so than cities that have just cracked down harder on illegal drug use. And what does the literature say on safe injection sites? Are these workable solutions or not?

Mr. Chester. I can get you an exact answer on kind of the science behind safe injection sites. And, in fact, I could turn it over to Dr. Volkow. I will tell you in broader terms, when it comes to harm reduction, it is saving people's lives and preventing them from overdosing to drugs. That is kind of one element.

The second element of that is it is the first step on the road, hopefully, to treatment leading to long-term recovery. That is ultimately the goal, but when it comes to the science behind safe injection sites, Dr. Volkow, if you would like to add something.

Mr. Crenshaw. Quickly, please, because I have another thing I want to hit.

Dr. Volkow. Yeah. We have done research in other countries but not in the United States, and from that research, it has actually mitigated some of the adverse effects of drug use, including HIV, hepatitis C, and overdoses, but we need to test these in our country.

Mr. Crenshaw. I understand. And thank you for being here. Thank you for your answers. I do want to point out something. When it comes to the opioid crisis and 100,000 deaths in the past year, we can talk about mandatory minimums. We can talk about harm reduction. And these things are very important to talk about, but we

wouldn't have to be talking about those things if there was no fentanyl in the system in the first place.

Now, we are lucky in a sense because we know where it is coming from, all right? The Chinese supplies the chemicals, and the Mexican drug cartels are pushing it across our southern border. I say we are lucky to know that, because it allows us to focus on something. It allows us to focus on the source of the problem, which is an open southern border, where our drug cartels are simultaneously shoving hundreds of people at a time across the border to tie up border patrol.

Meanwhile, border patrol is not actually patrolling the border, and the drug cartels can put their drugs through the gaps in our border. And then they come here, and we seize hundreds and hundreds of pounds of fentanyl, which can kill tens of millions of Americans. We seize that on a regular basis. I would like to submit for the record from Operation Lone Star these statistics from Texas, specifically, and I yield back. Thank you.

[The information follows:]

******** COMMITTEE INSERT ********

Ms. Eshoo. The gentleman yields back.

The chair recognizes the gentlewoman from New Hampshire, Ms. Kuster, for your 5 minutes of questions. Are you there, Ms. Kuster? Going, going, gone.

The chair recognizes the gentlewoman from Illinois, Ms. Kelly.

Ms. Kuster. I am here.

Ms. Eshoo. Are you there?

Ms. Kuster. I am here. I apologize.

Ms. Eshoo. Okay. Well, you are recognized.

Ms. Kuster. I am so sorry. I apologize. Thank you so much. Delighted to be here today to discuss the administration's recommendations on combating the fentanyl overdose epidemic. And I want to submit for the record a letter from over 150 advocacy groups and public health professionals in support of bipartisan legislation that I have introduced with Congresswoman Blunt Rochester to address the fentanyl overdose crisis. It is called the Stop fentanyl Act, and I hope our colleagues on both sides of the aisle will join us.

In New Hampshire, we saw very early on the devastation of this addiction epidemic. What began in the doctor's office with overprescribing pain medication evolved into a full-blown opioid epidemic that could literally be tracked along our highway map. Communities hooked on pills, they were prescribed by doctors, were inundated with less costly alternative, first heroin, and now other drugs and substances. Today, this epidemic continues to evolve with stronger, more dangerous synthetic opioids, like fentanyl and fentanyl-related substances. And what makes this even more concerning is that oftentimes, these lethal synthetic opioids are laced into other drugs, unbeknownst to the person struggling with addiction.

Since coming to Congress, I have worked tirelessly with my colleagues on the bipartisan Addiction and Mental Health Task Force, and on this committee, to help those with substance use disorder, but our work continues. As many have already pointed out, just this past year, over 100,000 Americans have died of drug overdose, but that number does not begin to capture the many other overdoses that have occurred during the pandemic.

I want to turn my attention to a comprehensive, holistic approach to ending this epidemic, one that invests in public health treatment, in prevention, and in support for those battling with substance use disorders. I want to focus on the interagency working group, examine and developing its recommendations on scheduling fentanyl. As policymakers, one of the challenges in keeping up with the pace of the overdose epidemic is working with lagging data from different sources that is not integrated in a readily available way, and we have focused on this in the Stop fentanyl Act.

Mr. Chester, the COVID pandemic has shown the value in real-time data. We know the number of deaths the next day and we wait -- yet, we wait months for overdose data and critical information on the synthetic opioids. How can we better access data in both public safety and public health?

Mr. Chester. Thank you, Congresswoman, for the question. And, you know, we agree. Data is the key to understanding the environment the best that we can, understanding where our vulnerabilities are, and being able to come up with policies in order to close those vulnerabilities. We are better than we used to be in data. Particularly, the National Center for Health Statistics within CDC now has the provisional data which is much -- which we get on a quarterly basis, and is much faster than the data we got before previously, and that has been very important.

The second thing that we do is we stay very much in touch with our State, local,

and Tribal partners who can feed us bottoms up data. Although you can't extrapolate it across the country, it gives us a sense for our understanding of what the environment is like.

And then the third one is to listen to the Congress. And the Congress, over the years, has been clear about what it is looking for in terms of this particular legislative proposal, and that was helpful in allowing the Departments of Justice and HHS to be able to shape what you have -- what we have here. But we don't disagree with the fact that we have some gaps on data, and it is an area that we need to work pretty heavily.

Ms. Kuster. Okay. Thank you. I am going to ask this last question with Mr. Chester and Dr. Throckmorton. A key priority of mine and the administration is increasing resources for harm reduction. Can you tell us what more can be done at the FDA perspective to make Naloxone more accessible?

Mr. Chester. I can start off, and then I will turn it over to Dr. Throckmorton. We know that Naloxone is incredibly effective at preventing overdoses and saving lives and that increasing Naloxone availability across the country is one of the critical elements of harm reduction under the first-year priorities under the Biden-Harris administration. But I will turn it over to Doug.

Dr. Throckmorton. Yeah. Thank you very much. I could not agree more. One of FDA's highest priorities is expanding the formulations, the available types of Naloxone that people can make use of. Just recently, we approved a higher dose formulation of Naloxone to make available for people that might use it. We believe we have recently started and continue to support --

Ms. Kuster. I am going to have to take your response for the record. My time is well up, and I will yield back.

Dr. Throckmorton. Happy to, ma'am. Thank you.

Ms. Eshoo. It has expired.

The chair is more than pleased to yield to the gentlewoman from Illinois, Ms. Kelly, for your 5 minutes.

Ms. Kelly. Thank you, Madam Chair, and Ranking Member Guthrie, for holding this important hearing to curb the opioid crisis in this country. Unfortunately, overdose deaths were beginning to rise even before the pandemic. I know we have talked a lot about that. And Black and Brown communities are experiencing the fastest increased rates of overdose deaths involving synthetic opioids.

I continue to be concerned about using the criminal justice system to address a public health issue. I worry about the impact this will have on the very communities that are suffering in silence without the sympathy of the media and of society at large. We need to make sure that we are taking a deep look at how this proposal to move fentanyl-related substances to Schedule 1 may perpetuate the existing racial disparities in our criminal justice system.

Mr. Chester, what is the evidence that increasing criminal penalties of fentanyl-related substances will actually reduce drug-related mortality and morbidity, particularly among Black and Brown communities?

Mr. Chester. Thank you, ma'am. I would offer you this, that we are -- that what we are not doing is increasing criminal penalties, but rather, gathering up a class of substances and placing them in Schedule 1, and I think it is an important distinction. And so I appreciate your question, but what we -- we are not increasing penalties, we are taking substances that are dangerous substances as part of a class of dangerous substances and placing them in Schedule 1, not increasing penalties.

Ms. Kelly. Okay. As fentanyl-related substances are increasingly criminalized, this may increase the development of new synthetic opioids. How does ONDCP plan to

address this to avoid a whack-a-mole approach to regulating harmful synthetic opioids?

Mr. Chester. Thank you, Congresswoman. You used the exact right word. I think you characterized it perfectly, whack-a-mole, right? So we have got to -- we have to ensure that that is not what we are doing. I think we need to understand a few things. The first one is, it is clear that when we take an action, drug traffickers change their behavior. It is almost impossible to get ahead of that, but at least we can close the gap. This particular action, class scheduling, was done for the exact reason that you just mentioned. So we were in a situation in the past -- and by the way, we asked the Chinese Government to do this as well, and they did. We were in a situation in the past where we would detect a fentanyl analog in the United States. We knew it came from China. We would go to the Chinese and say, please hold somebody accountable, and they would say, it is not illegal in my country, but we would be glad to do that. And by the time it was made illegal in China, and they were very cooperative on this, the traffickers had already moved to another substance. That necessitates class scheduling. So, you know, in my oral statement when I said that they are creating these substances faster than we can schedule them individually, it is exactly the situation that you are talking about.

Ms. Kelly. Thanks. I just want to make sure that Congress is taking a holistic approach to tackling this epidemic which includes investing significantly in prevention, treatment, and recovery also. This committee has heard from the research community that current research requirements under the Controlled Substance Act take significant time and effort to obtain. One of the criticisms of placing substances in Schedule 1 is the chilling effect that may have on research of those substances.

Dr. Volkow, the administration's fentanyl-related substances proposal seeks to establish a simplified process that would align research registration for all Schedule 1

substances more closely with the research registration process for Schedule 2 substances. Can you explain the difference between the two processes?

Dr. Volkow. Yeah. And this will make it, basically the proposal to do research on Schedule 1 equivalent to doing research on Schedule 2. And it eliminates the need of an extra review of the proposal of the researcher which is not necessary for Schedule 2, but it is Schedule 1. And that takes time and is much more lengthy, so it will facilitate that in addition to other provisions that will make it easier for researchers to actually perform their work. So with these in advance, and we are excited and supportive of this proposal.

Ms. Kelly. Thank you so much. Research is essential for understanding the opioid epidemic, identifying effective solutions, and informing our policymaking, and it is critical that we ensure that no barriers to this type of research exist. So thank you so much, and thank you to all the witnesses. I yield back.

Ms. Eshoo. I am going to recognize the gentlewoman from California, Ms. Barragan, but I also want to say before she begins her questioning, that we have votes on the floor. We still have several members that are in the queue to ask their question of the witnesses. So I think the good news for the witnesses is you are going to get a break for at least 45 minutes, and the downside is that we are going to be back after that 45 minutes to finish out our hearing by allowing all members who wish to question the time to do so.

So, with that, I recognize the gentlewoman from California, Ms. Barragan, for your 5 minutes of questions, and then we will recess after her questions for 45 minutes.

Ms. Barragan. Thank you, Madam Chair.

Ms. Eshoo. You are recognized.

Ms. Barragan. Thank you, Madam Chair. I am glad that we are here today to

discuss legislation that will hopefully allow us to stem the overdose epidemic that has taken far too many lives too soon. I want to thank all of our witnesses today for your testimony.

In Los Angeles County and across the country, we are seeing an unprecedented humanitarian crisis of people experiencing homelessness that requires a compassionate, thoughtful public health response. According to the Los Angeles County Department of Public Health, between 2017 and 2019, people experiencing homelessness in L.A. County were more than 36 times more likely to die of a drug overdose compared to the general L.A. County population.

Drug overdose deaths involving fentanyl tripled between 2018 and 2020. And drug overdose remains the primary cause of death for people experiencing homelessness in L.A. County. Comprehensive drug policy aimed at reducing harm caused by fentanyl-related substances must include an integrated public health approach and investments in infrastructure that addresses upstream social determinants of health.

This question is for Mr. Chester. Can you discuss strategies the Office of National Drug Control Policy are working on to tackle social factors, like homelessness, that exacerbate illicit fentanyl-related substance overdoses among the more than 500,000 people experiencing homelessness in our country?

Mr. Chester. Yes. Thank you, Congresswoman, for that question. I think you have brought up a very important point. The first thing I would like to say is that evidence-based prevention and prevention strategies are a key part of the first-year priorities that the office has laid out for the Biden-Harris administration when it comes to drug policy.

The second thing I will tell you is that the social determinants of drug use are an important part of our academic understanding of what it is that leads to the initiation of

drug use in the first place, and that is one of the key areas that the office will be working on in the coming year in order to reduce overall drug use around the country.

And as we say, and we have talked about it several times today, there is absolutely a direct linkage among the fentanyl-related substances that are available in our communities, their trafficking, and their use in our communities, and, therefore, overdose deaths. You can't pull one of those strands apart. You need to be able to deal with it in a comprehensive and holistic fashion, and that is the approach that we have taken.

Ms. Barragan. Thank you.

Dr. Volkow, in Los Angeles County, there was a 52 percent increase in accidental drug overdose deaths, and a 136.4 percent increase in the number of fentanyl-related death rates during the first 10 months of the pandemic compared to the same period in 2019. This alarming uptick of deaths is disproportionately affecting people of color. How can improving research with fentanyl-related substances help us address the opioid overdose crisis and combat drug overdose deaths within highly populated urban areas, particularly among people of color?

Dr. Volkow. First of all, I think that -- and we resonate completely with you about the question about the social determinants of health, because they do pertain very much about why you are seeing such a dramatic increase in overdose mortality during the COVID pandemic, and why it is affecting some populations that were vulnerable to start with more than others.

Understanding the processes and the challenges of people that are homeless, for example, is crucial for providing solutions. Without it, about people that don't have a place to sleep cannot sustain treatment, nor can they actually, when they go to jail, get exposed to others taking drugs. So understanding the social and cultural factors that have been exacerbated during the pandemic, including the uncertainties and the social

isolation, is crucial for containing the epidemic that we are seeing.

In terms of how the fentanyl research can help us, basically be better able to do treatment and prevention is, first of all, we need to understand what are the characteristics of the use of the substances, who is using them, how they are combining them. We need to also understand actually how to optimally, as I mentioned before, reverse them because Naloxone is not effective in all of the reversals.

And third, how do we optimally not just initiate people on treatment for their opioid use disorder, but retain them on treatment so they can recover, and we can prevent an overdose. That requires that we work with -- that researchers get their hands on working with fentanyl, so that they can develop animal models. They can actually develop new products, new ways of testing it, new ways of being able to document where people are dying from what so you can test rapidly right away as opposed to waiting months. So these are just some of the examples.

Ms. Barragan. Thank you so much, Doctor. I am out of time. With that, I yield back.

Ms. Eshoo. The gentlewoman yields back. We will now recess for 45 minutes, why don't we say 50 minutes. The ranking member and myself will race back after the third -- after we cast our third vote, and the witnesses take a break. I think that there you will find a cafeteria and whatever downstairs here in the Rayburn building. Thank you.

I am sorry we couldn't conclude before votes, but we have -- you are an all-star cast with just one department missing. But you can see that there is very deep, broad interest in this issue, and you are the experts, and we want to make sure that everyone be able -- is able to question. So we will be back at 2:15.

[Recess.]

RPTR GIORDANO

EDTR CRYSTAL

[2:32 p.m.].

Ms. Eshoo. All right. The subcommittee will come back to order.

The chair is pleased to recognize the gentleman from Utah, Mr. Curtis, for your 5 minutes of questions.

Mr. Curtis. I am so grateful, Madam Chair, to yourself and our ranking member and our witnesses. Obviously a very important hearing.

I feel like, if I am honest, compared to our witnesses and other members of the committee, that I actually knew very little about fentanyl when this hearing was called, and I decided to go on a fact-finding mission to learn how fentanyl was impacting Utahans directly.

It won't surprise you that I was shocked by the facts about fentanyl, particularly its use in Utah and the personal story of Utahans.

According to the Utah Highway Patrol, in Utah there has been a 900 percent increase in fentanyl seizures in the first 3 months of this year compared to the entire last year. It is 900 percent more in 3 months than in the entire last year.

The number of overdose deaths involving fentanyl in Utah doubled from 2019 to 2020. And the largest percentage increase in fentanyl deaths -- won't surprise you -- was 18 to 24, followed by 25- to 34-year-olds.

Obviously this is an increasing risk to our communities that needs local government, State government, and Federal Government, all hands on deck, everybody working together.

I also spent time with a coalition of entities fighting fentanyl addiction, including the Utah Attorney General's Office Overdose Strategic Response Team, DEA, and the Utah

State Bureau of Investigation's drug recognition experts.

Additionally, I put out word to my district that I would like to hear their stories, and within 24 hours I was delivered 250 personal stories of the way these families have been impacted.

Every one of these stories will break your heart. Every one of these stories represents not just an individual, but family and their network. And I think it has been said earlier today that it would be hard to find any one of us that hasn't been impacted by this. And if you will indulge me, I would like to read just a couple of quick parts of two of these stories.

"When my brother, Adam, was young, he was involved in an accident that saw him severely burned. The hospital prescribed him what turned out to be a highly addictive opioid, and for years afterwards he struggled with addiction, going in and out of rehab for alcohol, marijuana, and eventually heroin.

"In the fall of 2013, he enrolled in Utah Valley University after completing rehab with plans to get a degree in construction management.

"I remember the night of that September the 21st and what happened afterwards in a blur. I remember getting a call from my mom that night. I remember lowering my brother's coffin into the ground. I remember feeling numb for months. And, worst of all, I remember feeling ashamed of what my brother did.

"Nothing can turn back what happened to my brother, but I hope that we can talk more openly about addiction, opioid use, and the deadly influx of fentanyl into our country. Addiction doesn't discriminate, and the first step to solving this problem is talking about it. Thank you for taking that step."

Next story.

"I am a recovering heroin addict where my addiction began with prescription

opioids at age 13. I suffered a dislocated knee and was prescribed Percocet and other prescription opioids for ongoing knee injuries.

"My story isn't going out of the norm. By age 18, I was addicted to heroin and went through overdose, ambulance rides, being homeless, induced with a coma, went through immense trauma, put my family through more turmoil than any family should endure.

"In 2013, I went through treatment and have been sober since. But the story far from ends there. In 2015, I lost my older brother to a heroin overdose. And his story isn't out of the norm. His story is mine. It is all of ours.

"We feel like enigmas in our society that has made us into a taboo, when in reality every family and community is affected by this. It is a societal norm that no one talks about.

"Currently, I work as a program director and utilization review specialist for a residential and outpatient substance abuse and mental health treatment facility in Utah County where I can work on breaking the stigma against this in other recovering addicts."

A couple of questions.

Mr. Milione, Deputy Administrator, I learned that fentanyl can be prescribed, but most of the fentanyl in Utah is illegally produced, I was told as much as 90 percent of it related to substances or analogues that are being distributed through illicit channels.

As you know, the 5-year mandatory minimum for illicit fentanyl is 40 grams, but one gram of illicit fentanyl can potentially contain 500 lethal doses. That is 500 potentially dead people.

Fentanyl-related substances can be even more deadly. A Department of Justice official from the prior administration testified before the Senate Judiciary Committee that the current quantity thresholds necessary to trigger mandatory minimum penalties for

fentanyl and fentanyl analogues are extremely out of date and inadequate.

Given what we know about the tremendous potency, toxicity, and harm associated with these substances, do you agree?

Mr. Milione. Congressman, thank you for sharing those letters. We get those letters also. And, yeah, members of the DEA have lost loved ones also, myself included. It is a challenge. It is a terrible thing. And that is why we are focused on trying to help those that are being harmed by this, going after those that are harming the community.

As far as the mandatory minimums, we are a law enforcement agency. Our mandate is to go after those that are harming the community, those that are flooding the country. That is where we focus. We work with our prosecutorial partners. And judges, working with the construct that Congress has provided them, will dole out sentences.

Mr. Curtis. Dr. Throckmorton, I understand the Biden proposal includes a streamlined process for rescheduling fentanyl analogues, but when considering the potentially dangerous nature of these substances why should we not go through the eight-factor analysis to ensure due diligence? Why are we rushing this?

Dr. Throckmorton. It is a really good question.

I don't think we are rushing it. I don't think the proposal does that. I think the proposal identifies appropriately the pharmacology --

Mr. Curtis. I am going to run out of time, so I just want to --

Mr. Throckmorton. Thank you.

Mr. Curtis. One more quick. Is there precedence for this?

Dr. Throckmorton. Is there precedence for decontrol?

Mr. Curtis. For skipping the eight-factor analysis and just using one factor?

Dr. Throckmorton. I am not familiar with the precedent that would be exactly

the same as what is proposed under this proposal. Normally we would go through the full --

Mr. Curtis. And I apologize. Unfortunately, I am out of time. I would love to let you explore that a little bit more.

But, Madam Chair, I yield my time.

Dr. Throckmorton. Happy to help.

Ms. Eshoo. Gentleman yields back.

The chair now recognizes the gentlewoman from Delaware, Ms. Blunt Rochester, for your 5 minutes of questions.

Ms. Blunt Rochester. Thank you so much, Madam Chairwoman, for the recognition.

And thank you to our witnesses for being here today to discuss the Biden administration's interagency proposal to reduce illicit fentanyl drug substances.

Like my colleagues, I have heard from parents, small businesses, State officials, and even children about the devastation that illicit fentanyl has inflicted on Delaware communities and families.

In 2020, more than 80 percent of the overdose deaths in Delaware involved fentanyl, and provisional data from 2021 suggests that we may be on track for another record-breaking year.

This underscores how important it is that we get these policies right. And the last time that the Acting Director of the Office of National Drug Control Policy was before this committee, I highlighted my concerns on previous approaches to drug control that were rooted in stigma and punishment and not public health.

And as a result, Congresswoman Kuster and I introduced the STOP fentanyl Act, a comprehensive package of public health policies to address the proliferation of synthetic

opioids like fentanyl-related substances.

I want to thank the witnesses who have provided feedback on our bill and hope that we continue to work together.

Mr. Milione, in 2020 we tragically lost over 93,000 people to drug overdoses. Based on the most updated data you have, can you tell us how many overdose deaths were caused, not just present, but caused by fentanyl-related substances?

Ms. Eshoo. Can you use your microphone, please?

Mr. Milione. I apologize.

Ms. Eshoo. That is all right.

Mr. Milione. Thank you for the question.

I believe that the number is 70,000 of the 100,000, but I would want to confirm with the colleagues on the panel. But it is a massive number. The vast majority are attributed to the fentanyl overdose deaths.

Ms. Blunt Rochester. And does the DEA have surveillance systems in place to understand how many overdose deaths are attributed to fentanyl and illicitly manufactured fentanyl, including fentanyl analogues and related substances?

Mr. Milione. We work -- we do work with our interagency partners to try to collect that information. There is always more to do in those partnerships across the health community and with the science community.

So we are moving in that direction with our current Administrator, Anne Milgram, who is very much focused in those heat maps and how better to understand where the threats are.

Ms. Blunt Rochester. Great. Thank you.

And, Dr. Throckmorton, has the United States ever implemented a classwide schedule based solely on structure of a substance?

Dr. Throckmorton. Thank you.

Yes, we have. The best recent example would be the androgenic steroids, which are scheduled as a class based on structure.

Ms. Blunt Rochester. And is it possible to tell if a substance would lead to opioid-related harms by just looking at the structure?

Dr. Throckmorton. Thank you.

No, it is absolutely not possible to do that yet. Structure gives us one piece, and it is an important piece. We think it is sufficient to identify compounds at high risk of being dangerous substances in the FRS class.

But that is why we are recommending the potential for using other testing, the pharmacologic testing that we are proposing in the Biden administration proposal, because we believe that those kinds of data are necessary to fully understand whether a product is going to be dangerous or whether, in fact, it is less dangerous or not dangerous at all and should be eligible for research more easily.

Thanks.

Ms. Blunt Rochester. And a structural definition of fentanyl-related substances could potentially classify thousands of substances as Schedule I drugs under the Controlled Substances Act without knowing whether they are addictive or have potential medical use.

What are the consequences of that?

Dr. Throckmorton. Well, I share your concern, but I think the proposal, as it is laid out, addresses that in the right balance. It recognizes the emergency that we face with this class of dangerous compounds, uses a structure-based mechanism to place them under control so that the DEA can make sure that they are not available, but then also puts in place a mechanism to remove them quickly from that scheduling if the data

show that they are not dangerous.

I think that balance really is the right approach to take here. It affords the greatest public health protection while still protecting the need to be able to support the research of compounds that are not like oxycodone, that are not like fentanyl, that have less danger.

Ms. Blunt Rochester. Right. And could potentially -- maybe there is some kind of cure or thing that we could use like Naloxone or other things.

Mr. Chester, representatives from the criminal justice and civil rights communities believe that a classwide scheduling would remove the prosecutorial burden to prove that a substance has a psychoactive effect similar to fentanyl. And I know that my time is up, so if maybe, as a follow-up, if we could comment on that concern.

And I don't know, Madam Chair. I think we have votes.

So I am going to ask if you could submit that in writing to us. And I am going to say thank you so much for your answers.

And I yield back my time.

Ms. Eshoo. The gentlewoman yields back. And just make sure that you submit that last question in writing so that it is actually seen and not have to be -- don't rely on me to repeat it.

Ms. Blunt Rochester. Thank you, Madam Chair.

Ms. Eshoo. We want everyone's questions answered.

No Republicans?

The chair is very pleased to recognize, last but not least, the gentlewoman from Minnesota, Ms. Craig, for her 5 minutes of questions. Great to see you.

Ms. Craig. Great. Thank you so much, Madam Chair. And thank you, in particular, for calling this really important hearing. Clearly the fentanyl and opioid crisis

remains one of the defining public health challenges of our time.

I want to dig in a little further on the focus of the administration's proposal on fentanyl-related substances and clarify how they are distinct from other controlled substances.

The opioid epidemic has been described in really three waves. When it began, overdose deaths were mostly due to prescription opioid pills. Then heroin-related overdose started rising. Now, synthetic opioids, such as fentanyl, are responsible for the majority of overdose deaths. This wave is causing more deaths than ever.

In September, the DEA issued a public safety alert on the unprecedented amount of fentanyl-laced counterfeit prescription pills in circulation. By midyear, the Minnesota Department of Public Safety had already seized 23,000 pills, a dramatic increase over the previous year.

These fake pills are often sold through social media platforms to people who think they are purchasing painkillers. That is what happened to a young man from my district, Devin, who died from an accidental overdose last year after he took a pill that he bought on Snapchat.

Devin's birthday is December 19. This year, he would have turned 21 years old. Like too many others, Devin should still be with us.

I look forward to working with my colleagues and the administration on crafting an effective and humane strategy to deal with the scourge of fentanyl and fentanyl-related substances.

As we confront the challenges that synthetic opioids pose, it is important that we understand these substances as we consider how to regulate them most effectively.

In Mr. Chester's testimony, he noted that based on substances seized and identified by CBP, partner forensic laboratories, and international labs, it may be possible

to synthesize as many as 48,000 fentanyl analogues with relatively simple modifications.

Can you explain in layman's terms why it is relatively simple to manufacture and produce these fentanyl-related substances?

Mr. Chester. Yes, Congresswoman. Thank you very much.

And I may have misspoke earlier. That is 4,800 substances.

Ms. Craig. Okay.

Mr. Chester. Yes. So, in layman's terms, which I am not a chemist and so I have chemists who explain this to me in simplistic terms, what you are talking about is a base fentanyl molecule that has four distinct rings on it, and then other molecules that are attached to it. And so you can make an addition to that skeleton or a substitution, substitute one chemical for another.

That causes an alteration in the chemical itself that turns it into a fentanyl analogue or ultimately a fentanyl-related substance. And that is the basic chemistry of how these things are altered. Although I could turn it over to Dr. Volkow or Dr. Throckmorton for probably a bit of a more sophisticated examination.

Ms. Craig. Dr. Volkow, any other comments on that?

Dr. Volkow. Well, it basically does identify with the advances that we have actually done in chemistry, so now we can modify molecules in ways that were unprecedented, and we could use it for good or for nefarious purposes, as is the case for the drug dealers.

Unfortunately, technology is not just in the hands of those that want to do healthcare intervention. So there is an enormous amount of innovation in the chemistry side. And that is why I said before these synthetic drugs are here to stay, because they are tailored and manufactured to get extremely addictive and toxic compounds and very, very profitable.

Ms. Craig. Yeah. Thank you so much.

Mr. Milione, the Federal Analogue Act allows for substances that are chemically similar to a Schedule I or II substance to be treated as if it were listed in Schedule I. Some have suggested that we should instead utilize the authorities under the Federal Analogue Act to control fentanyl-related substances.

Was this considered during the intra-agency conversations? And, if so, why does the administration's proposal not take that approach?

Mr. Milione. With the massive amount of fentanyl that is coming in, the fentanyl-related substances that are flooding the country, and the risk that it poses to all of the members of our community we need a proactive response, and the most certain way to do that is to keep everything scheduled so that we can seize it before it comes in and deal with it when we encounter it in our communities.

The Analogue Act has some parts of it that are very reactive and very cumbersome, and it doesn't meet the current threat sophisticated drug traffickers and the threat that the fentanyl substances pose.

Ms. Craig. Thank you so much for that answer.

And with that, Madam Chair, it looks like I am out of time.

So thank you all for testifying today. It is certainly an issue we all have to be engaged and work on together.

Madam Chair, I yield back.

Ms. Eshoo. The gentlewoman yields back.

Mr. McKinley has joined us, but I am told that, because you are waiving on, I need to take the Democrats first.

Mr. McKinley. Yeah, that is fine.

Ms. Eshoo. All right. So the chair recognizes Dr. Schrier of Washington State

for your 5 minutes of questions.

Ms. Schrier. Thank you, Madam Chair.

And thank you to our witnesses today.

This is such an important issue. I am listening to all my colleagues, and it clearly affects every community. And I think about 100,000 people lost just in the last year from opioid overdoses, mostly from fentanyl.

And I am so glad to see the Biden-Harris administration working across all of these agencies to find solutions, curb demand, crack down on traffickers, and save lives.

In my home State of Washington, like every other State, fentanyl has had a profound and devastating impact. In 2020, there were 672 deaths involving synthetic opioids, fentanyl, and fentanyl analogues, which is double the number we saw in the year before.

And just for perspective, 672 compared with 3,700 people who have died from COVID in Washington State in 2020. And there has been a massive effort to manage the pandemic, and we really need a proportionate response to take on the challenge of fentanyl and similar compounds.

I have to tell you this hit way too close to home in 2019 when three high school students in King County ingested fentanyl-laced pills. They had no idea what it was, like all of these stories, and they died. Two of those were at my community's high school, the one my son will attend.

So this issue is very personal, just like it is for so many of you, and we need to ensure that less of this is imported and it is not accessible.

Mr. Chester, given your background in international drug policy, can you explain briefly, just in plain language, the impact this proposal would have on the prosecution of fentanyl-related substance importation and exportation offenses and how these penalties

differ from those corresponding to the importation or export of fentanyl?

Mr. Chester. Thank you very much, Doctor, for the question.

And the first thing is, and I think one of the most elegant things about this solution, is there would be no difference between fentanyl-related substances and fentanyl itself, because they would both be Schedule I drugs, with the exception of prescription fentanyl, which is Schedule II. But talking about illicit fentanyl, so there is no difference between a fentanyl-related substance and an illicitly produced fentanyl substance.

When you talk about the international side of the house, I am glad you asked that question, because the --

Ms. Schrier. Can you --

Mr. Chester. Yes, ma'am. Go ahead.

Ms. Schrier. Well, I was just going to say thank you for clarifying that.

Can you tell me how this might impact international affairs with China and other countries?

Mr. Chester. Excellent question.

The issue of fentanyl and synthetic opioids is not a U.S.-only problem. It is a global problem. And the United States is a global leader on this issue. And for better or worse, we are global leaders in the issues of addiction medicine and understanding the opioid crisis and all of the things that we have been through as a Nation over the last decade or so on this, and other countries look to us for our leadership.

We went to the Chinese Government in 2018 and asked them if they would schedule fentanyl as a class because they were the preponderant source of these substances coming into the United States and we wanted their help, and they did that. And when they did that, it had a demonstrable effect on the amount of fentanyl coming

from China into the United States.

This action allows us to do two things. Number one, to meet the Chinese requirement that we asked them to do in order to do this. But, number two, to show other countries around the world that the United States understands how difficult this is, can come up with comprehensive, commonsense solutions, even in our complicated government, in order to be able to get a handle on this particular problem.

I think it is enormously helpful for our legitimacy around the world in dealing with this problem.

Ms. Schrier. I agree. We lead, and others follow in respect.

I have just a couple of quick questions. I am just going to turn to Dr. Volkow for yours.

In my pediatrics residency -- and I am dating myself -- we used fentanyl all the time for sedation and pain management, for hospital procedures, and in the ICU, in drips and the like. And I was just wondering if you could just clarify, can Morphine, hydromorphone, some other opioid easily substitute for fentanyl to fill all of those in-hospital medical uses? Are there any things that fentanyl can do that nothing else can?

Ms. Eshoo. Your microphone, please.

Dr. Volkow. Sorry. I keep on doing this mistake.

Fentanyl is actually a very helpful pharmacological agent, and it is used in anesthesia departments all around the United States. So it enables, by combining it with anesthetic agents, this allows you to decrease the amount of drug that you are giving to subjects. Also, because of its short half-life, it gives you the ability to bring them back rapidly.

So fentanyl, as a drug, has many advantages when used properly and under

supervised conditions. The problems become when it is an illicit substance, and most of the drug that is misused and leading to the overdoses is illicitly manufactured fentanyl.

So I think that in understanding that a drug has potential for negative actions with misuse, we cannot neither jeopardize all of the potentially valuable things that fentanyl offers as a pharmacological agent.

Ms. Schrier. Thank you. I appreciate that.

I yield back. I am out of time.

Ms. Eshoo. The gentlewoman yields back.

The chair is pleased to recognize the gentlewoman from Massachusetts, Mrs. Trahan, for your 5 minutes of questions.

Mrs. Trahan. Thank you, Madam Chair.

And thank you to the witnesses here today.

I really appreciate the administration's urgency to properly address the opioid and overdose crises, especially the COVID pandemic.

Unsurprisingly, since the temporary classwide scheduling of fentanyl-related substances in 2018, offenses involving fentanyl and fentanyl analogues have rapidly increased.

However, evidence also shows overdoses involving fentanyl and analogues have drastically risen. The provisional data from the CDC show that drug overdose deaths exceeded 100,000, as all of my colleagues have mentioned today, from 2020 to April 2021, the highest number of overdose deaths ever recorded in a 12-month period.

Clearly more needs to be done to save lives, and Congress must take the multipronged approach to pass policies that experts say will work.

So in addition to the interagency proposal to address fentanyl-related substances, the Biden administration recently released an overdose prevention strategy which

prioritizes primary prevention and highlights the FDA's consideration of mandatory prescriber education.

Ensuring that prescribers have a baseline knowledge of how to prevent addiction and identify, treat, and manage patients who have a substance use disorder is tremendously important. My bipartisan bill, the Medication Access and Training Expansion Act, requires prescribers to complete a one-time 8-hour training on identifying, treating, and managing patients with a substance use disorder.

In practice, the requirement is a minimal burden for practicing physicians in most States, as many continuing medical education requirements already include training requirements for opioid prescribing and pain management. The bill would simply result in addiction training being more widely incorporated into CME programming for physicians.

So, Mr. Chester, could you provide an update on ONDCP's work with medical schools to ensure adoption of a curriculum that includes a focus on preventing addiction as well as treating patients with a substance use disorder?

Mr. Chester. Yes, Congresswoman. I would be glad to.

One of the major points of emphasis in both the first-year Biden-Harris administration priorities and one of the things that Dr. Gupta has emphasized as well is building the addiction treatment workforce.

I think there is an understanding that the addiction treatment workforce that we have is being overwhelmed by the subject that we are talking about today, which is this dynamic nature of synthetic opioids, in that the need for treatment, the need for quality treatment is so large that we need to leverage more resources in order to be able to provide that.

And the second thing is that an addiction treatment workforce that is not as large

as it should be is a barrier in and of itself, just like all of the other barriers that we have discussed.

So reducing barriers to treatment, providing evidence-based, quality treatment, and building the addiction treatment workforce are three areas of big emphasis that Dr. Gupta has had since he has shown up as the Director.

Mrs. Trahan. Great. And the MATE Act also reauthorizes the practitioner education grant program established by SAMHSA, which expands the integration of SUD education into the standard curriculum of healthcare education programs.

And just last month, I had the opportunity to visit UMass Medical School's substance abuse and mental health services administration program, and they are already aligning with the provisions in the MATE Act, and it is just critical for medical schools across the country to build up its comprehensive curriculum.

Again, Mr. Chester, could you just comment on the value of practitioner education grant programs in mainstreaming SUD education and expanding the number of practitioners who can provide this high-quality, evidence-based treatment?

Mr. Chester. Thank you for that question.

As we just discussed, the ability for an individual who clearly has -- and we will just call it an opioid use disorder now -- who clearly has an opioid use disorder and clearly needs to get access to treatment, the gap between their ability to be able to identify for themselves that they need it and to be able to get it is absolutely critical.

And into that gap one or two things can happen. Either the treatment can be provided by the mainstreaming, as to what you talk about, or, as we talked about earlier, the mobile vans for OUD treatment or telemedicine, there is a whole series of things that we could do in order to close that gap.

What is most important is that we ensure that the illicit actors that we have talked

about all day today who have these substances available, they are not the ones that fill that gap and serve as a barrier to keep a person from getting the treatment that they need.

And that is why this particular proposal is important to forestall the production and the movement of these substances into the country. However, it is part of a more comprehensive approach that we need to do to provide treatment leading to long-term recovery for Americans who need it desperately.

Mrs. Trahan. Thank you for that.

I am out of time, Madam Chair. I yield back.

Ms. Eshoo. The gentlewoman yields back.

The chair recognizes the gentlewoman from Illinois, Ms. Schakowsky, who is waiving onto our subcommittee -- and she often does, and she is always welcome -- for 5 minutes of questions.

Ms. Schakowsky. Thank you, Madam Chairman. As usual, I thank you so much for allowing me to waive on.

I have a question both for Mr. Chester and also for Mr. Milione. Here is my question. The interagency proposal and the agencies themselves seem to agree that classwide scheduling will inevitably lead to misclassification as Schedule I and that some individuals could be wrongly prosecuted.

So here is my question. How are you addressing the concerns -- at least it is certainly my concern -- to ensure that we are not contributing to the mass incarceration crisis by cause of inevitability, I think, of misclassification?

Mr. Chester. Yes, Congresswoman. I can start, and then I can turn it over to our interagency partners here.

I don't know if we could say it inevitably will lead to that, but we do know that

there is some possibility that that could be the case, because these are substances that have not yet been examined yet, and so there is the case that, within class scheduling, which is necessary to ensure public safety because these are dangerous substances, there may be one that gets scooped up that is ultimately not harmful.

So the question is, what do we do about that?

Ms. Schakowsky. Right.

Mr. Chester. And what we have done is two things.

The first one is to allow the colleagues that are at the table with me here today to have an unprecedented level of access to these substances, even though they are in Schedule I, to have a streamlined process so that they can do the testing on them and they can determine where they fall within the scheduling regime and if they are, in fact, harmful or not.

In the case that something is scooped up and an individual is convicted of that and it subsequently is determined that the substance should be moved, either unscheduled or scheduled down, then there are provisions in this to ensure that individuals are not unduly harmed by that from a criminal justice perspective.

And so, when we talk about this being a comprehensive approach and being balanced, those are the elements that we use in order to make sure that we don't do undue harm in our desire to protect the American people.

But I can turn it over to Dr. Volkow.

Ms. Schakowsky. Before she does, so you are saying that those provisions are already in there, that they are locked into the provisions?

Mr. Chester. The researcher access, yes. Yes, ma'am, absolutely.

Ms. Schakowsky. Yes. Well, let's go to Mr. Milione.

Mr. Milione. Thank you for the question.

Look, we believe that the administration's proposal will allow us to protect the public and keep them safe from these deadly drugs.

The challenge, the balance, as Mr. Chester managed, there are proposals in here that will streamline access to research. We have worked with the interagency. We are committed to working with them to streamline where we can, consistent with the CSA. But we have to balance that against these deadly substances that are killing so many every day in our communities.

Ms. Schakowsky. Well, thank you. That is really all I had.

But I just want to say we have lived through this, the war on drugs. Obviously we want to protect the public. What we don't want to do is to set up a process that is going to end up with incarcerating people who really shouldn't be.

And I hope that this process of making sure that the drugs that are classified or misclassified don't end up incarcerating people that shouldn't be.

We have been there. We have done that. It was a really bad mistake. And we want to make sure that there is really vigorous oversight, investigation, and that it be timely, that we don't have to go unlock jail doors of people that have been misclassified.

So I will be watching for that, because we don't want to repeat the mistakes of the past.

Thank you very much, Mr. Milione, and your answers.

Ms. Eshoo. Gentlewoman yields back.

The chair is more than pleased to recognize the gentleman -- and that, he is -- from West Virginia, Mr. McKinley, for your 5 minutes of questions.

Mr. McKinley. Thank you, Madam Chairman, for letting me waive on, and thank you for the patience of your panel that have been going on for hours here today.

My question. Unfortunately, during this COVID pandemic the Nation, I think, has

overlooked the opioid crisis. We took our eye off the ball, as we have heard testimony all day how overdoses have skyrocketed by 30 percent. We have experienced such deadly numbers in West Virginia. We are the epicenter of that.

No other industrialized nations have a drug crisis like we have in America. Our death rates from overdoses are 50 times higher than Japan, 33 times higher than Europe, and 5 times higher than the U.K.

A hundred thousand people lost their lives last year. Husbands have lost their wives. Wives have lost their husbands. Parents have lost their children. We could go on and on with this.

So I want to make sure I understand this. Let me get this straight. The Biden administration's policy to combat this overdose epidemic is to shorten sentences for fentanyl traffickers? Seriously? This is your answer?

Come on, man. We can do better than this. Our communities in States like West Virginia and New Hampshire and Delaware are expecting something far better than that kind of response.

So, Dr. Volkow, you have probably more experience in the treatment aspect of this disease, so I would like -- I have heard from other doctors -- I am an engineer, not a doctor -- I have heard from other doctors that have said that the methadone, having methadone clinics, could be a real key to the reduction of overdose deaths. Would you agree?

I am sorry. I can't hear you very well.

Dr. Volkow. Methadone clinics are clearly part of the solution, and the solution is to expand --

Mr. McKinley. So I want to build off that. West Virginia has the highest death rate in the Nation, unfortunately, and, unfortunately, we only have, our ratio is about one

methadone clinic per 200,000 people. New Hampshire used to be number two in the Nation in overdose deaths, but they have concentrated on methadone clinics and increased their ratio to one per 100,000, twice the situation we have in West Virginia. And in response, they lowered their numbers.

But here is the catch, Doctor. Delaware is now the number two in the country, but they have one methadone clinic per 60,000 people, three times a higher ratio than we have in West Virginia. So the numbers just don't add up to me.

Could you reconcile why Delaware has emerged as number two, but yet they have three times the number of methadone clinics as part of the solution? Can you give me some idea how to reconcile that?

Dr. Volkow. Well, there are multiple factors that are driving higher numbers in one State versus the other. And I was 3 weeks ago in West Virginia, Morgantown, and I was visiting some of the treatment programs.

So we have to recognize that it is not just about methadone clinics, which are very valuable, but also at the expanded use of buprenorphine and the increased utilization of healthcare systems to be able to treat.

Mr. McKinley. But the people in New Hampshire said that is -- they credit that for driving it from -- they had one in 200,000, like West Virginia, but now they have markedly increased the number of clinics, and they have seen their number drop, they are no longer number two. So they are looking for it. Are you saying they are wrong?

Dr. Volkow. No, I am not saying they are wrong. I am saying that there is actually -- methadone clinics will help. They are not the only treatment available. And, if we use healthcare systems to deliver buprenorphine, we massively expand.

Think about New Hampshire. It is a rural area. West Virginia, a lot of rural areas. There is no transportation. There are no methadone clinics, no way to get

there and get treated with buprenorphine.

Mr. McKinley. So given the time, and I only have 15 seconds, 14 seconds, what would you suggest is, if we could do in States that are hard hit, what would be the first thing you think would be the best thing that a State like ours could do?

Dr. Volkow. Expand all types of treatment, no barriers. Expand all types of treatments for opioid use disorder.

Mr. McKinley. Thank you very much. I yield back.

Mr. Cardenas. [Presiding.] Hello. This is Congressman Cardenas.

As the chairwoman has left the dais, I remotely will be chairing the committee.

It appears that we do not [inaudible] list of documents for the record. I would like to ask my Republican colleagues to waive the reading of the list to enter them into the record.

Mr. Guthrie. Are you yielding to me? This is Ranking Member Guthrie.

Mr. Cardenas. Yes.

Mr. Guthrie. I couldn't quite follow because you broke up here.

Mr. Cardenas. Oh, I am sorry.

Mr. Guthrie. But I would like to enter a video of parents telling their story for the record. It can be found at stop the V-O-I-D, "Dead on Arrival," stoptheVOID.org. So I would like to introduce that to the record. I think the majority has been made aware.

Mr. Cardenas. That will be introduced for the record, yes.

[The information follows:]

******** COMMITTEE INSERT ********

Mr. Cardenas. Can you hear me, Mr. Guthrie? Mr. Guthrie, can you hear me?

Mr. Guthrie. Yes, I can hear you now. I can hear you now. You are breaking up a little bit, but I can hear you.

Mr. Cardenas. Pertaining to the list of other documents that like to be entered into the record by our colleague, are you willing to approve the reading of the list -- waive approving the -- waive the reading of the list?

Mr. Guthrie. I will approve waiving of the reading. Yeah, I have no objections. We will approve waiving. I have no objections.

Mr. Cardenas. Okay. Thank you so much.

Therefore, the record will reflect the documents that have been entered into the record.

[The information follows:]

******** COMMITTEE INSERT ********

Mr. Cardenas. Thank you very much for your cooperation, Ranking Member Guthrie.

With that, being no other responsibilities and duties of the committee at the moment, then this committee is now adjourned. So ordered.

[Whereupon, at 3:15 p.m., the subcommittee was adjourned.]