

FENTANYL ANALOGUES: PRESPECTIVES ON CLASSWIDE SCHEDULING

HEARING BEFORE THE SUBCOMMITTEE ON CRIME, TERRORISM, AND HOMELAND SECURITY OF THE COMMITTEE ON THE JUDICIARY HOUSE OF REPRESENTATIVES ONE HUNDRED SIXTEENTH CONGRESS SECOND SESSION

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FENTANYL ANALOGUES: PERSPECTIVES ON CLASSWIDE SCHEDULING

Tuesday, January 28, 2020

HOUSE OF REPRESENTATIVES

COMMITTEE ON THE JUDICIARY

Washington, DC

The Subcommittee met, pursuant to call, at 10:07 a.m., in Room 2141, Rayburn Office Building, Hon. Karen Bass [Chairman of the Subcommittee] presiding.

Present: Representatives Bass, Jackson Lee, McBath, Cicilline, Dean, Mucarsel-Powell, Ratcliffe, Sensenbrenner, Chabot, Gohmert, Lesko, Reschenthaler, Cline, and Steube.

Staff present: John Doty, Senior Advisor; Madeline Strasser, Chief Clerk; Moh Sharma, Member Services and Outreach Advisor; Anthony Valdez, Professional Staff Member; John Williams, Parliamentarian; Ben Hernandez-Stern, Counsel, Crime, Terrorism, and Homeland Security Subcommittee; Joe Graupensperger, Chief Counsel, Crime, Terrorism, and Homeland Security Subcommittee; Milagros Cisneros, Detailee, Crime, Terrorism, and Homeland Security Subcommittee; Ebise Bayisa, Counsel, Crime, Terrorism, and Homeland Security Subcommittee; Veronica Eligan, Legislative Aide/Professional Staff Member, Crime, Terrorism, and Homeland Security Subcommittee; Jason Cervenak, Minority Counsel; and Andrea Woodard, Minority Professional Staff.

Ms. BASS. [Presiding.] Good morning. The Subcommittee will come to order.

Without objection, the chair is authorized to declare recesses of the Subcommittee at any time.

We welcome everyone to this morning's oversight hearing entitled "Fentanyl Analogues: Perspectives on Classwide Scheduling." I want to take the opportunity at the outset to express my condolences to Mr. Holman for the tragic death of his son. As someone who knows that particular type of pain, I give you, my condolences. Your presence here is a stark reminder that we do indeed need to find a way to stem the tide of drug addiction and deaths by opioid overdose. We also must do it in a responsible way, and that is based on scientific analysis and proper public health responses. As Members of the Judiciary, we also have a responsibility to ensure that we protect people from dangerous drugs, like fentanyl, but don't put systems in place that perpetuate incarceration.

Our country faces an opioid crisis, including incidences of overdoses involving fentanyl and fentanyl analogues. By some measures, more than 40 percent of heroin-related deaths in recent years involve some level of fentanyl. In 2017, a drug overdose crisis tragically claimed the lives of over 70,000 of our fellow Americans. Many died from overdoses. In a disturbing trend, illicit drug manufacturers, particularly in places like China, have found ways to change the composition of fentanyl-related substances to avoid or postpone the control and prosecution of these substances in the United States. Because of these dangers, 2 years ago, the DEA placed fentanyl analogues temporarily on Schedule 1 of the Controlled Substances Act, an administrative action that will expire February 6th.

Schedule 1 controlled substances are substances that have no currently medically-accepted use and a high potential for abuse. Because of this and the risk of diversion, research is significantly restricted when a drug is on Schedule 1. Research licenses from DEA are difficult to obtain and maintain. Now that we are approaching the deadline, there is a concern from many that banning the entire class of fentanyl-related substances, especially on a permanent basis, could, in fact, significantly restrict important and valuable research into substances that could, in fact, be beneficial, such as overdose antidotes and treatments for opioid addiction. We want to make sure that our response does not undermine the indispensable role of our public health agencies.

The Department of Health and Human Services is critical in promoting treatment responses and medically and scientifically assessing drugs, including those like fentanyl analogues that are on Schedule 1. Because some substances that are chemically similar to fentanyl could be found to be medically helpful, we have to think about the medical and scientific research of fentanyl analogues. This research, which is necessary for the development of new treatments and antidotes for overdoses, must continue. So, including a class-wide placement of such analogues into Schedule 1 of the Controlled Substances Act could lead to research delays and could be a disincentive to engage in this research in the first place.

We also have to make sure that it doesn't cut into the Department of Health and Human Services processes that determines whether or not drugs placed on Schedule 1 are, in fact, harmful. HHS' critical role of analyzing drugs and making evidence-based recommendations helps ensure the integrity of the scheduling process and helps anchor policy decisions in scientific analysis.

I am, of course, very concerned about the need to provide law enforcement with tools to battle this serious issue in our communities, but I also have a concern of a complete criminal justice response to the crisis. I am concerned that addiction is a health issue, and rather than relying solely on incarceration, we need to also focus significantly on treatment. Under current Federal sentencing guidelines, many defendants who are not high-level traffickers may be unnecessarily subjected to mandatory minimums that, in fact, become life sentences. I want to make sure that we don't repeat what we have done in past epidemics, which is the overcriminalization of an addiction, and making sure that we put adequate resources into prevention, intervention, and treatment.

So, our approach to this issue, I also believe, should reflect the growing bipartisan recognition that we must do some reforms, such as those in the First Step Act, which included modest reforms to begin addressing the crisis of incarceration. I also want to make sure that we don't expand the scope of mandatory minimum sentences. We must consider the appropriate use of other mechanisms that give the Justice Department the ability to hold traffickers of analogues responsible without using the temporarily scheduling authority. For instance, we should discuss the appropriate use of the Analogue Act, the mechanism already provided in the law that allows the Justice Department to prosecute the trafficking in analogues without use of overbroad class-wide scheduling.

I am encouraged by recent reports that China has been cracking down on its manufacturers of illicit fentanyl and fentanyl-related substances, and I am hopeful that these efforts will curb the supply of these substances, but we need to also address the problem here in the United States. The temporary extension of the DEA order concerning fentanyl analogues and the more permanent solutions that have been proposed require careful consideration. Today we have the opportunity to discuss these issues with government representatives and subject matter experts so that we may consider how we should proceed informing a long-term strategy to stem the tide of this public health episode.

I now yield to the Ranking Member of the subcommittee.

Mr. RATCLIFFE. I thank the chair, and I ask unanimous consent to submit the statement of the Ranking Member of the full committee, Mr. Collins, into the record.

Ms. BASS. Without objection.

[The information follows:]

DOUG COLLINS FOR THE RECORD

STATEMENT DOUG COLLINS

Good morning.

Nine days.

Nine days are all that remain until the Drug Enforcement Administration's (DEA) 2018 order making all fentanyl-related drugs illegal in the United States expires.

What does that mean?

It means that all drugs seized by U.S. investigators over the past two years that have tested positive as illicit fentanyl analogues will no longer be illegal.

Yes, you heard that correctly. It means that these substances that are killing people in communities across the country will no longer be illegal.

Illicit fentanyl and other synthetic opioids are now the most lethal category of opioids used in this country. In my home State of Georgia, between February 2017 and May 2017, the Georgia Bureau of Investigation had received 50 overdose cases involving "gray death." "Gray death" is a drug cocktail described as a mixture of illicit opioids with the appearance of concrete.

When DEA's temporary order expires, fentanyl analogues will undoubtedly flood our streets. No doubt, drug dealers and traffickers are counting down the few days we have left with much anticipation.

How did we get here? Why are we here at the eleventh hour?

It is our job in Congress to ensure that the DEA has the tools to protect our communities from these deadly drugs. Last month, during negotiations of the spending bill, we had the opportunity to extend the temporary scheduling order. That provision would give Congress time to continue negotiating a way to permanently schedule these dangerous substances. The chairman and Ranking Member of the Senate Judiciary Committee supported that provision. In fact, it was bipartisan in the Senate. I supported that provision. However, Chairman of this Committee objected, and it was not included in the final bill.

Less than two weeks ago, the Senate unanimously passed a bill extending DEA's temporary scheduling order of fentanyl analogues. The bill now sits here in the House awaiting action. What will the Speaker and Chairman of this Committee do now? I pray they do the right thing: Immediately pass this bill and send it to the President's desk. Those peddling these deadly drugs are hoping we don't Act at all. So far, they've gotten their wish, because House Democrats have failed to take this obviously necessary step.

The most absurd irony in this entire ordeal is that China has permanently outlawed all fentanyl-related substances. If we allow DEA's temporary scheduling order to expire, we will be behind China in dealing with fentanyl analogues. They will flood our streets.

Mr. Chairman, I plead with you to expeditiously allow the Senate bill to move to the floor. It really is a matter of life or death and time is extremely short.

While I look forward to today's hearing and listening to our witnesses, particularly Mr. Holman, I would be remiss if I didn't point out that both the DEA and the Office of National Drug Control Policy (ONDCP) are absent. As I understand it, ONDCP very much wanted to be here today, but our majority did not invite them. It is puzzling why our majority would not want to hear from the office that works to reduce drug use and its consequences by leading and coordinating the development, implementation, and assessment of U.S. drug policy. Like many things we've seen as of late, something tells me it simply comes down to politics.

This is an issue where we must rise above political tribalism. It is far too important to too many Americans to let politics get in the way of finding solutions to combat this plague. Our constituents deserve no less.

Mr. RATCLIFFE. I thank Dr. Giroir and Ms. Liskamm, our witnesses, for being here today. During the rise of the opioid crisis, amidst the many lives lost in its wake, law enforcement found that the challenge to cracking down on the supply of synthetic opioids like fentanyl analogues was that drug traffickers could sell a slightly-changed substance that did not fall under the existing schedule of the Controlled Substances Act. In February of 2018, the Drug Enforcement Administration under President Trump's watch used its authority to ban all fentanyl substances by placing them into Schedule 1 of the Controlled Substances Act. By that decision, criminals would now face the consequences of the destruction they have left throughout our country.

However, under existing law, the Drug Enforcement Administration is only allowed to use its emergency regulatory powers to ban all fentanyl substances for 2 years. After that, it could be extended for, at most, 1 year after consultation with the Department of Health and Human Services. You would think that the least this Congress could do is to extend the scheduling of fentanyl under the Controlled Substances Act indefinitely.

A proposed bill, the Stopping Overdoses of Fentanyl Analogues Act, is supported by attorneys general in all 50 States. This isn't a conservative issue. It is not a liberal issue. It is not a rural issue or an urban issue. If the attorney general of Texas and the attorney general of California can find common ground on this issue, the very least we could do is Act on this issue. Instead, we are racing toward an expiration on the ban on fentanyl analogues simply because Congress is unwilling to act. This is entirely preventable.

Congress had a chance during the last year's appropriations debate to include a measure empowering the DEA to keep the ban on fentanyl and fentanyl-related substances indefinitely. It failed. According to a Washington Post editorial, it appears that the reluctance with giving the DEA this essential authority may be due to the concerns of some in Congress about sentencing guidelines. I think the reason we haven't heard any public opposition from Members about this is that, quite frankly, it is hard to publicly stand up and oppose extending the scheduling of fentanyl analogues. It is crazy to think that the reason we are in this position is that some in Congress are concerned that convicted drug traffickers would spend a little extra time in jail. A concern about the amount of time drug traffickers spend behind bars is a difficult explanation to give to the families of people who have died from drug overdoses, but here we are. Next week, the scheduling of fentanyl analogues expires.

I urge my colleagues to put partisan politics aside and put the needs of our constituents and the American people first. Some may think that a public health approach is the best way to solve the opioid crisis. Some think that providing law enforcement with the tools to hold suppliers and traffickers accountable is the best way to solve this issue. But doing nothing, waiting until 1 week before the deadline to do something, is not the answer. The failure to Act is a disservice to our communities. It is a disservice to our constituents. It is a disservice to the families of the victims who have lost their lives. I yield back.

Ms. BASS. We welcome our witnesses and thank them for participating in today's hearing. Now if you would rise, I will begin by swearing you in. Raise your right hand.

Do you swear or affirm under penalty of perjury that the testimony you are about to give is true and correct to the best of your knowledge, information, and belief, so help you God?

[A chorus of ayes.]

Ms. BASS. Let the record show the witnesses answered in the affirmative. Thank you, and you can please be seated. We will proceed with witness introductions, starting with the first panel. Admiral Brent Giroir—is that right?

Admiral GIROIR. Yes, ma'am.

Ms. BASS. —serves as assistant secretary for health at the U.S. Department of Health and Human Services. As the assistant secretary for health, he leads the development of HHS-wide public health policy recommendations and oversees several of the Department's core public health offices, and leads many critical national initiatives, including a historic new plan to end the HIV epidemic in America and the physical activity guidelines for Americans. He is also responsible for coordinating HHS' efforts across the agency to fight the opioid crisis.

Amanda Liskamm is the director of opioid enforcement and prevention efforts in the Office of the Deputy Attorney General at the Department of Justice. As director, she is responsible for assisting the Attorney General, deputy attorney general, and Department components in formulating and implementing Department initiatives, policies, grants, and programs relating to opioids, and coordinating these efforts with law enforcement. Previously, she served as deputy chief of litigation in the Narcotic and Dangerous Drug section in the Department Criminal Division.

We will now start with the first panel. Please note that each of your written statements will be entered into the record in its entirety, and, accordingly, I ask that you summarize your testimony in 5 minutes. To help you stay within that time, there is a timing light on your table. When the light switches from green to yellow, you have 1 minute to conclude your testimony. When the light turns red, it signals your 5 minutes have expired.

Admiral, you may begin.

TESTIMONY OF ADMIRAL GIROIR

Admiral GIROIR. Chair Bass and Ranking Member Ratcliffe, thank you for the opportunity to speak with you today about the opioid overdose epidemic, and, specifically, the role of fentanyl and fentanyl analogues in fueling that epidemic. As you said, I'm the assistant secretary for health in the Department of Health and Human Services and also the senior adviser to the Secretary for opioid policy.

Between 1999 and 2018, over 770,000 people died of drug overdoses in our country, the majority of which were caused by opioids. Although 2018 witnessed the first decrease in overdose deaths in nearly 2 decades, still over 68,000 Americans died of drug overdoses, and over 47,000 of these were caused by opioids. In the first waves of the crisis, opioid deaths were predominantly caused by misuse of prescription opioids, heroin, or both. In 2016, the pre-

dominant cause of opioid deaths became synthetic opioids, including fentanyl and chemical analogues of fentanyl, illegally manufactured, and transported into our country either through international mail or smuggled across the border. Unfortunately, deaths caused by fentanyl and analogues are still increasing at approximately 10 percent annually.

A significant factor that complicates enforcement against illicit fentanyl and analogues is that there are several thousand potent opioids that can be derived by chemical manipulation of the basic fentanyl structure. These are called analogues or derivatives. While some of have been identified and undergone the formal process of scheduling as controlled substances, the power of modern chemistry had led to a deadly game of whack-a-mole, such that when an analogue is identified and undergoes the process of scheduling, clandestine manufacturers are able to synthesize different, equally deadly molecules that evade enforcement and at a much faster rate than they can be identified and undergo the rigorous process of scheduling. For this reason, HHS supports the permanent scheduling of fentanyl analogues as a class, but we also need protections and facilitation of critical research on these and other classes of molecules.

Why research protections? Because certain analogues of fentanyl that would be scheduled in the class could potentially have profoundly important uses as new medicines, and we cannot put barriers on innovation, research, and development when tens of thousands of Americans die each year and nearly 2 million struggle with opioid addiction.

So, what are some specific examples of potential medical applications? Naloxone has saved tens of thousands of lives, but many of the new synthetic opioids overpower naloxone, causing patients to fall back into life-threatening overdose symptoms within 1 hour after Administration. We need a much better version of naloxone, and that version may reside in the class of molecules we would schedule. *Another example:* The NIH is leading exciting and potentially transformational research using monoclonal antibodies that can effectively reverse even the most potent analogues and last for a month, not 30 minutes. How could scientists even test this innovative medicine against fentanyl analogues if they don't have ready access to these analogues for research?

Another example: Medication-assisted treatment, or MAT, works substantially better than treatment without MAT, but still at least 40 percent of patients have a relapse into their opioid use disorder within 6 months. An improved MAT drug might have a chemical structure included in the proposed scheduling. Finally, if we don't have protections that enable access to these analogues, we cannot develop clinical diagnostic tests to determine what analogue caused an overdose. In short, we might not even know what is killing us.

Currently, obtaining or modifying a Schedule 1 research registration involves significant administrative challenges that not only delay research, but deter many of the young and brightest scientists from entering the field, exactly the opposite of what America needs. These challenges impede critical research on Schedule 1 substances and deter or prevent scientists from pursuing their work. The good news is that HHS has worked closely with our col-

leagues at ONDCP and the Department of Justice and DEA on a plan that both supports the scheduling of the entire class of fentanyl analogues, while allowing de-scheduling or reducing the scheduled class based on scientific evidence, and several provisions to streamline research on Schedule 1 molecules. Details of the research issues are indicated in my written testimony, and I would be pleased to provide details in today's question period.

Thank you again for the opportunity to testify today on this critically important public health topic.

[The statement of Admiral Giroir follows:]

STATEMENT OF ADMIRAL BRETT P. GIROIR

Chair Bass and Ranking Member Ratcliffe, thank you for the opportunity to participate in this hearing. I am the Assistant Secretary for Health at the Department of Health and Human Services (HHS), as well as the Senior Advisor to the Secretary for Opioid Policy. I appreciate the opportunity to speak with you today about the opioid overdose epidemic, and specifically the role of fentanyl and fentanyl analogues.

America's Overdose Epidemic

America's drug overdose epidemic is the most daunting public health challenge of our time. Between 1999 and 2018, over 770,000 people died of drug overdoses in our country, the majority of which were opioid-related.¹ Although in 2018, we witnessed the first decrease in overdose deaths in over two decades, still, more than 68,500 mothers, fathers, sons, daughters, friends and colleagues died of drug overdoses, more than 47,600 of which were caused by opioids.²

In the first waves of this crisis, opioid deaths were caused predominantly by misuse of prescription opioids, heroin, or both. But in 2016, the predominant cause of opioid deaths became "synthetic opioids," including illicit fentanyl and derivatives of fentanyl known as fentanyl analogues, illegally manufactured, and transported into our country, either through international mail, express consignment facilities, or smuggling across the border.

The Food and Drug Administration (FDA)—approved, pharmaceutically manufactured molecule known as fentanyl is an extremely powerful opioid, and when I was engaged in clinical practice as a physician, I used it safely and effectively nearly every day on children undergoing surgery, or in severe pain in my intensive care unit.

Because of its potency and potential for respiratory depression or respiratory arrest, only highly trained specialists were allowed to prescribe and utilize this drug, and only in carefully controlled settings. Contrast that to illicitly manufactured, non-prescription fentanyl and fentanyl analogues, entering our country in the thousands of pounds, with some shipment having the potential to kill millions or tens of millions of Americans, which drives the bulk of the opioid overdose crisis today.

Our most recent data unfortunately demonstrates that deaths caused by illicit fentanyl and chemical analogues of fentanyl are still increasing at about 10 percent, year over year, and threaten the overall progress we have made against prescription opioids and heroin.³ We are seeing new and highly dangerous patterns of use, including polysubstance use of both methamphetamine and fentanyl or fentanyl analogues—particularly dangerous and potentially deadly combination.

With the leadership of President Trump and Congress, HHS has implemented unprecedented and effective efforts to combat this crisis, including encouraging appropriate prescribing practices that have reduced the total amount of opioids prescribed

¹Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999–2017 on CDC WONDER Online Database, released December 2018. Data are from the Multiple Cause of Death Files, 1999–2017, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program.

²Ahmad FB, Escobedo LA, Rossen LM, Spencer MR, Warner M, Sutton P. Provisional drug overdose death counts. National Center for Health Statistics, 2020.

³Ahmad FB, Escobedo LA, Rossen LM, Spencer MR, Warner M, Sutton P. Provisional drug overdose death counts. National Center for Health Statistics, 2020.

by more than 32 percent since January 2017;⁴ a greater than 400 percent increase in naloxone prescriptions,⁴ in addition to more than double that amount directly distributed to first responders and community organizations; an estimated 1.28 million people receiving medication-assisted treatment, also known as MAT;⁵ and investing billions of dollars in enhanced data and basic, translational, and clinical research.

The Challenge of Fentanyl Analogues

In addition to these public health measures implemented by HHS and other sectors in our nation, we must prevent these dangerous drugs from coming into our country, through the mail, express consignment carriers, or across our borders.

A significant factor that complicates enforcement against illicit fentanyl and related compounds is that there are a myriad—thousands and perhaps tens of thousands—of potent opioids that can be created by chemical manipulation of the basic fentanyl structure. These are called analogues. While some have been identified and undergone the formal process for scheduling as controlled substances, under the Controlled Substances Act (CSA), the power of chemistry has led to a deadly game of “whack a mole” such that when an analog is identified and undergoes the process of scheduling, clandestine manufacturers are able to synthesize a different, potentially even more deadly chemical that evades enforcement, and at a much faster rate than the chemical can be identified and undergo the rigorous process of scheduling.

For this reason, HHS supports the permanent scheduling of these fentanyl analogs as a class, but with critical protections and facilitation of potentially vital research on this and other classes of molecules.

The Process of Scheduling Controlled Substances

HHS plays an important role in scheduling-controlled substances. For a substance to be permanently scheduled under the CSA, the FDA conducts a scientific and medical evaluation, also known as an “eight factor analysis,” on the specific drug (molecule). Following consultation with the National Institute on Drug Abuse, FDA makes a recommendation to the Assistant Secretary for Health (ASH) on the appropriate level of permanent controls for a substance with the potential to be abused. The ASH, who has the delegated authority from the HHS Secretary for matters related to scheduling, then conveys the HHS recommendation to the Drug Enforcement Administration (DEA) for action.

The CSA also allows the DEA to place certain substances not already scheduled, and not subject to an approved or investigational new drug application, into schedule I on a temporary basis to address an imminent hazard to the public health. Under these circumstances, HHS receives notice from the Attorney General (through DEA) of the proposed action. FDA then reviews the records of drugs approved or being investigated for therapeutic use, communicates the findings to the ASH, and the ASH conveys to DEA whether or not HHS has any objection to the proposed temporary order to place the substance in schedule I.

In this regard, on November 6, 2017, the DEA Acting Administrator notified the HHS Acting Assistant Secretary for Health, of the DEA’s intent to publish in the **Federal Register** a Notice of Intent to issue a temporary order adding all fentanyl-related substances (*a.k.a.*, fentanyl analogues) to schedule I of the CSA. The Acting ASH responded on November 29, 2017, that according to FDA, there did not at that time appear to be any approved new drug applications or active investigational new drug applications for these fentanyl-related substances and that HHS did not object to the temporary placement of these substances in Schedule I of the CSA. DEA subsequently issued the temporary order on February 6, 2018. HHS was not asked for, and did not produce, an “eight-factor analysis,” on fentanyl-related substances as a class. Such an evaluation for permanent scheduling of a class of substances, rather than specific substances, would be a significant change from the normal process of scheduling, and might not be feasible for the FDA to develop.

The Need to Advance Research

As the leading cause of overdose deaths in our nation, and in many nations around the world, fentanyl and fentanyl analogues are our highest priority to keep

⁴IQVIA National Prescription Audit. Retrieved November 2019. *Note:* These data are for the retail and mail service channels only and do not include the long-term care channel.

⁵IQVIA National Prescription Audit; SAMHSA Opioid Treatment Program Self-Report; N-SSATS.

off our streets. The chemical structures and pharmacological activity targeted by illicit opioid manufacturers overlap not only with illicit, and potentially dangerous, schedule I substances, but also with many molecules that may be shown by future research to have a potential for legitimate therapeutic uses. Research with fentanyl-related substances and other synthetic opioids is important in the development of new and improved treatments for opioid addiction and overdose, chronic pain, and other neurologic and psychiatric conditions, as well as to understand the effects these substances have on human health. That is why we must ensure access to these substances for legitimate research to develop new therapies and improve scientific understanding of their effects on human health.

Currently, obtaining or modifying a schedule I (and, in some cases, a schedule II–V) research registration involves significant administrative challenges. Under the law, scientists who wish to conduct research on schedule I substances, including fentanyl-related substances pursuant to the temporary scheduling order issued by the DEA, must hold a schedule I research registration. Obtaining a schedule I research registration is a multistep process that involves review and approval of a scientist’s research protocol by multiple regulatory or review bodies, including the DEA, FDA, institutional review boards (for research with humans), and institutional animal care and use committees (for research with animals). The DEA conducts background checks on individuals who would be granted access to the substances for which a registration is sought and may perform site inspections to ensure that appropriate security safeguards are in place to mitigate against diversion. In addition to obtaining a federal schedule I registration, researchers may be required to obtain a separate registration from their State licensing authority before their federal application can be processed.

Researchers have reported that obtaining a new registration can take more than a year. Adding new substances to an existing registration can also be time-consuming. These challenges can impede critical research on schedule I substances and deter or prevent scientists from pursuing such work. HHS has worked closely with our colleagues at the Office of National Drug Control Policy (ONDCP), the Department of Justice (DOJ), and DEA on the following proposals to mitigate potential negative impacts on research or development of therapeutics, including those mentioned above.

Working together this summer, we reached an interagency solution that balances the need to control these substances as a class, with the researcher access necessary to study these substances. We submitted the results of our work to House and Senate Committee staff in early September.

1. Allow HHS to identify a substance with no potential for abuse, based on consideration of certain of the eight factors, and require DOJ to remove the substance from schedule I within 90 days. Additionally, allow HHS to identify a substance with a low potential for abuse, based on consideration of the same factors, and allow DOJ 180 days to decide whether to remove the substance from scheduling for research purposes only.
2. Allow individuals conducting research with a substance subsequently placed into schedule I who hold a registration to conduct research with any other schedule I or schedule II substance to continue work on the newly scheduled substance until their new or amended registration application is approved or denied. These individuals will have to submit their new or amended registration application within 30 days of the substance being added to schedule I.
3. Clarify that individuals who are agents or employees of the person holding the research registration are not required to have a separate registration.
4. Allow registered researchers to store, administer, and otherwise work with any substances for which they hold a researcher registration at multiple practice sites, on a single contiguous campus so long as the registrant notifies the Attorney General prior to conducting research at those sites.
5. Allow a researcher who is registered to do research with a controlled substance, and who needs to perform limited manufacturing activities on small quantities of that substance consistent with their research protocol (for example, creating a particular dosage formulation for research purposes), to do so without having to obtain a separate manufacturing registration.
6. Require the Attorney General and the HHS Secretary to conduct a review of the process for obtaining or modifying a research registration under the CSA to identify redundancies, inefficiencies, or burdens on persons seeking registrations that can be reduced while ensuring public safety, and subsequently require the Attorney General and the HHS Secretary to issue joint guidance clarifying the registration process.

7. Clarify that if a person is registered to conduct research with a controlled substance and applies to conduct research with a second controlled substance that is in the same schedule or in a schedule with a higher numerical designation, an inspection that was performed for purposes of the existing registration shall be sufficient to support the application.

Thank you for the opportunity to testify today on this important topic. I am happy to answer any questions you have.

Ms. BASS. Ms. Liskamm?

TESTIMONY OF AMANDA LISKAMM

Ms. LISKAMM. Chairwoman Bass, Ranking Member Ratcliffe, and Members of the committee, thank you for the opportunity to discuss the Department of Justice's work to combat the opioid episode, the challenges our prosecutors face, and the expiration of DEA's Emergency Temporary Scheduling Order of Fentanyl-Like Substances. As discussed before, I am the Department's director of opioid enforcement and prevention efforts. I have over 13 years of experience as a drug prosecutor, working both as an assistant United States attorney and as the deputy chief in the Criminal section of the Department, where I have prosecuted the most dangerous drug traffickers and cartels. I know drug traffickers, and I know the deadly lengths that they will go to make money.

As our Nation faces unprecedented overdoses and deaths caused by opioids, the Department is responding with every tool available. My position in the Deputy Attorney General's Office was created to focus entirely on this issue, to implement the Department's initiatives and policies relating to opioids and coordinate the efforts of our many components. Over the years, the demand for illicit opioids became more pervasive following years of over-prescription of legal medications. Yet while the Department and the Nation have seen usage of controlled prescription drugs decrease, the number of overdose deaths in the United States has reached record levels. One of the chief causes is the proliferation of fentanyl and, relevant for today's hearing, of illicitly produced potent substances structurally related to fentanyl.

Traffickers of these fentanyl-like substances specifically engineer them to skirt a coverage gap in U.S. drug control laws, and, oftentimes, the first time we would learn of these new fentanyl-like substances was through a sudden rash of overdose deaths in our communities. This unprecedented threat called for unprecedented measures, and in February of 2018, DEA responded by scheduling the entire class of fentanyl-like substances on a temporary emergency basis.

Since DEA's scheduling action, this gap has been filled. In response to the class-wide scheduling order, we've seen a significant decrease in encounters of fentanyl-like substances and a reduced production of these substances by traffickers. DEA's emergency temporary scheduling action controlling all fentanyl-like substances will expire on February 6th, 2020 absent further action by Congress to make it permanent. That's in just 9 days. If that gap in U.S. law controlling fentanyl-like substances reemerges, the Department and DEA fully expect drug traffickers to fill it and take the United States back to the even more deadly phases of this epidemic.

I can personally tell you how savvy these drug traffickers are. When there's a gap in U.S. law, they take full advantage of it, which results in more drugs and more deaths. We've seen Chinese criminal organizations, Mexican cartels, and other traffickers push illicit fentanyl for its profitability and its potency. Permanent class-wide scheduling is the necessary step to counter these criminal organizations. From a legal perspective, class-wide scheduling alleviates DEA's cat-and-mouse game of emergency scheduling newly encountered fentanyl analogues substance by substance, and gives law enforcement and prosecutors like me an efficient tool to bring these traffickers to justice.

With DEA's temporary order, the United States became an international leader in addressing the emergence of fentanyl-like substances. The U.S. has engaged with many countries who are likewise facing these public safety challenges. Prompted in part by the urging of the United States, China announced the class-wide scheduling of fentanyl-like substances on May 1st of 2019, a significant step to alleviate the production in China and the influx of these poisonous substances in our communities. We must Act and make DEA's order permanent to ensure the United States is doing as much as China in responding to our own Nation's opioid epidemic.

To close, I want to reiterate the importance of this issue to the Department and to me. As a prosecutor, I can tell you that a legislative solution for class-wide scheduling of fentanyl analogues is necessary. We are running out of time, and if a solution isn't found, prosecutors will undoubtedly be hindered, and drug traffickers will undoubtedly be helped. There are many proposed solutions to counter the threat from fentanyl being debated, but permanent class-wide scheduling is a necessary step. We cannot afford to take a step backwards in our fight against fentanyl and other synthetic opioids. We are at a crossroads, and in just 9 days, we have a choice to make with dealing with this public health crisis. We can revert to the reactive phase that we dealt with each substance on a substance-by-substance basis only after a rash of deaths in our communities, or we can continue the class-wide scheduling which has proven effective and is working in keeping this deadly poison out of communities.

Thank you for the committee's interest and attention to this important issue, and I look forward to answering your questions.

[The statement of Ms. Liskamm follows:]

STATEMENT OF THE AMANDA LISKAMM

Chairwoman Bass, Ranking Member Ratcliffe, and Members of the Committee: Thank you for the opportunity to discuss the dangers posed by illicit fentanyl and its analogues, and the challenges the Department of Justice (Department) faces when holding traffickers accountable. The Department appreciates the Committee's interest in this important topic.

It is well-known that overdose deaths in the United States have been on the rise and have already reached record levels. While the most recent provisional overdose death data published by the Centers for Disease Control and Prevention (CDC) indicate that deaths have plateaued and that we are finally starting to see a slow decrease, deaths from synthetic opioids continue to rise. From 2016 to 2017, 31 states experienced an increase in synthetic opioid overdose deaths, including Arizona, California, Georgia, New York, Ohio, Rhode Island, Tennessee, Texas, Virginia, and Wisconsin.

Although a number of factors appear to be contributing to this public health crisis, one of the chief causes is the proliferation of illicitly produced, potent substances

structurally related to fentanyl, commonly called “fentanyl analogues” or “fentanyl-related substances.” Fentanyl is approximately 100 times more potent than morphine. Because of fentanyl’s low dosage range and potency, one kilogram of fentanyl purchased in China for \$3,000–\$5,000 can generate upwards of \$1.5 million in revenue on the illicit market—and is enough to support 1,000 users for 2 years’ worth of abuse. The lethality of fentanyl is virtually unmatched. It is 30–50 times more potent than heroin, which is quite lethal in its own right. That unmatched lethality is not reflected in sentencing ranges for fentanyl trafficking, which punish dealers of fentanyl and fentanyl-related substances less severely than sellers of less lethal drugs.

However, licit fentanyl is an important treatment agent in the practice of medicine and is utilized for its potent analgesic effects. Because of its potency, careful dosing and titration are essential. Some forms of the drug are indicated for use in people who have high opioid tolerance. Due to their high potential for abuse, fentanyl and various fentanyl-related substances were controlled in Schedule I or Schedule II of the Controlled Substances Act (CSA) on a substance-by-substance basis. Unfortunately, clandestine chemists have with relative ease created new synthetic variations of fentanyl by introducing minor structural modifications, resulting in new, non-controlled fentanyl-related substances. These substances are specifically engineered to skirt U.S. law.

Whether delivered via mail, express consignment, or through Mexico, China is a major source of fentanyl-related substances and other synthetic opioids, producing most illicit fentanyl and fentanyl-related substances that reach U.S. users. The Drug Enforcement Administration (DEA) has worked with, and continues to work closely with, China to bring attention to, and help combat, the rise of illicit fentanyl and fentanyl analogues. Because of this robust engagement, China has made great strides in this space, and, on April 1, 2019, announced the classwide control of fentanyl-related substances effective May 1, 2019.

The Chinese scheduling action, coupled with the DEA’s regulatory authority, enacted on February 6, 2018, which placed all non-scheduled fentanyl-related substances in Schedule I temporarily, on an emergency basis, for two years, has resulted in a significant decrease in *direct* Chinese-origin fentanyl-related substances being encountered in the United States since Fiscal Year 2019.

In addition to China, many countries have experienced their own ongoing public safety challenges caused by the rapid emergence of fentanyl-related substances. The DEA’s temporary actions are the catalyst for communication with a number of international counterparts who are interested in following our example and implementing a similar class-based control for fentanyl related substances. The Department, DEA, and ultimately the United States are leading from the front with our efforts to establish controls on fentanyl-related substances as a class on an emergency basis, and did so, by utilizing authority provided by Congress in the Comprehensive Crime Control Act of 1984. The action is believed to have saved many lives related to the unpredictable nature of fentanyl-related substances by removing an incentive for traffickers to attempt to circumvent the control, and, thus, reducing supply on the illicit market. However, this potentially life-saving temporary scheduling action, absent extension, expires soon. Absent an approach to permanently schedule these dangerous, lethal substances as a class, in just 9 days from today, they will again fall out of our controls. Should the temporary order expire, it will result in significant consequences for our communities.

DEA’S Temporary Emergency Scheduling of Fentanyl-Related Substances

DEA utilizes its regulatory authority to place many synthetic substances into the CSA, pursuant to the aforementioned temporary scheduling authority. As provided by Congress, Factors 4, 5, and 6 of the Eight Factor Analysis are considered for temporary control to make the finding that a substance poses an imminent hazard to public safety. Once a substance is temporarily placed in Schedule I, DEA may move toward permanent control by requesting a scientific and medical evaluation, and a scheduling recommendation, from the Department of Health and Human Services (HHS). DEA and HHS also gather and analyze additional information in order to consider the eight factors for permanent control. Since March 2011, DEA has utilized this authority on 24 occasions to place 74 synthetic drugs temporarily (using emergency control) into Schedule I, including 17 fentanyl-related substances. In comparison, during the first 25 years (1985–2010) after Congress created this authority, DEA utilized it a total of 13 times to control 25 substances. The process is workable but is highly reactive, lagging behind the dynamic pace of illicit drug producers and distributors.

In recognition of the unprecedented escalation in opioid-related overdoses, as well as the White House directive to declare the opioid crisis a national public health emergency,¹ on February 6, 2018, DEA used its authority under section 201 of the CSA² to place all nonscheduled fentanyl-related substances into Schedule I temporarily, on an emergency basis, for two years to combat the scourge of these illicit substances.³ As a result, anyone who possesses, imports, distributes, or manufactures any illicit, fentanyl-related substance is subject to criminal prosecution in the same manner as any other Schedule I controlled substance. This makes it easier for federal agents to seize fentanyl-related substances and investigate traffickers of these substances, and for prosecutors to prosecute such traffickers.

The positive impacts in the two years since implementation are significant. Since 2018, there has been a significant decline in law enforcement reports to the National Forensic Laboratory Information System (NFLIS) of substances structurally related to fentanyl, including those captured under the February 2018 class control temporary order. In the 24 months preceding the temporary order (February 2016 through January 2018), there were more than 17,500 reports of these substances to NFLIS, excluding those controlled prior to 2016.

Conversely, since the temporary class control (February 2018 through December 2019), and as of January 7, 2020, there were fewer than 8,800 reports to NFLIS for substances structurally related to fentanyl, a 50 percent reduction. It should be noted that NFLIS reporting is still on-going for 2019. The DEA attributes this significant decline to the series of control actions in recent years, culminating in the February 2018 class control. Under the temporary emergency scheduling order, there is little incentive for drug trafficking organizations to invent new substances related to fentanyl for the purpose of evading DEA's control.

DEA's experience under the relatively short temporary scheduling regime is proof of concept that classwide scheduling of fentanyl-related substances produces solid law enforcement results, while also having a positive impact on the controlled substances research application process. Instead of an application for research based on individual substances, the temporary order allows for research on an entire class of compounds for the licensee. It must be noted that expiration of a temporary classwide scheduling results in the termination of this streamlined process, which results in research reverting to an individual substance-by-substance application.

The Department and DEA worked with our colleagues at the Office of National Drug Control Policy (ONDCP) and the Department of Health and Human Services to develop a legislative solution to this problem. This proposal, which represents the Administration's intent to promote public safety by aggressively fighting the scourge of synthetic opioids, while protecting the medical community's ability to perform critical research, would permanently schedule the very substances that are the cause of so many of deaths.

Department of Justice Interactions With Chinese Counterparts

China: Government Action and Cooperation

As part of the Administration's whole-of-government approach, the Department and DEA, which has an active Beijing-based country office, have engaged Chinese counterparts on the control of emerging fentanyl-related substances and other new psychoactive substances.

When China controls a drug or precursor chemical, we see a significant drop in the use of that substance for illicit purposes in the United States. It is through these bilateral communications and bridge-building efforts that we can work to reduce the supply of illegal substances around the world.

On April 1, 2019, China announced that it would schedule fentanyl-related substances as a class, effective May 1, 2019; the Department understands that the action is now in place. This will help prevent chemical work-arounds by clandestine synthetic opioid producers in China, and will allow the United States and China to cooperate on a broader range of cases. Like DEA's temporary scheduling order of fentanyl-related substances, this is a novel approach in China, and responsive to our

¹President Donald J. Trump is Taking Action on Drug Addiction and the Opioid Crisis, The White House Office of the Press Secretary, Oct. 26, 2017, <https://www.whitehouse.gov/the-press-office/2017/10/26/president-donald-j-trump-taking-action-drug-addiction-and-opioid-crisis>.

²U.S.C. § 811(h)(1).

³Schedules of Controlled Substances: Temporary Placement of Fentanyl-Related Substances in Schedule I, 83 Fed. Reg. 5188 (Feb. 6, 2018), <https://www.federalregister.gov/documents/2018/02/06/2018-02319/schedules-of-controlled-substances-temporary-placement-of-fentanyl-related-substances-in-schedule-i>. There is a possibility of extending temporary scheduling for one additional year if proceedings are underway for permanent scheduling. 21 U.S.C. § 811(h)(2).

Nation's unprecedented opioid threat. Indeed, officials from the Ministry of Public Security Narcotics Control Board in China had indicated that their scheduling process was long and complicated, that China had always scheduled one drug at a time pursuant to its law, and that any change in that process would be groundbreaking for China.

As the opioid threat continues, the Department and DEA are committed to working with Chinese officials through well-established bilateral efforts: Liaison presence; the Counter Narcotics Working Group; Bilateral Drug Intelligence Working Group; regular meetings of scientists; and enhancing collaboration with DEA's inter-agency partners stationed abroad and in the United States. The Department remains encouraged by China's classwide controls of fentanyl-related substances.

Legal Implications of Expiration of Temporary Scheduling

DEA's emergency temporary scheduling action controlling fentanyl-related substances will expire on February 6, 2020, absent Congressional action. At that time, any substance that meets the definition of a fentanyl-related substance, but has not completed the multi-step, dual agency review process, which includes scientific and medical evaluation and recommendation by HHS to place permanently under the CSA on a substance-by-substance basis, will no longer appear on a controlled substance schedule. Re-scheduling of such substances may encounter regulatory obstacles, and trafficking of such substances would then have to be prosecuted under the Controlled Substance Analogue Enforcement Act of 1986 (Analogue Act, enacted at 21 U.S.C. § 802(32) (definition) and § 813 (operative)).

Regulatory Challenges

Upon the expiration of classwide scheduling, the Department will utilize all available tools to protect the public, continuing to collect information on incidents of trafficking and harm to prioritize the most harmful and persistent of fentanyl-related substances for scheduling on a substance-by-substance basis. As per previous experience, it will remain critical to rapidly identify new encounters of these substances and connect them to their harm and lethality. This remains a significant challenge for public health and law enforcement in a rapidly evolving illicit market where traffickers outpace our ability to determine the potential harm of newly developed analogues. However, in doing so, the Department would enter uncharted legal and regulatory terrain. It is unknown whether a newly encountered fentanyl-related substance, having just been allowed to lapse from the class-scheduling regime, could later be quickly subject to temporary control. The Department will continue to evaluate all options to best protect the public; however, the introduction of new fentanyl-like substances will only result in additional deaths and continuing the cycle of problematic opioid use.

Law Enforcement: Investigation and Prosecution

If class scheduling of fentanyl-related substances expires, the overall effect on law enforcement activities by DEA, U.S. Immigration and Customs Enforcement Homeland Security Investigations, and others, as well as on Department prosecutions, is unknown, but may be significant. DEA expects savvy clandestine manufacturers and traffickers to respond to the re-emerging gap in U.S. law by again producing novel fentanyl-related substances. This is the normal response of traffickers who wish to avoid prosecution and still profit from peddling poison, and is consistent with previous attempts to circumvent reactive substance-specific control measures. While China has helpfully taken the bold step of scheduling all fentanyl-like substances, we run the risk that manufacturers and drug traffickers may move operations to other countries.

Legal Significance of Legislative Scheduling of Fentanyl-Related Substances

A legislative solution to adopt class scheduling of fentanyl-like substances would remove any legal uncertainty surrounding the authority of the Attorney General, through DEA, to schedule fentanyl-related substances. Implicit in the structure and text of the CSA's scheduling authority is the concept that specifically identified substances are scheduled one at a time. The Department is confident that the DEA temporary scheduling action would withstand judicial scrutiny, but it remains an untested approach. Temporary scheduling actions, while not subject to direct judicial review, are subject to challenges. One or more rulings invalidating fentanyl

class scheduling would yield confusing and possibly devastating consequences, both in pending cases and post-conviction. Congressional action would resolve this issue and permanently address the United States' response to these deadly fentanyl-related substances. Class scheduling of fentanyl-related substances is an urgent and necessary first step. This situation highlights the need to next address the scheduling system on a more comprehensive basis in order to avoid having this situation re-occur when the next broad class of dangerous analogues is developed, as we know it will, by savvy illicit drug manufacturers seeking to avert current controlled substances scheduling authorities.

Conclusion

Absent extension, DEA's temporary class scheduling of fentanyl-like substances expires on February 6, 2020, at which time any substances that have not been permanently scheduled will fall outside the CSA drug schedule. As a result, the Department and DEA would enter relatively unknown territory. Temporary class control has been shown to be very effective in substantially reducing the number of fentanyl analogue encounters in the United States. The class of fentanyl-related substances needs to be categorically and permanently scheduled. A solution that prevents fentanyl-related substances from falling out of control is essential to continue tackling the opioid epidemic our Nation currently faces, and the Department firmly believes that a solution can be found that will achieve this goal, while also accommodating interests in continued research on these substances.

Thank you for the opportunity to testify today, and the Department looks forward to continuing to work with Congress to find solutions necessary to address the threats posed by illicit fentanyl and its analogues.

Ms. BASS. Thank you very much. We will now proceed under the 5-minute Rule with questions, and I will begin by recognizing myself for 5 minutes.

Admiral, I wanted to know if you could, in plain English, if you could describe a little bit about the process that you go through in determining a scheduling decision. So, there is the 3-factor analysis for a temporary scheduling decision, and then there is an 8-factor analysis for a permanent decision. I was wondering if you could explain a little bit about what that means.

Admiral GIROIR. Yes, ma'am. So traditionally, the DEA requests that the FDA does a scientific analysis based on a specific molecule that they are concerned about to potentially be put in a schedule according to the Controlled Substances Act. Without going into a huge amount of detail, here are 8 factors that should be considered the law: The potential for abuse; the scientific evidence of its effect; the State of current scientific knowledge; history and current pattern of abuse; scope, duration, and significance of abuse; what, if any, risk there is to the public health; psychic or physiologic dependence; or whether it is an immediate precursor of another drug.

So, the FDA does its analysis based just on the evidence that is there. They make a recommendation to the ASH, the assistant secretary for health, who is the designated official by the Secretary to make a recommendation to DEA. So, after that process occurs, and this occurs on a regular basis for schedules, we make a recommendation back to the DEA, and the Attorney General and his or her delegates make the decision on whether to schedule. That is the basic process that is undergone.

Ms. BASS. So the only way you know to do that is, I believe, what you were describing. There are a rash of deaths, and then you take that sample. It goes to you, and then you go through that factor analysis? Is that how that process occurs?

Ms. LISKAMM. That is correct. Either the substances are seized by law enforcement or we respond to a rash of deaths in the community, which is a more typical way that we encounter this, and we send that over to HHS.

Ms. BASS. So you were explaining that with the permanent ban, you are still able to do that, what you described in your—

Admiral GIROIR. So, the issue with the fentanyl analogues is we estimate there are over 3,000 of them within the class, any of which could be deadly, even more deadly than the ones we see right now. The scientific evidence to try to look at 3,000 chemicals—

Ms. BASS. Right.

Admiral GIROIR. —and try to do that is just not meant for what the process is meant to be. So, our approach that we really came up with is we know one thing for a fact, and that is 65,000 to 68,000 Americans are going to die of drug overdoses this year, the majority of which are from fentanyl and analogues, and we have to stop that, but we tried to put in research protections. For example, if one of those 3,200 turns up to not have potential for abuse or to be an important molecule for research, then we could rapidly de-schedule or reduce the schedule so it can be available to researchers, and a number of other items like just streamlining some of the processes of inspection and clarifications that inhibit the process.

Ms. BASS. So, you know if it is a problem by the deaths, but how do you know if it has the potential to have an advantage? I mean, I was shocked to hear what you said, that there are now analogues that are stronger than Narcan.

Admiral GIROIR. So, you know, it could be discovered anywhere in the world or by academic scientists that a particular compound that they are focusing on or investigating on might have an important effect. Remember, the naloxone, the reversal drug looks a whole lot like morphine.

Ms. BASS. Yeah. Right.

Admiral GIROIR. It was—

Ms. BASS. Is it called “Narcan?”

Admiral GIROIR. Pardon me, ma’am?

Ms. BASS. Narcan, is it—

Admiral GIROIR. Narcan, yes, ma’am.

Ms. BASS. Yeah.

Admiral GIROIR. Narcan is a specific form, the nasal, but it looks a whole lot like morphine, but it has no effect. In fact, it reverses all those effects.

Ms. BASS. Right.

Admiral GIROIR. So, it is certainly possible and likely, I would say, that among those 3,200 compounds, there are going to be some that are very, very interesting that could be reversal agents. When I talked about overpowering naloxone or Narcan—

Ms. BASS. Uh-huh.

Admiral GIROIR. —it is drugs like carfentanil, you know, the elephant tranquilizer that unfortunately is at least 100 times more potent than fentanyl. Although Narcan works within a few minutes or 15 or 20 minutes, a new word that I learned from Dr. Volkov is people become re-narcotized. They fall right back into their over-

dose because the naloxone is overpowered. So, these are the kind of things that we really need to work on, particularly as the transnational cartels become more and more sophisticated in bringing these horrible analogues to us.

Ms. BASS. So, the analogues are created either in Mexico or China?

Ms. LISKAMM. That is correct. What we have seen is a growing trend of chemists in Mexico who are working with these cartels, specifically the Sinaloa Cartel and the CJNG, to manipulate the chemical structure to create these analogues. They will do anything they can to make profits and bring this poison into the country, which is why this tool is so necessary to the Department.

Ms. BASS. Thank you.

Mr. RATCLIFFE. I thank the chair. Ms. Liskamm, as a former DOJ alumnus, thank you for your service and good work. From your testimony, you very clearly believe that the current ban is working. What would happen to the ongoing prosecutions of traffickers of fentanyl analogues if this temporary scheduling order will expires next week on February 6th?

Ms. LISKAMM. So, we are going to have to look at those cases on a case-by-case basis to determine how we are going to handle them. It is going to create, at a minimum, a lot of legal uncertainty about whether we can still proceed forward under the current statute, or whether we would have to turn back to prosecute under the Analogue Act, which poses a whole host of issues, and, as I am sure you may know, in trying to get a conviction against these individuals.

Mr. RATCLIFFE. I was afraid that was going to be your answer, and I think it just underscores the urgency of the issue that we are facing. Dr. Giroir, actually Admiral, when we crossed paths back in Dallas years ago, you were "Doctor." So, congratulations on your promotion.

Admiral GIROIR. Thank you.

Mr. RATCLIFFE. In your testimony, you described the different ways the basic fentanyl structure can be manipulated to create analogues, and that that is a significant factor, I think you said, in how that complicates enforcement against illicit fentanyl and fentanyl analogues. I was particularly struck by your description of how the process of scheduling each individual analogue under the Controlled Substances Act one at a time leads to what you referred to as a deadly game of whack-a-mole, where clandestine manufacturers are able to synthesize a different fentanyl analogue to evade enforcement. Given all of that—I think I know the answer—is it your opinion that permanent scheduling of fentanyl analogues will further efforts to combat the opioid crisis? Assuming that it is, can you expand in practical terms how that would be effective?

Admiral GIROIR. So let me reaffirm that HHS and I absolutely support the permanent scheduling of fentanyl analogues. Of course, as I testified, we would like to see coincident with that the research protections, because out of those 3,200 or so classes/compounds, there are going to be ones that are very important that we need to do research on. As I said, we know tens of thousands of Americans will die this year, and we have to support DOJ's enforcement.

Now, how does this really work? I think it has worked, as Ms. Liskamm says, and we work together literally all the time to get the public health and the law enforcement working together simultaneously. We have to treat anyone who has opioid use disorder, but we have got to keep these substances from coming in on our streets as much as possible. And when there is a loophole, we see that manufacturing going up, and we see overdoses because of those agents.

So, we are strongly supportive of DOJ trying to keep these off our streets because addiction is treatable. That is the good sign, but it is really hard. Once you have a use disorder, it is a chronic brain disease. It is a lifelong struggle. So, keeping these away from everyone in our country is the most important thing we can do. Of course, treatment is equally important for those who currently suffer.

Mr. RATCLIFFE. Ms. Liskamm, do you want to expand on that at all?

Ms. LISKAMM. The Department takes research very seriously. As Admiral Giroir said, we have been working in partnership to make sure that we can do everything that we can to combat this opioid epidemic. As an example, there is an Appalachian Regional Task Force that goes out and works to prosecute individuals in one of the hardest-hit areas in the country in Appalachia. They are medical professionals who are charged with title 21 offenses. Yes, we are taking it off the street, but we work hand-in-hand with HHS to deploy these rapid responses to the area so that individuals who are seeking legitimate medical treatment or addicts who need assistance are not just left out in the cold and turning to street dealers. It has been a really great collaboration between the two departments.

Mr. RATCLIFFE. Well, I thank you both for your efforts in this vitally important issue. With that, I yield back.

Ms. BASS. Ms. Dean?

Ms. DEAN. Thank you, Madam Chair, and I thank you for offering us this hearing today. As I sit here, Madam Chair, I am hearing testimony, and do you ever have that feeling of both things are true? Both what you are talking about is importantly true, and I think it is our job as policymakers to figure out that place in between. How do we balance criminal justice-appropriate behaviors while not harming the attempts for research? So, know that I come at it from that perspective, and that I admire both Prosecutor Liskamm and Admiral Giroir, the work that you are doing and how you bring this to us.

The numbers are staggering. This is an issue I care deeply about. It is an issue that is closely connected to my community, to my own family. I have a son in recovery, 7 years, 3 months, from opioid addiction. So, I have learned through our family experience of the real knowledge that this is a disease. This is a public health crisis, and I have seen how it has wrecked our communities. We have friends who have lost children and adults as well.

I want to avoid the overcriminalization. I want to avoid the overuse of mandatory minimums where it is not appropriate. I want to protect the ability to do research. So maybe I will begin with you, Ms. Liskamm. Knowing that the opioid crisis takes more 50,000, or

up to 50,000, people a year as of 2018, 70,000 folks die of overdose in a single year. I call it a jetliner a day. It is staggering: Monday, Tuesday, Wednesday, Thursday, 365 days a year. What is the best way for us to attack this problem?

I worry that we will effectively go for low-level so-called traffickers using resources to incarcerate and over-incarcerate, when really what we are dealing with often is addiction, the public health crisis. How do we more effectively, how does DOJ more effectively use our resources to go at the cartels, to go at the border, to make sure that that which is coming in from China or Mexico is not getting into our communities, because that is where our problem is?

Ms. LISKAMM. Understood, and I appreciate all those comments. I have to say the Department, again, is using every tool that we have at our disposal. I think that if you look at the past 2 years since this order has gone into effect, since February of 2018, that the results speak for themselves. The amount of fentanyl and analogues we see coming through the mail from China has dropped drastically. The number of fentanyl encounters that DEA has seen here in the United States since 2018 has dropped by 50 percent. It went from 17,500 to 8,800, which is—

Ms. DEAN. What are those numbers reflecting, 17,000 what?

Ms. LISKAMM. Encounters of fentanyl analogues. So, before the order, DEA was seeing 17,500 examples of fentanyl analogues that were found here in the United States. Once that order went into effect, that dropped by 50 percent. That shows that it is working. I just want to point also to, and we are very cognizant of the concern about overcriminalization, and that is not the Department's goal here. I think, again, pointing to the last 2 years, we have not seen a big uptick, and we have not seen overcriminalization bear that out over the past 2 years. The Department—

Ms. DEAN. Could I just give you an example and ask your opinion of it? I don't know what the answer is. I am not presupposing what the justice was in this case. I am from suburban Philadelphia, but in neighboring Bucks County, a young woman, now 24, 25 years of age, was incarcerated for 20 years' imprisonment. She and her friend sadly were shooting heroin in a KFC. Emma left her friend to die in that bathroom at a KFC. Emma went on, and the death of the woman, trust me, it is just crushing and heart-breaking. She was only 20. It was her birthday, and her friend had shared drugs with her. Now, that friend, the one who survived, went on to recovery, to work in the area of addiction, but was sentenced to 20 years' imprisonment. I don't know what justice looks like in that case. Do you have an opinion on mandatory minimums in that kind of a case?

Ms. LISKAMM. So, I don't know the underlying facts and why that case was prosecuted the way that it was. I know that in Fiscal Year 2018, the fentanyl prosecutions that we saw that year, we saw less than half of those fentanyl prosecutions were subject to the mandatory minimum. Then of those, about half of those had either a safety valve provision that they were eligible for, so if they were a low-level criminal history and they pled guilty, that would apply, or those individuals pled guilty and cooperated with the gov-

ernment, and 5K or Rule 35 substantial assistance was available to them.

Ms. DEAN. I see my time is up, and, unfortunately in this case, under the statute in Pennsylvania, a new statute in Pennsylvania, that wasn't an option. Admiral, I apologize. I would love to have asked you more questions. Maybe I can privately. Thank you, Madam Chair.

Ms. BASS. Mr. Sensenbrenner?

Mr. SENSENBRENNER. Thank you, Madam Chair. Before I begin, I would like to unanimous consent to insert 3 items into the record: First, a Washington Post op-ed by Attorney General Barr dated January 10th, 2020, saying we ought to pass legislation; secondly, a letter from all of the attorneys general in the country, State attorneys general in the country, supporting legislation; and thirdly, an extensive report from Dr. Tim Westlake, who is a full-time emergency room physician in Oconomowoc, Wisconsin, who has been involved in this issue as a result of what he has seen in the ER in the hospital in which he works. So, I ask unanimous consent that they be included.

Ms. BASS. Without objection.

[The information follows:]

MR. SENSENBRENNER FOR THE RECORD

1/27/2020

William Barr: Congress has to pass a bill to restrict fentanyl - and save lives - The Washington Post

The Washington Post
Democracy Dies in Darkness

William Barr: Fentanyl could flood the country unless Congress passes this bill

By **William P. Barr**

Jan. 10, 2020 at 3:49 p.m. EST

William P. Barr is the U.S. attorney general.

While the political circus drags on inside the Beltway, Congress is sitting on critical legislation needed to deal with the deadliest opioid fueling the nation's drug overdose crisis. During the last few years of the Obama administration, drug overdose deaths began skyrocketing and have climbed steeply to more than 70,000 a year — more Americans than were killed during the entire Vietnam War.

The surge is now being driven by an especially deadly synthetic opioid called fentanyl. As much as 80 times more powerful than heroin, only a few grains of this chemical compound are enough to cause a fatal overdose.

AD

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<https://www.washingtonpost.com/opinions/william-barr-congress-pass-this-bill-so-we-can-attack-the-onslaught-of-illegal-fentanyl/2020/01/10/cbb8ccdc-...> 1/8

1/27/2020

William Barr: Congress has to pass a bill to restrict fentanyl - and save lives - The Washington Post

Unfortunately, the legal prohibitions on the various forms of fentanyl expire next month unless Congress reauthorizes them. If Congress fails to act, illegal labs in Mexico and China stand ready to flood the United States with what would be a legalized poison. There is broad bipartisan support for reauthorizing the fentanyl ban, but House leadership, despite the looming deadline, is blocking the measure.

A Post editorial on Monday, urging Congress to act, suggested that the delay may be because of congressional consternation over related sentencing guidelines. That may be true, but the House has yet to make public any rationale for the delay.

Fentanyl has been predominantly produced in China, and increasingly in Mexico. Before 2018, drug traffickers were able to stay one step ahead of U.S. law by making slight modifications to fentanyl compounds, adjusting, for example, a single molecule. These so-called fentanyl analogues had the same narcotic properties as fentanyl but, because of their minuscule molecular variations, technically skirted the existing ban on fentanyl.

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1/27/2020

William Barr: Congress has to pass a bill to restrict fentanyl - and save lives - The Washington Post

Through hard diplomacy, we persuaded the Chinese government to prohibit fentanyl analogues. Here at home, the Drug Enforcement Administration in February 2018 used its emergency regulatory powers to ban all fentanyl substances, but, by law, this ban can only last two years.

It is easy to understand why fentanyl is so deadly. Only a tiny amount is enough to trigger an overdose, and because the quality and precision of compounding done in the illicit labs vary, users cannot be sure of the amount of active ingredients they are ingesting.

That is bad enough when the user intends to take fentanyl by itself, but drug traffickers increasingly are mixing fentanyl with a wide range of other drugs, including cocaine, heroin and methamphetamine. Drug users thus may have no idea whether they are ingesting fentanyl and, if so, how much they are taking.

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These risks are even higher with fentanyl analogues, which usually are more potent than “classic” fentanyl. Trafficking fentanyl amounts to outright murder.

1/27/2020

William Barr: Congress has to pass a bill to restrict fentanyl - and save lives - The Washington Post

There is no question that overdose deaths are being turbocharged by fentanyl. In 2016, synthetic opioids (primarily illegal fentanyl) passed prescription opioids as the most common drugs involved in overdose deaths in the United States. In that year, 42,249 drug overdose deaths involved opioids, and of those deaths, 45.9 percent involved synthetic opioids.

By attacking the overdose crisis on a broad front, the Trump administration in 2018 was able to stop the increase in overdose deaths, and even slightly reduce them, for the first time in several decades. Much of that success stemmed from substantial progress in controlling the abuse of legal opioids. But the progress will be reversed if the country is hit by a tsunami of newly legalized fentanyl analogues. Without congressional action, the Justice Department would not have the legal tools to prevent this onslaught.

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1/27/2020

William Barr: Congress has to pass a bill to restrict fentanyl - and save lives - The Washington Post

The proposed Stopping Overdoses of Fentanyl Analogues legislation is broadly supported — attorneys general in all 50 states signed a letter urging its passage — and is essential to addressing the drug overdose crisis. It is unthinkable that at the very time China has been willing, at our urging, to restrict fentanyl analogues, Congress would be willing to open the floodgates to this poison. The Senate is poised to act, and the House should follow suit. Thousands of American lives are in the balance.

Read more:

The Post's View: Congress should act to allow a ban on fentanyl indefinitely

Robert Gebelhoff: Safe injections sites aren't immoral. But attempting to block them sure is.

The Post's View: We're finally getting some accountability for the opioid crisis — long after victims are dead

The Post's View: Americans need to know the whole truth about the opioid crisis

Robert Gebelhoff: Opioid deaths are down for the first time in decades. But the crisis of addiction is as severe as ever.

AD



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The Honorable Mitch McConnell
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United States Senate
317 Russell Senate Office Bldg.
Washington DC 20510

The Honorable Nancy Pelosi
Minority Leader
235 Cannon House Office Bldg.
Washington, DC 20515

The Honorable Charles Schumer
Minority Leader
United States Senate
322 Hart Senate Office Bldg.
Washington, DC 20510

August 23, 2018

Dear Speaker Ryan, Majority Leader McConnell, Minority Leader Pelosi, and
Minority Leader Schumer:

We, the undersigned Attorneys General, write to express our support for swift
passage of the Stopping Overdoses of Fentanyl Analogues (SOFA) Act.

There is little doubt that the nation's ongoing battle against heroin and opiates
is unlike any other public health emergency. It touches all corners of our
society. States and localities are on the front line of this crisis and are a large
part of winning the battle from both a law enforcement and public health
perspective. We are grateful for the steps that Congress has taken to assist our
states, including passing the International Narcotics Trafficking Emergency
Response by Detecting Incoming Contraband with Technology (INTERDICT)
Act earlier this year.

Unfortunately, as states have taken measures on a local level to solve this
crisis, a new front has emerged in the form of trafficking in fentanyl and
fentanyl analogues. As you are probably aware, fentanyl is a synthetic opioid
that is used to treat late-stage cancer patients. Sadly, fentanyl and its analogues
have made their way onto our streets with alarming regularity and overdose
deaths related to fentanyl now surpass deaths related to heroin. These
troubling facts were expressed in detail recently in a May 8, 2018, hearing in
the House of Representatives Judiciary Committee entitled, "Challenges and
Solutions in the Opioid Abuse Crisis."

The SOFA Act will eliminate the current loophole which keeps the controlled
substance scheduling system one step behind those who manufacture fentanyl
analogues and then introduce these fentanyl analogues into the opioid supply.
In short, the SOFA Act utilizes catch-all language which will allow the Drug
Enforcement Administration to proactively schedule all newly modified
fentanyl analogues and thus will assist law enforcement's efforts on the front
end. The SOFA Act unplugs the entire fentanyl machine in the first instance

by making fentanyl analogues illegal as soon as they are manufactured, which occurs most often abroad in countries without adequate controls.

While there remains much work to be done on all levels of government to address the opioid crisis, we urge Congress to act expeditiously and pass this important piece of legislation.

Very truly yours,



George Jepsen
Connecticut Attorney General



Steve Marshall
Alabama Attorney General



Mark Brnovich
Arizona Attorney General



Xavier Becerra
California Attorney General



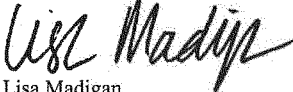
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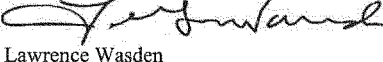
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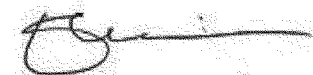
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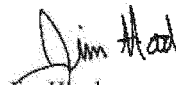
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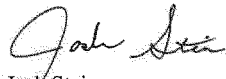
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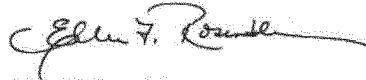
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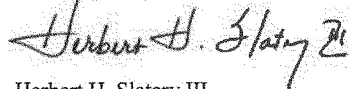
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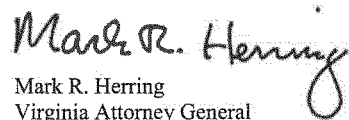
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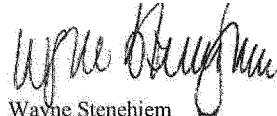
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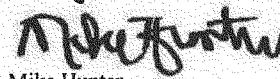
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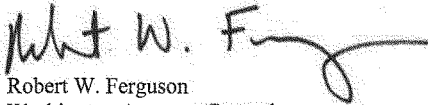
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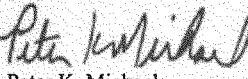
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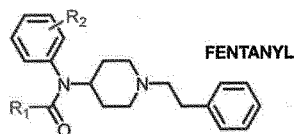
To Congressional Policymakers:

January 24th, 2020

When fully unpacked, it is clear that the SOFA Act is not a punitive law, it is fundamentally preventative by specific design. The goal is not to incarcerate low level dealers and drug users, rather it is to stop the creation and spread of deadly new fentanyl-related substances coming from transnational drug trafficking organizations. It is important to understand the origins of the SOFA Act. It did not originate from within the DEA, DOJ, or within the Administration, it started with me. My name is Tim Westlake and I'm a full-time emergency physician and part-time medical regulator who has been the physician architect of the prescription opioid reform strategy in Wisconsin. I am Vice Chairman of the Wisconsin Medical Examining Board and serve on the Wisconsin Board Controlled Substances Board, (the statewide regulatory agency in Wisconsin responsible for controlled substance scheduling at the state level).

At the time of my origination of the fentanyl-class control idea in 2016, there were 9 separate but almost identical fentanyl variants that we in Wisconsin were attempting to control separately. This means that each variant was responsible for multiple overdose deaths in Wisconsin and across the U.S., but were as of then still legal substances, having not yet been scheduled federally by the DEA or at the state level by us on the Controlled Substance Board. In Wisconsin, when deaths result, then the CSB can use emergency scheduling authority. We had to literally wait for people to die and the body count to pile up before we could schedule the new fentanyl variants.

Table 1. Examples of recent structural modifications to fentanyl observed on the illicit market.



Substance	R ₁	R ₂
fentanyl ¹⁴	-CH ₂ CH ₃	H
acetyl fentanyl	-CH ₃	H
butyryl fentanyl	-CH ₂ CH ₂ CH ₃	H
furanyl fentanyl	-furan-2-yl	H
4-fluoroisobutyryl fentanyl	-CH(CH ₃) ₂	<i>para</i> -F
acryl fentanyl	-CH=CH ₂	H
<i>ortho</i> -fluorofentanyl	-CH ₂ CH ₃	<i>ortho</i> -F
tetrahydrofuranyl fentanyl	-tetrahydrofuran-2-yl	H
methoxyacetyl fentanyl	-CH ₂ OCH ₃	H
cyclopropyl fentanyl	-cyclopropyl	H
valeryl fentanyl	-CH ₂ CH ₂ CH ₂ CH ₃	H
isobutyryl fentanyl	-CH(CH ₃) ₂	H
<i>para</i> -chloroisobutyryl fentanyl	-CH(CH ₃) ₂	<i>para</i> -Cl
<i>para</i> -methoxybutyryl fentanyl	-CH ₂ CH ₂ CH ₃	<i>para</i> -OCH ₃
cyclopentyl fentanyl	-cyclopentyl	H
ocfentanil	-CH ₂ OCH ₃	<i>ortho</i> -F
<i>para</i> -fluorobutyryl fentanyl	-CH ₂ CH ₂ CH ₃	<i>para</i> -F

I have been on the front lines in the opioid battle for more than 20 years as a full time emergency physician and part time medical regulator. I was deeply saddened by having to tell far too many families in the Emergency Department that their loved one and family member was never coming home due to an opioid overdose. In 2016 I came up with the idea to selectively schedule likely bioactive fentanyl derivatives as a class. Why keep playing “whack a mole” when we could unplug the whole fentanyl related substance machine. The goal was simple, to take away the incentive that foreign transnational drug trafficking organizations and chemical/drug manufacturers had in modifying the fentanyl molecule by adding one little chemical group to stay ahead of US scheduling and find new legal drugs that could not be stopped until they killed many people, at which time they would minimally alter the structure again to stay ahead of law enforcement.

My idea was if we could get it enacted in Wisconsin, then we could get it passed federally, and then spread to China and internationally, thereby shutting down the whole fentanyl related substance machine. Cognizant of not wanting to over-reach and have as light a touch as possible, I went to the DEA looking for language to use that would specifically target just the likely bioactive chemical modifications to the fentanyl molecule. DEA was already also looking for a novel solution and came up with the language based on current UK fentanyl-class scheduling language (which means the Brits have already been effectively using fentanyl-class scheduling), and we put it into state legislation. This targeted fentanyl-class scheduling language was the basis of the SOFA Act that was released in July of 2017. Wisconsin Act 60 was signed into law in Wisconsin on Nov 9th, 2017, after passing unanimously in the Wisconsin legislature.

Within that very week, the DEA published the intent to use emergency scheduling powers to temporarily schedule fentanyl as a class federally, which then took effect February 2018. The results have been incontrovertible, the intended result has clearly been accomplished. As a result of the federal fentanyl class scheduling language, the creation of new fentanyl related substances has ground to a halt internationally. From 2016-2018 there were at least 20 new fentanyl related substances found to have caused overdose deaths in multiple states in hundreds of Americans across the country. Since then, only 3 new fentanyl related substances has been found, and it is suspected that they may have been already developed prior to the temporary scheduling was published in the federal register.

The goal of stop signs isn't to find a way to cite people for traffic violations, it is to help make the roads safer, which they do. The goal of the SOFA Act isn't to lock up drug users, it is to stop the very existence of the deadly fentanyl poisons from at their origins in chemistry labs overseas. Opposition to the SOFA Act says that there would be a huge increase in the societal costs of increased incarceration of people with substance use disorder if the SOFA Act was passed. However, the societal effects of the SOFA Act can already be seen; there are already thousands of Americans who are alive now who would have been dead if new fentanyl related substances were still being developed and trafficked in the US. It is the ultimate form of prevention. You can't die

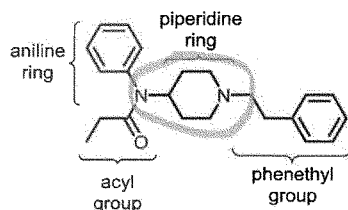
from ingesting something never created, nor can you be incarcerated for selling something that doesn't exist.

One cannot deny that criminal justice and mandatory minimum sentence reform is needed in the United States, but that is a separate issue from whether the U.S. Congress should enact the SOFA Act as reasonable legislation to combat the availability of the toxic and deadly fentanyl. It is also clear based on outcomes that the War on Drugs has not been a success, but again that needs to be kept separate from the SOFA Act. This is addressed in detail further along in the discussion.

It is also important to remember that when the scheduling language was initially created, it was specifically targeted to control the likely bioactive modifications of only the fentanyl molecule. Concern about not wanting to impede general research was thoughtfully considered, and great care was given to insure the language would be as specific as possible. In fact, the detailed scheduling language includes modification to just 5 portions of the fentanyl molecule, which means it only controls molecules that are almost identical to the fentanyl molecule with just minor structural differences. It does not even control all possible modifications to the fentanyl molecule, just the most likely to be bioactive. It is not a hand grenade approach, it is akin to a surgical scalpel. The idea that anything other than fentanyl variants would be included is simply not accurate.

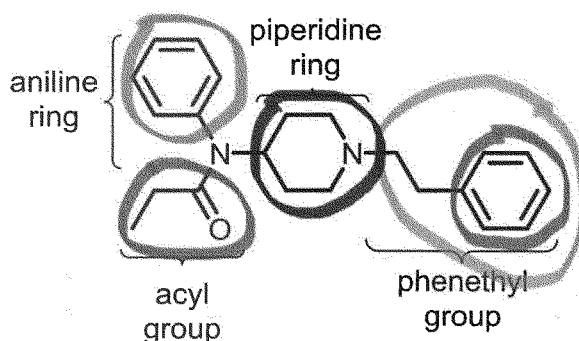
It had been suggested by those opposing the SOFA Act that these compounds could possibly be used to develop and test new medications for preventing opioid addiction and overdose. Concerns were also noted that putting fentanyl analogues into Schedule I without accommodating scientists with a streamlined approval process could slow valuable research aimed at addressing the opioid crisis. It has even been proffered that research on new substances like new versions of Narcan would be impacted. That is a misunderstanding of how specific and targeted the language actually is. Sadly, I use Narcan on almost a daily basis in my work in the Emergency Department and I would in no way support any law that oversteps and gets in the way of research that could better treat opioid abuse and overdose.

Fentanyl falls into the 4-anilidopiperidine class (defined by the aniline ring in the 4-position of the piperidine ring). By definition, in order to structurally classify as a fentanyl-related substance under the SOFA Act language, the base chemical structure must be that with Nitrogen at the 4-position of the piperidine ring (highlighted in yellow below). Any chemical without that exact base structure and any of the specified modifications would not be included in the class scheduling allowed by the SOFA Act.

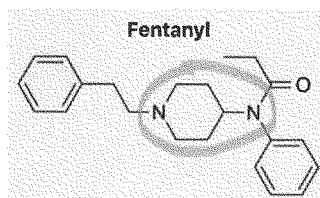
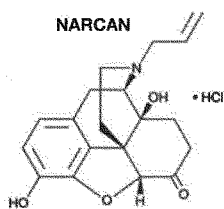


**SOFA Act-Specified Fentanyl-Class Modifications:
one or more of the following-**

- (A) By replacement of the phenyl portion of the phenethyl group by any monocycle, whether or not further substituted in or on the monocycle;
- (B) By substitution in or on the phenethyl group with alkyl, alkenyl, alkoxy, hydroxy, halo, haloalkyl, amino or nitro groups;
- (C) By substitution in or on the piperidine ring with alkyl, alkenyl, alkoxy, ester, ether, hydroxy, halo, haloalkyl, amino or nitro groups;
- (D) By replacement of the aniline ring with any aromatic monocycle whether or not further substituted in or on the aromatic monocycle and/or
- (E) By replacement of the N-propionyl group by another acyl group.



The language in the SOFA Act fentanyl-class controls would only impact other chemicals that are almost structurally identical to fentanyl. It would clearly not effect Narcan or any other classes of opioids or chemicals that do not have the structure of the Nitrogen at the 4-position of the piperidine ring.



I'd like to discuss the origins and specificity of the SOFA Act language in more detail. It was intentionally designed to capture the modifications (already well described in the scientific and medical literature) which have been used by transnational criminal organizations exploiting the legitimate research information on structure activity relationships to stay one step ahead of the CSA and Analogues Act and continue the spread of these deadly poisons in the United States and internationally.

There is an excellent detailed discussion on the chemistry and history of fentanyl and fentanyl-related substances in a statement attached from Michael Van Linn, PhD taken from testimony before the United States Sentencing Commission in December, 2017. <https://www.uscourts.gov/sites/default/files/pdf/amendment-process/public-hearings-and-meetings/20171205/Van-Linn.pdf> . As noted in the Van Linn testimony, many of the new FRS's (fentanyl related substances) responsible for overdose deaths is the U.S. recently are previously well described in the patent and scientific literature, often accompanied by pharmacological data and detailed instructions on synthesis. These are essentially precise maps that guide legal as well as illicit chemical manufacturers in creating new FRS's that are almost certain to be bioactive. The pathway to synthesize fentanyl and FRS's is relatively straight forward and well defined, and creation of a new FRS is as simple as plugging in a different chemical precursor at one step or another in the process of synthesis. The ease of creating new FRS's is attractive to medicinal chemists and unfortunately is also very attractive to illicit chemists for the same reason.

The SOFA language was created exclusively to close these known pathways to new likely bioactive FRS's, and not affect other chemical substances. There are very precise and specific modifications that would lead to inclusion in the SOFA Act scheduling. All elements of the fentanyl molecular chemical scaffolding must be present. If there are any deletions from the scaffold, then the chemical wouldn't be scheduled under SOFA. If there are any substitutions not specifically included in the specific language, then those chemicals wouldn't be included in scheduling under SOFA.

The concerns that research would be negatively impacted were thoughtfully considered and the language was crafted as narrowly as possible to only include likely bioactive modifications based on the already known structure chemistry relationships. Furthermore, ongoing research accommodations have been negotiated to the point that HHS, NIDA, FDA, and NIH all signed off on the SOFA Act in an Administration interagency position statement in December 2019.

In the normal sequence of events, the DEA reviews and investigates chemical compounds individually, then collaborates with HHS and the FDA for final decision in the scheduling process. It is true that this process would be circumvented with the SOFA Act and would allow the DEA to schedule certain fentanyl related substances based on the specific, limited, targeted criteria and not include HHS/FDA input.

Proactively, in response to research concerns raised by HHS, the DEA has already significantly simplified the research requirements for fentanyl. The agency streamlined the research registration process, requiring a single registration for all chemicals in the entire fentanyl class instead of separate registrations for each individual substance like it does for all other substances. Currently, there are 20 research registrations for fentanyl-related substances, of which only six new ones were added in the last year. It is significant to note that many of the research registrants for the fentanyls class are through the Department of Defense to be used in researching new fentanyls for use as new chemical weapons agents. It is also important to remember that almost all the development of new fentanyl-related substances has been done overseas (in China mostly) and not by American scientists and researchers.

There seems to be considerable concern over SOFA stopping or hindering development of a new "Super Narcan" - this is the major component voiced to us of the research concerns. It is not a factually strong argument. Ask any emergency physician. It is important to be aware that literally no one dies from narcan not being potent enough; they might in rare cases need more than one dose, but there are not deaths as a result. Narcan works well almost all the time, and if it wears off, then it's simple to use more. If people die after being given Narcan, it is because they took a lethal dose of narcotic and Narcan wasn't given in time, not because it wasn't potent enough. But thousands are dying from the availability of fentanyl related substances. There were 900 deaths in New York City alone from 2017-2018 attributable to fentanyl related substances. That's why Gov Andrew Cuomo is calling for fentanyl class scheduling language in NY state copying what Wisconsin started and many other states are now following enacting.

In a recent development in December 2019, the Senate Judiciary Committee was presented with the official Administration interagency position that stated HHS, FDA, NIH and NIDA are all now in agreement that the provisions provided the committee are sufficient and they have no further research concerns, based on recent negotiated inclusion of the appropriate sought after protections for researchers.

If a chemist wanted to research any fentanyl related substance in America, all that is needed is to follow the registration needed to research other schedule 1 substances. In fact, in the past year there were 6 research registration requests to the DEA for the fentanyl class substances and all were approved in an average of 53 days. Is that really too burdensome, to require governmental oversight in order to study and develop chemicals that can be and in many cases are as deadly as the deadliest chemical warfare agents.

There are very valid concerns about the dearth of research on the chemicals in marijuana directly caused by the negative effect on marijuana research from the restrictive rules surrounding the research of schedule 1 drugs. Marijuana and the thousands of chemicals that compose it are organic molecules found in nature. Fentanyls are not natural substances and only exist due to intentional and already well researched chemical synthesis. Comparing marijuana research to fentanyl research is not apples to apples. It is important to not consider all schedule 1 drugs in the same

light. Most physicians would agree that if you were forced to have one and only one drug class to be scheduled as a schedule 1, then it would be the fentanyl.

Lethal Doses of Chemical Warfare Agents and Narcotics

Chemical Agent/ Drug	Lethal Dose	Route
Botulinum Toxin	.00007mg	Inhaled/Ingested/Injected
Tetanus Toxin	.0001mg	Inhaled/Ingested/Injected
CARFENTANIL	.02mg	Inhaled/Injected
Tabun Nerve Agent	1-1.5mg	Inhaled/Ingested/ Percutaneous
Ricin	1.78mg; 10mg	Inhaled/Injected; Percutaneous
FENTANYL	2mg	Inhaled/Injected
VX Nerve Agent	2.1mg; 10mg	Inhaled/Injected; Percutaneous
Strychnine	70-140mg	Ingested
HEROIN	70mg	Inhaled/Injected
Cyanide	100-200mg	Ingested
MORPHINE	200mg	Inhaled/Injected
Methamphetamine	200mg	Inhaled/Injected
Cocaine	200mg	Inhaled/Injected
MDMA (Ecstasy)	1000mg	Ingested
Marijuana	***NONE***	
	One teaspoon of Fentanyl is enough to kill 2,000 people	

When analyzing the cost/benefit ratio of ease of doing research and oversight, it is critical to consider the extreme lethality of fentanyl related substances. It is more appropriate to consider them more akin to chemical weapons than narcotics. One teaspoon of fentanyl is enough to kill 2,000 people. There was a recent drug bust at the Nogales AZ border crossing where 115KG of fentanyl was seized. This amount could actually be stored in a footlocker, and is enough to kill 57 million people.

Fentanyl is slightly less deadly than VX nerve gas and almost as deadly as Ricin. The most accurate way to view fentanyl related substances is as weapons of mass destruction, not just simply as recreational drugs or intoxicants like marijuana. Framing the discussion in this manner is what helped the SOFA Act last September garner a letter to Congress urging swift passage of the SOFA Act with the unanimous bipartisan support of all 50 Attorneys General from every single state as well as from Washington DC and Puerto Rico- almost unheard of in today's political climate.

Annualized deaths caused by Fentanyl and related substances now surpasses heroin and are responsible for the overdose death spike and lowering of the average life expectancy for Americans for the first time since the development of immunizations and antibiotics.

This begs the critical question, what is more important- the theoretical possibility of research being hampered slowed, or the actual overdose deaths of thousands of Americans and the immeasurable suffering associated?

We understand that the targeted control of specific fentanyl related substances as a class and not as discrete chemicals is not a minor change to the US Controlled Substance Act. It has been carefully and thoughtfully crafted and wouldn't even be considered but for it's significant impact already seen in the battle of the public health crisis of our times.

Opposition to the SOFA Act is arguing that targeted fentanyl class scheduling is not needed, that the Analogues Act of the CSA is sufficient to give DEA and DOJ all the power needed to act against FRS's (fentanyl related substances), and that all the SOFA Act would do is make it easier to incarcerate people. That is patently not accurate. In order to be able to use the Analogues Act, a substance must be proven substantially similar to a listed schedule I or II, and also intended for human consumption. This is highly problematic because those findings must be adjudicated in court and the usual threshold to even trigger looking at a substance as an analogue is when it is found to be killing people, usually many people across multiple states.

According to the 2019 Florida Medical Examiners Commission Report, deaths directly attributable to FRS overdose rose 65% in just one year from 965 in 2016, to 1,588 in 2017- (in just Florida). Between 2017 and 2019 in New York City alone there were over 900 deaths from FRS's. How many thousands of our children must continue to serve as proverbial canaries in a coal mine?

As an emergency physician, parent of teenage daughters and medical regulator, that is what drove me to come up with a legislative solution to preventing the development of new FRS's by illicit overseas chemists- we needed to shut down the FRS mine (while at the same time also not impeding needed research). The SOFA Act threads that needle. It already has a track record as a proven preventative legislative solution, working since the temporary scheduling went into effect 2 years ago.

There have been criminal justice based concerns raised about the SOFA Act possibly causing the incarceration of people for distributing non-psychoactive FRS's that would be classified as schedule I under the SOFA Act. This is an extremely unlikely scenario for a couple of reasons.

1) Simple charges of possession and low level dealing of FRS's are not prosecuted by federal prosecutors.

2) FRS's do not exist naturally, they are synthesized in illicit clandestine overseas labs by chemist suppliers to transnational criminal organizations. The process of FRS synthesis is intentional and based on well known researched and readily available information on the structure activity relationship. It isn't grown in a back yard. There is no bathtub lab manufacturing occurring. There is never going to be accidental synthesis, manufacturing and distribution of a new FRS.

3) What is the likelihood of the transnational criminal organizations/drug cartels synthesizing, manufacturing, and distributing new FRS that aren't bioactive/that don't get people high? I'd argue that would be as close to 100% improbable, almost impossible. The cartels definitely won't have DEA/FDA CDER level drug analysis, but it's not plausible that they would go to the trouble of not somehow testing and putting new FRS's in their distribution networks that were duds (non-psychoactive). How long would they be able to sell them if they didn't get users high?

Due to the specific and targeted nature of the SOFA language based on stopping the exploitation of known fentanyl/FRS structure activity relationships, it is almost certain that a newly developed FRS covered under the SOFA language that is then manufactured and then internationally trafficked would be bioactive. If the bioactivity was similar to fentanyl, it would be potentially at the level of chemical weapons lethality.

Since coming up with the class control idea over 3 years ago, what has fueled my passion for getting the SOFA Act enacted is wanting desperately to stop the frequency of times that I and other emergency physicians have to take a family in the grieving room and tell them their loved one is never coming home due to an overdose. The SOFA Act has already made a significant step in that direction.

Targeted Fentanyl-class language was seen as so important in the arsenal of tools available in the fight of the opioid epidemic that the Administration has made it a key priority in their negotiations with the Chinese government in the recent trade talks.

President Trump and President Xi discussed it directly at the G20 in Buenos Aires in December 2018, and as a result, China enacted fentanyl class scheduling language on May 1st, 2019.

Targeted Fentanyl-class language is seen as such a powerful tool for nations to wield in the opioid abuse fight that the United Nations includes it in the UN toolkit of model opioid legislation for member nations.

It is incontrovertible that temporary targeted fentanyl class control has already been exceedingly effective in closing the fentanyl related substance loophole overseas and saving countless lives in the process. It is critical to enact permanently, and time is running out. If the United States lets the fentanyl-class scheduling expire (which will happen without action by Congress on February 6th, 2020), how long will it be before other countries including most importantly China restart the fentanyl related substance creation machine and unleash the devastation associated?

Theoretical concerns over how easy it is to research chemical weapons grade level substances, or the highly unlikely event someone intending to traffic deadly fentanyl/narcotics ends up trafficking an FRS that's not psychoactive does not keep me up at night. What deeply concerns me is what will happen if the SOFA Act is not made permanent by Congress, and FRS's start to flood the streets again. 1,588 deaths from fentanyl analogs in one state (Florida) alone in 2017, and 900 in just New York City; how many more shattered lives and broken families will it take?

So it comes down to prioritization. Which should be more highly valued by federal policy makers, the theoretical concerns that targeted fentanyl-class control could increase incarceration and/or impede research (even though I would argue that careful examination does not support this) or the immeasurable suffering and loss caused by thousands of deaths annually resulting from the existence and widespread availability of these deadly chemical agents that would inevitably follow letting the fentanyl-class scheduling controls expire?

Timothy Westlake, MD, FFSMB, FACEP
Wisconsin Medical Examining Board, Vice Chairman
Wisconsin Controlled Substance Board
Governor Walker's Task Force on Opioid Abuse

Mr. SENSENBRENNER. Now, Madam Chair and Members of the committee, let me say what got me interested in this entire issue probably about 4 years ago, was a constituent named Lauri Badura. Her son died of an overdose. Dr. Westlake was the ER physician that saw her son go into the hospital and could not save him. So, I introduced both in the last Congress and this one the SOFA bill. It is an acronym. It is called Stopping Overdose of Fentanyl Analogues or Save Others for Archie.

Now, we are talking about saving lives here, and unless the fentanyl analogues are scheduled the same way that fentanyl is scheduled, you are going to see the drug pushers using the analogues if the temporary order expires because they know they won't get prosecuted, and it is as simple as that. Now, nobody here wants to inhibit any type of research on how we can develop better antidotes on that, and there should be some kind of an exemption where government-licensed research can be done.

To say that we shouldn't put fentanyl analogues under Schedule 1 because if you are convicted of a fentanyl-related offense, you are subject to a mandatory minimum, and we shouldn't subject more people to a mandatory minimum, ends up saying that we ought to put our opposition to mandatory minimums ahead of savings of hundreds of thousands of lives. If there ever were wrong priorities, that is it. You know, keeping people out of jail on a mandatory minimum and hundreds of thousands of people dying is no tradeoff that should be acceptable to this Congress or to anybody else, and that is why the SOFA Act ought to be passed. It shouldn't be tweaking fentanyl a little bit, so you get off the hook if you are pushing drugs. That we ought to say that there is no scheduling of that, is an argument that in the forum of public opinion will not stand up very long at all.

So, what should we do about this? We have got temporary scheduling expiring next week. I wish we had been able to do this sooner, but there has been opposition to doing this sooner from a whole lot of corners. You know, it is time to realize that the opposition, while valid in a number of instances, is small in bringing forth the public good compared to saving all of these lives. I am sure that the DEA will take the extra year that it is given under the law, but it means that we have to pass the SOFA Act, maybe as amended, some time this year through both houses and have it gone to the President for signature. When are we going to put lives first?

All our civil rights laws are supposed to protect people's civil rights. I think the right to life is the paramount civil right because if you are not alive, all the other laws aren't going to mean anything when you are in the graveyard. So, let's get on with doing the right thing. Let's pass the SOFA Act. Let's get it through the House and through the Senate, and make sure by February 6th, 2021, the law is such that it has no loopholes left. I yield back.

Ms. BASS. Ms. Mucarsel-Powell?

Ms. MUCARSEL-POWELL. Thank you, Chairwoman, for having this hearing. You know, I think that we all agree that we have a public health crisis on our hands, and the opioid epidemic has devastated thousands of communities across the Nation. I represent southern Florida. In Florida alone, over 5,500 opioid-related deaths were reported in 2018, and a lot of these deaths were not only from use

of heroin, but they are actually from fentanyl and analogues like you were stating now. They are highly addictive substances which have deadly consequences. I actually toured an area in my district, Banyan Health Systems, that treats individuals that continue to come back for treatment because of these highly addictive substances.

In 2018, there were at 3,100 fentanyl- and analogue-caused deaths in my home State, a 35 percent increase from 2017, but we are unsure that the State is accurately measuring all the effects of fentanyl. Analogues are very hard to track, and especially when screening incidents of overdose, they are difficult to measure. So, I wanted to hear directly from an ER doctor in our community. He works at Jackson Memorial Health System, which covers my district, and he is the medical director of the Florida Poison Control Center and the toxicologist for Jackson Memorial. He outlined the drastic increase in fentanyl-related overdoses that he has witnessed in recent years.

He described to me that just 2 years ago, in one particularly bad day in the ER, he treated 16 fentanyl overdoses in just 1 shift alone. This is just one story from my community. I can tell you hundreds of stories that are similar to those. I wanted to start with Admiral Giroir. I wanted to ask you, going back to Dr. Bernstein's story, why do you think it is so difficult to track fentanyl- and analogue-related deaths?

Admiral GIROIR. So, I think, as you pointed out, we have invested over the last couple of years, with obviously the support of Congress, hundreds of millions of dollars from the CDC to support local testing laboratories. So, in the past, you might not have been able to detect all the analogues. That is really changing very drastically and very rapidly. So, we feel pretty good about our ability to detect, but what we don't want to see is after the person dies, over 2 months for a medical examiner to be able to detect it. We really need to keep them out of the limelight of use to begin with.

We are doing many things right now, for example, trying to do novel things working together with DOJ, like getting anonymized so we don't know who the patient is, but anonymized data from all over the country about urine drug screens at a very high level so we could begin to start seeing in real time when fentanyl analogues or other substances are starting to invade a community. Again, we need to treat patients. It is a chronic brain disease. If a new fentanyl analogue comes around, the local public health department or emergency room may not know that. What if it is a very potent one and you reverse it, and that ER doctor says everything is good, but 30 minutes later the person becomes re-narcotized and back into a coma? So, these are the kinds of things we struggle with. What you talked about, ma'am, that is happening every day all over the country.

Ms. MUCARSEL-POWELL. Yeah.

Admiral GIROIR. There is no question about that, Florida, ma'am, Pennsylvania. I was visiting Pennsylvania. I was just visiting Florida.

Ms. MUCARSEL-POWELL. I do think that, you know, it is a huge systemic problem, but we need to deal with supporting those individuals that have become highly addicted to the substances be-

cause I don't think we do enough to support these centers that treat addiction. So, I mean, it is a whole chain, a whole system. I want to ask very quickly, and I wanted to ask the Department of Justice. Ms. Liskamm, can you tell me what the mandatory sentence is for individuals and the amounts—

Ms. LISKAMM. Sure.

Ms. MUCARSEL-POWELL. —that they carry when you find someone, and you convict someone?

Ms. LISKAMM. Sure. So, with respect to fentanyl analogues, and I am glad you asked this because I think there is a misconception about what levels are actually at those thresholds. To get a 5-years mandatory minimum sentence, in doing the math, with just 2 milligrams of a fentanyl substance being a lethal dose, a 5-year mandatory minimum would require 5,000 lethal doses.

Ms. MUCARSEL-POWELL. A hundred milligrams, correct?

Ms. LISKAMM. Correct.

Ms. MUCARSEL-POWELL. So, that is like half a cup of fentanyl.

Ms. LISKAMM. It is. I don't know how large it is, but 2 milligrams is—

Ms. MUCARSEL-POWELL. I was just looking at the formulas.

Ms. LISKAMM. —2 granulars of salt or something like that.

Ms. MUCARSEL-POWELL. Right. When someone carries 100 milligrams of fentanyl, is that for personal use that you have found, or is it to distribute?

Ms. LISKAMM. So, we would have to look at the circumstances of the case, and that is one of the things that I think is so important to remember. Everyone keeps pointing to the fact that we have the Analogue Act to fall back on. One of the prongs is that the prosecutors must prove under the Analogue Act that something is meant for human consumption, which, in my experience, takes months of investigation to prove that this substance is being used for human consumption. We have wiretaps. We use confidential sources, undercover buys, as opposed to a package coming through the mail or stopping a load coming into the U.S. The government is charged with proving beyond a reasonable doubt that that substance, that kilo of fentanyl crossing the border, is meant for human consumption, which is a large challenge for the prosecutors who are on the line prosecuting these cases every day.

Ms. MUCARSEL-POWELL. Would you say that at the bottom of the distribution chain, those are the people that get convicted at high numbers?

Ms. LISKAMM. No, I actually would disagree with that. The Department is always trying to work those cases up and go after the El Chapo Guzmans, the leaders of these cartels who are responsible for bringing all this poison into the country.

Ms. MUCARSEL-POWELL. What do you need from us?

Ms. LISKAMM. We need permanent class-wide scheduling.

Ms. MUCARSEL-POWELL. Thank you. I yield back.

Ms. BASS. Oh, Mrs. Lesko?

Ms. LESKO. Thank you, Madam Chairman. First, before I ask any questions, I would like to ask unanimous consent to place in the record a letter from the Major Cities Chiefs Association, which represents the police chiefs.

[The information follows:]

MS. LESKO FOR THE RECORD



MAJOR CITIES CHIEFS ASSOCIATION

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Virginia Beach
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Winnipeg, Canada
York, Canada

January 22, 2020

The Honorable Nancy Pelosi
Speaker
United States House of Representatives
Washington, DC 20515

The Honorable Steny Hoyer
Majority Whip
United States House of Representatives
Washington, DC 20515

The Honorable Jerrold Nadler
Chairman
House Judiciary Committee
United States House of Representatives
Washington, DC 20515

The Honorable Kevin McCarthy
Minority Leader
United States House of Representatives
Washington, DC 20515

The Honorable Steve Scalise
Minority Whip
United States House of Representatives
Washington, DC 20515

The Honorable Doug Collins
Ranking Member
House Judiciary Committee
United States House of Representatives
Washington, DC 20515

Dear Speaker Pelosi, Leader McCarthy, Majority Whip Hoyer, Minority Whip Scalise, Chairman Nadler, and Ranking Member Collins,

I write to register the Major Cities Chiefs Association's (MCCA) support of S. 3021, the *Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act*. MCCA membership is comprised of Chiefs and Sheriffs of the sixty-nine largest law enforcement agencies in the United States and nine largest in Canada. Collectively the MCCA represents over 79.9 million people and a workforce of 251,082 officers and non-sworn personnel.

Over the past few years, the opioid epidemic has wreaked havoc on communities throughout the United States. The dramatic increase in drug overdose deaths that accompanied this crisis can be partially traced to fentanyl, a synthetic opioid. For example, in 2016, there were more than 60,000 drug overdose deaths in the United States. Of these overdoses, 42,249 involved opioids, and of those deaths, 45.9 percent involved synthetic opioids such as fentanyl.¹

¹"Overdose Death Rates," *National Institute on Drug Abuse*, January 2019.

<<https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates>>

Attorney General William Barr, "Fentanyl could flood the country unless Congress passes this bill," *The Washington Post*, January 10, 2020. <<https://www.washingtonpost.com/opinions/william-barr-congress->

The Drug Enforcement Administration (DEA) took action to classify fentanyl and its analogues as a Schedule I controlled substance. This scheduling is temporary and is set to expire on February 6th. S. 3021 will extend the temporary scheduling of the fentanyl class for an additional 15 months, until May 6, 2021, providing Congress, the Administration, and other stakeholders additional time to develop a more permanent solution.

If the current scheduling of the fentanyl class is allowed to expire, the United States risks opening itself up to a flood of new fentanyl analogues. Specifically designed to skirt current law, these analogues are slight molecular variations of fentanyl and despite being just as dangerous as traditional fentanyl, are technically new, non-scheduled, and non-controlled substances. Furthermore, if the scheduling of the fentanyl class lapses, the penalties for manufacturing, trafficking, and distributing fentanyl and its analogues will be severely diminished. Classifying the fentanyl class as a Schedule I controlled substance is a strong deterrent to criminals that should be maintained.

For the reasons outlined above, MCCA strongly encourages the House to take up and pass S. 3021 as quickly as possible. We look forward to working with you to advance this important piece of legislation. Please do not hesitate to contact me at art.acevedo@houstonpolice.org if we can be of any assistance.

Sincerely,



Art Acevedo
Chief, Houston Police Department
President, Major Cities Chiefs Association

Mrs. LESKO. Thank you. In that letter, it specifically asked to support Senate Bill 3021 to extend temporary scheduling of the fentanyl class. It also says, "If the current scheduling of the fentanyl class is allowed to expire, the United States risks opening itself up to a flood of new fentanyl analogues," as we have heard already. Specifically designed to skirt current law, these analogues are slight molecular variations of fentanyl, and despite being just as dangerous as traditional fentanyl, are technically new, non-scheduled, and non-controlled substances.

Furthermore, if the scheduling of the fentanyl class lapses, the penalties for manufacturing, trafficking, and distributing fentanyl and its analogues will be severely diminished. Classifying the fentanyl class as Schedule 1 controlled substance is a strong deterrent to criminals that should be maintained. As others have said, at least on my side of the aisle, I wish we had done this sooner instead of waiting until the last minute.

I represent Arizona, and just on January 22nd of this year, just the other day, the U.S. Border Patrol agents in my State seized more fentanyl on a man they arrested that had bags of fentanyl taped to his thighs. This is a fairly common problem and as has been attested, either they are manufacturing these analogues in Mexico, or China is shipping them to cartels in Mexico, and then they are being shipped across the Arizona border and other southern borders, and Canada, so I have heard.

In Arizona, I used to be in the State legislature, and we tried to combat this because the opioid addiction is a huge problem there. We allowed naloxone to be given by pharmacists basically over the counter without a prescriptions. It is prescribed along with opioids over a certain strength, I guess is the right word. One of the changing subjects, one of the concerns that I have about not acting on this is what is going to happen with China. We convinced China to do this and go along and schedule fentanyl, and they did so on May 1st, I think, of 2019. Now we are not going to do it here, and then, you know, what message is that sending to China? I think this is a really bad move, and I am really concerned actually for the lives of all Americans.

One of the questions that I have for you, Doctor, is do you know of any specific cases where research has been hindered because of this class-wide temporary scheduling, because that was one of the concerns that was brought up.

Admiral GIROIR. So I can't give you at this moment in time a specific name of a specific person particularly related to this, but we know that as a general rule, any substance in Class 1 requires very significant research, and I am going to say, of course, we all have to balance the needs, right, because we are worried about diversion, we are worried about people working with those investigators, but it requires a very significant period of time. On average, it could be about 100 days, but it can take up to a year.

It is very complicated. When you want to use another substance or a different protocol even for the same substance, it requires re-application. If you move your laboratory to a different part of the campus, it is unclear whether that needs a whole separate registration or not. If a lot of people work for you, as many of these groups do, it is very unclear still whether all of those need to be reg-

istrants as well. So, what we did together, and, again, we did work this together, is, and I want to be clear. We support, HHS supports, permanent scheduling of fentanyl analogues for all the reasons I said. We would like to see simultaneous, or in the future, the actions that we agreed upon to enable research to continue, because it is a problem with Schedule 1 drugs now, and it could be more of a problem as we schedule 3,000 as part of this class.

Mrs. LESKO. Thank you very much. I think I have gone over time, so I will yield back.

Ms. BASS. Ms. JACKSON LEE.

Ms. JACKSON LEE. Thank you very much and thank you to the witnesses. Good to see you, Dr. Giroir, Admiral, and as well to Ms. Liskamm. Let me say that we have a sense of urgency that I know we are working on, and I thank this Committee for convening this hearing. Let me make a few pointed statements and then raise questions with all of you.

Fentanyl, of course, has been used to enhance other drugs, and it is deadly. I want to make that very clear. It has killed people. I have no opposition. It needs to remain on Schedule 1. I hope we will move as swiftly as possible, but you must separate the two. You must give comfort to loved ones who have lost children, family Members. Fentanyl, my recollection is it came out of China, or at least it has been used, and it has now proliferated here in a deadly manner. So, I am interested in, you know, what you think are your tools that you need.

I do want to go on record that mandatory minimums have never helped anything. It hasn't solved any problems, and I will not cede to that. What I will cede to is what I did when we were discussing in passing legislation in the last 2 Congresses on the issue of drugs. I made note of the point that the rise in empathy for opioid users and the devastation and spread of such did not likewise engage my community in the epidemic of crack and then cocaine. They were victims of mandatory minimums, and it served no purpose, and it created mass incarceration. So, I can't sit here and not put on the record what I am willing to do, which is to have it on the list, Schedule 1, but I want to see what the government intends to do. I think there is a second panel, and I hope to be able to hear from them, but how we intend to raise the ante of treatment and promoting treatment.

So, I will start with you, Admiral, and then to Ms. Liskamm, how will you frame your prosecution, because Schedule 1 puts it clearly in the Department of Justice's wheelhouse, but getting the poor guy or girl down on the street taking this deadly, devastating drug and not trying to respond to the larger marketers and sellers. I want to see what legislative tool you think you need. Obviously, we know what happens with Schedule 1 drugs. DEA, all are involved. How will you focus your efforts in trying to weed this out? So, first, Admiral?

Admiral GIROIR. So, thank you, ma'am. It is good to see you again.

Ms. JACKSON LEE. It is good to see you.

Admiral GIROIR. I have used this analogy before, but I think it works. If I could ask anyone on the Committee to hold their breath for 10 minutes and not breathe, I can ask a person with a chronic

brain disease of addiction of opioid use disorder to just stop. You cannot do it. It is a chronic brain disease that requires treatment, and that is why everything we have been doing at HHS is focused on treatment; of course, prevention, but on treatment, and that treatment requires medications in almost all circumstances. And we work very closely with the DEA and DOJ to be able to do that. Psychosocial support, and it requires wraparound services, right? If a person is on the street, has food insecurity, does not have employment, does not have education, does not have a faith-based home, they are going to go right back to where they were because we must fix those parts of it, too. So, I couldn't agree with you more.

I will just make just a brief comment is that thanks to the work of Congress and working with the Administration, the billions of dollars that have gone on the streets to support States have been used very well to provide naloxone, to provide therapy. What we are trying to enter now, and sort of one of our themes, is more sustainable, resilient solutions. We need to keep supporting, for example, the expansion of the behavioral health workforce that can take care of people with chronic behavioral disorders like addiction, both in our cities as well as in our rural areas. We have to work on ways to make this longstanding because this is not going away tomorrow.

I would just highlight that we all are very afraid and working diligently against the next wave, which are methamphetamines. Now methamphetamines are being combined with fentanyl and fentanyl analogues, which is really an even more poisonous cocktail. So, the next wave is upon us, and we need to keep our efforts going.

Ms. JACKSON LEE. Can she have a second just to answer? DOJ, yes?

Ms. LISKAMM. Yeah, I just wanted to make a couple points. First, I take your comments very seriously, and I just want to assure you that the Department is not targeting drug addicts. We need this tool of permanent class-wide scheduling to go after the cartels, the transnational criminal organizations who are trying to flood our streets in order to make enormous profits.

Ms. BASS. Thank you.

Ms. LISKAMM. I would just also point out that this order has been in effect for almost 2 years now, since February 6th of 2018, and we have not seen the overcriminalization that many critics have pointed to as a concern for the permanent class-wide scheduling. Lastly, I would just point out that the Department is very much committed to its outreach efforts as a part of a sort of whole-of-government approach to solving this crisis, and we have been working, as I mentioned, hand-in-hand with HHS on a number of initiatives. Every district throughout the country has an opioid coordinator, and part of their mission is to not only focus the prosecution efforts, but also the outreach efforts depending on what that district looks like.

Ms. BASS. Thank you.

Ms. LISKAMM. Thank you.

Ms. BASS. Mr. Cline?

Mr. CLINE. Thank you, Madam Chair. I appreciate holding this timely hearing on this issue. I would ask unanimous consent to

enter into the record a letter from the Federal Law Enforcement Officers Association and the National Sheriffs Association urging passage of S. 3201, the Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act.

Ms. BASS. Without objection.

[The information follows:]

Mr. CLINE FOR THE RECORD

January 24, 2020

The Honorable Nancy Pelosi
Speaker
United States House of Representatives
Washington, DC 20515

The Honorable Steny Hoyer
Majority Whip
United States House of Representatives
Washington, DC 20515

The Honorable Kevin McCarthy
Minority Leader
United States House of Representatives
Washington, DC 20515

The Honorable Steve Scalise
Minority Whip
United States House of Representatives
Washington, DC 20515

Dear Speaker Pelosi, Leader McCarthy, Congressman Hoyer, and Congressman Scalise:

On behalf of the undersigned organizations we write to express our strong support for the Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act (S. 3201), which would extend for 15 months the classification of fentanyl-like substances under Schedule I of the Controlled Substances Act. We urge the House to pass S. 3201 to ensure our collective efforts to prevent drug poisoning deaths are not interrupted.

Drug overdose deaths are surging across the country due in large part to synthetic opioids, including fentanyl. To help combat this, the Drug Enforcement Administration has used an authority that Congress granted to temporarily include fentanyl and its analogues under Schedule I. S. 3201 would extend the temporary scheduling for 15 months and it is critical that Congress pass bill before the existing designation expires on February 6, 2020.

We urge Congress to pass this bipartisan legislation to help law enforcement do its part to save lives. We appreciate your efforts to provide resources to counter the drug epidemic impacting our communities. Quickly passing this legislation before February 6, 2020 will allow that important work to continue.

Please do not hesitate to call upon our associations for additional information.

Sincerely,

Federal Law Enforcement Officers Association
National Association of Police Organizations
National District Attorneys Association
National Narcotic Officers' Associations' Coalition
National Sheriffs' Association
Major Cities Chiefs Association
Major County Sheriffs of America
Sergeants Benevolent Association

January 27, 2020

Speaker Nancy Pelosi House
1236 Longworth H.O.B.
Washington, DC 20515

Minority Leader Kevin McCarthy
2468 Rayburn H.O.B.
Washington, DC 20515

House Majority Leader Steny Hoyer
1236 Longworth H.O.B.
Washington, DC 20515

House Minority Whip Steve Scalise
2049 Rayburn H.O.B.
Washington, DC 20515

On behalf of the undersigned organizations, we write to express our concern with the Senate-passed Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act (S. 3201), a bill to temporarily extend the Drug Enforcement Administration's "class-wide" emergency scheduling of fentanyl-related substances. The bill will expose more people to prosecutions seeking harsh mandatory minimum sentences.

While this measure is an improvement over a permanent approach, like the Stopping Overdoses of Fentanyl Analogues Act, it does not address the civil rights implications of the Drug Enforcement Administration's unprecedented placement of a potentially limitless number of substances on Schedule I.¹ We urge leaders in the House of Representatives to ensure that before an extension measure is enacted, the legislation precludes mandatory minimums and protects people with limited knowledge, responsibility, and authority in the importation of fentanyl analogues.

We urge the House to address the following issues as it considers S.3201:

- Substantial increases in the length of sentences and DOJ's intention to seek mandatory minimums in cases prosecuted under the authority of the class-wide ban. **Any extension of the class-wide ban should bar the use of mandatory minimum sentences in cases prosecuted under this authority.** Legislation introduced in the Senate by Senator Rob Portman and three other Senate colleagues attempts to do exactly this. The House should adopt this approach. It has been only a year since Congress and President Trump enacted the First Step Act, which eased the length of some drug sentences and reflected broad bipartisan recognition that mandatory minimum sentences are costly and counterproductive. Congress should not undermine this progress on sentencing reform.
- The directive to the Government Accountability Office to evaluate the class-wide scheduling does not incorporate an examination of the effectiveness of the class-wide approach in reducing overdose deaths from fentanyl and its analogues, reducing demand for and supply of these and other substances, or how this control will interdict and stop extraterritorial manufacturers and exporters, or domestic high-level importers. We are still rebuilding after a failed war on drugs that did not improve public safety, ameliorate the high rates of substance misuse in the United States, or reduce the

¹ "Coalition Opposes S. 1622 Stopping Overdoses of Fentanyl Analogues Act (SOFA)," <https://www.hrw.org/news/2019/07/03/coalition-opposes-s1622-stopping-overdoses-fentanyl-analogues-act-sofa>

demand for or supply of harmful substances. In light of these failures, it is deeply troubling that Congress is considering measures that would expand the Department of Justice's authority to schedule and prosecute substances without analyzing if this measure—founded on the idea that incarceration is the answer to a drug epidemic—will somehow succeed where every similar prior measure has failed. **It is critical that any study evaluating the class-wide ban assess the impacts of this expanded authority on public safety, including overdose deaths and interdiction efforts.**

- Federal sentencing data shows that since 2014 the majority of those sentenced for fentanyl trafficking have been involved at the bottom of the distribution chain (such as street-level sellers and couriers/mules), and available data indicates that the vast majority of those prosecuted did not have clear knowledge that they were trafficking fentanyl.² Additionally, 2018 sentencing data reveals that 77% of individuals sentenced at the federal level for fentanyl trafficking are people of color,³ showing that fentanyl enforcement is exacerbating racial disparities in the criminal justice system.⁴ **Any extension of the class-wide ban should include an analysis of the impact of this expanded authority on the interdiction of high-level exporters, importers, and manufactures of fentanyl and its analogues.**

Congress must resist the appeal of simplistic solutions to complex problems and redouble its investment in public health approaches to reducing fentanyl overdose deaths and decreasing substance misuse rates. A punitive approach to addressing these public health concerns undermines evidence-based health approaches. We cannot allow enforcement-first rhetoric to divert our focus away from public health approaches that have been proven effective in reducing the harms associated with fentanyl and its analogues. Congress should prioritize removing barriers to medication-assisted forms of treatment, increasing access to overdose prevention tools like naloxone, and increasing investments in funding to help communities scale up access to treatment and harm reduction interventions that save lives and aid recovery.

Ultimately, we remain convinced that granting the Drug Enforcement Administration class-wide scheduling authority for fentanyl analogues will exacerbate already disturbing trends in federal drug prosecutions and incarceration levels and excise public health authorities from their critical role in promulgating drug policy. Congress made progress with its bipartisan passage of the First Step Act and we oppose efforts to undermine this reform.

We look forward to working with lawmakers on alternative approaches that would effectively address fentanyl overdoses and reduce the harms and unfairness of federal mandatory minimum sentences, and address our crises of overincarceration. If you have questions or

² "Public Data Briefing: Synthetic Drugs" – United States Sentencing Commission, https://www.ussc.gov/sites/default/files/pdf/research-and-publications/data-briefings/2018_synthetic-drugs.pdf; https://www.ussc.gov/sites/default/files/pdf/research-and-publications/quick-facts/Fentanyl_FY18.pdf

³ "Quick Facts: Fentanyl" – United States Sentencing Commission, https://www.ussc.gov/sites/default/files/pdf/research-and-publications/quick-facts/Fentanyl_FY18.pdf

⁴ "Criminal Justice Reform in the Fentanyl Era: One Step Forward, Two Steps Back," <http://www.drugpolicy.org/resource/criminal-justice-reform-fentanyl-era-one-step-forward-two-steps-back?spJobID=1682077373&spMailingID=41601505&spReportId=MTY4MjA3NzM3MwS2&spUserID=MTAwNiQyOTM2MDMzMAS2>

concerns, please contact Kara Gotsch at kgotsch@sentencingproject.org or Grant Smith at gsmith@drugpolicy.org.

Cc:

House Judiciary Chairman Jerrold Nadler
2141 Rayburn H.O.B.
Washington, DC 20515

Ranking Member Doug Collins
1504 Longworth H.O.B.
Washington, DC 20515

House Subcommittee on Crime, Terrorism, and Homeland Security Chair Karen Bass
2138 Rayburn H.O.B.
Washington, DC 20515

House Committee on Energy & Commerce Chairman Frank Pallone
2125 Rayburn H.O.B.
Washington, DC 20515

House Committee on Energy & Commerce Ranking Member Greg Walden
2322 Rayburn H.O.B.
Washington, DC 20515

Sincerely,

A New PATH (Parents for Addiction Treatment & Healing)
AIDS Alabama
Alliance for Positive Change, LES Harm Reduction Center
American Civil Liberties Union
Baltimore Harm Reduction Coalition
Broken No More
Charles Hamilton Houston Institute for Race and Justice at Harvard Law School
College and Community Fellowship
Colorado CURE
Congregation of Our Lady of the Good Shepherd, U.S. Provinces
CURE BOARD
Desiree Alliance
Dr. Bronner's

Drug Policy Alliance
Drug Policy Forum of California
Empire State NORML
FAMM
FedCURE
Free Minds Book Club & Writing Workshop
Friends Committee on National Legislation
Friends of Recovery New York Dutchess
Harm Reduction Coalition
Health in Justice Action Lab at Northeastern University School of Law
Human Rights Watch
International CURE
Iowa Justice Action Network/Catholic Charities
Justice Arts Coalition
Justice Roundtable
LatinoJustice PRLDEF
Law Enforcement Action Partnership
Legal Action Center
Life for Pot
Multidisciplinary Association for Psychedelic Studies
NAACP
National Advocacy Center of the Sisters of the Good Shepherd
National Association of Criminal Defense Lawyers
National Association of Social Workers
National Center for Lesbian Rights
National Center for Transgender Equality
National Juvenile Justice Network
National LGBTQ Task Force Action Fund
NETWORK Lobby for Catholic Social Justice
Operation Restoration

Prevention Point Pittsburgh
Protect Families First
R Street Institute
Reframe Health and Justice
Research For A Safer New York
Safe Streets Arts Foundation
Safer Foundation
StoptheDrugWar.org
Students for Sensible Drug Policy
Substance Use Policy, Education, and Recovery PAC
Texas CURE
The Center for HIV Law and Policy
The Leadership Conference on Civil and Human Rights
The Sentencing Project
The Taifa Group
The United Methodist Church - General Board of Church and Society
Treatment Action Group
Treatment Communities of America
Trinity United Church of Christ, Chicago
Truth Pharm
Virginia CAN (Change Addiction Now)
VOCAL-NY
Witness to Mass Incarceration
Women With A Vision

Mr. CLINE. Madam Chair, I want to thank the witnesses for being here as well. The opioid crisis has ravaged our Nation and has touched the lives of thousands of American families who have lost loved ones to this terrible plight. Since 2013, fatal drug overdoses have been the leading cause of unnatural deaths in my home State of Virginia. In 2018, 54 percent of the fatal drug overdoses in Virginia were caused by fentanyl. In total, there were over 800 fatal fentanyl-related drug overdoses, and over 300 were from fentanyl analogues.

Later today, this Committee will hear firsthand from Dr. Donald Holman, whose family previously lived in Lynchburg in the 6th Congressional District of Virginia and has been forever impacted by the opioid crisis. Tragically, Mr. Holman lost his son, Garrett, in 2017 after he took a synthetic opioid delivered through the mail. The courage of the Holman family has shown to tirelessly advocate to keep these dangerous drugs off our streets is inspiring. Mr. Holman's story and Garrett's story offers Members of Congress and others a window into the opioid crisis, which has taken a heavy toll on our local communities.

In just a few short days, the DEA's emergency scheduling will end, and communities already battling opioid addiction will face a wave of deadly drugs flooding our cities and towns if Congress does not Act swiftly. Yes, the issue of mandatory minimums is one that we should debate, but in the meantime, people are dying, and we can take action to prevent these tragedies from occurring. I hope my colleagues here in Congress will come together to ensure that dangerous fentanyl analogues remain scheduled and are kept off our streets.

So, I would ask Ms. Liskamm, you stated that the quantity of analogues seen in law enforcement actions has decreased since the class scheduling was enacted 2 years ago. Are we seeing fewer fentanyl analogues at land border seizures as well?

Ms. LISKAMM. I can't speak to the border seizures as the Department of Homeland Security through Customs and Border Patrol controls that area. I do know that, my understanding is at least, that the data that DEA is reporting with respect to a 50 percent decrease are for fentanyl analogues that are coming in through any manner. I don't have the statistic, but we have definitely seen a large decrease in the amount of fentanyl and fentanyl analogues coming through the mail from China. So, again, this is a testament to the fact that this scheduling order is working.

Mr. CLINE. How has the current temporary scheduling order helped DOJ in their efforts to pursue and prosecute individuals for drug trafficking? If you could focus on the process by which they are sent through the mail.

Ms. LISKAMM. Sure. So, I think the biggest distinction is that DOJ prosecutors are able to prosecute these crimes under title 21, United States Code 841, as opposed to using the Analogue Act. Under the Analogue Act, which is incredibly resource and time consuming, the Department is required to prove that the substances are intended for human consumption, that they are chemically similar to the underlying substance, such as fentanyl in this case, and that they have the same—I am summarizing here—but the same psychostimulant effect.

That requires experts on both sides. Many of those experts are actually DEA chemists who are being taken away from labs and actually testing the drugs. The prosecutors have to get savvy on all of this type of lingo. They have to educate the jury and the judge, and then they have to sort of walk the jury through and get them to a point where they can find this individual guilty beyond a reasonable doubt. It is a huge resource drain, and being able to prosecute under title 21, 841 and 846, allows us to go after these transnational criminal organizations and use our resources correctly.

Mr. CLINE. Good. What would be the impact on communities already battling the opioid epidemic if Congress doesn't extend the scheduling of fentanyl-related substances?

Ms. LISKAMM. So, again, I think we can point to what we have seen over the past 2 years: A 50 percent decrease in the amount of fentanyl analogues coming in. That is what the communities are seeing on the street, a 50 percent decrease in these substances that are killing Americans.

Mr. CLINE. Thank you. Madam Chair, I yield back.

Ms. BASS. Mrs. McBath?

Mrs. MCBATH. Thank you, Madam Chair. Thank you both so much for being here today and being here to discuss this serious public health crisis that we have before us. I want to thank the many researchers at the Centers for Disease Control and Prevention, which is part of my district and basically near my district. Their research is critical to making sure that we are making informed decisions that will our communities and our loved ones safe.

Admiral, in your testimony, and I have actually had a chance to read a bit of your testimony, you discuss several recommendations that are a part of what you described as an interagency solution that balances the need to restrict access to these substances with the need for continued research. Are there any policies that you feel are especially important so that we can continue to get a better understanding and a better sense of this life-threatening problem without overburdening our researchers?

Admiral GIROIR. Yes, ma'am, thank you, and thank you for reading the testimony. We outlined about 8 steps that we agreed to, and, again, I want to say this was truly interagency. We had Members of the Centers for Disease Control and Prevention, multiple centers at the National Institutes of Health, the FDA, as well as representatives of myself, along with Mr. Dhillon, the administrator of the DEA, and Deputy Attorney General Jim Carroll, that we all worked on this together because we do recognize there is a balance that we need to achieve both goals. We need to get analogues and keep them off the street and keep them scheduled, but we do need to make both these and other Schedule 1 substances more available to CDC, NIH, even the FDA to approve drugs.

So, we outlined those 8 simple steps that might not be all inclusive, and one of those steps was that the Attorney General and the Secretary of HHS would put a task force together to really look at this comprehensively to see if there were further things we can do. But clearly the first 7, as we saw in the testimony, I don't want to waste your time, but would be really, really important, and everybody around the room agreed.

Mrs. MCBATH. Thank you for that. Also can you elaborate on how HHS considers the impact of special populations, such people that have particular illnesses, and how do we make sure that we are keeping kids safe from these dangerous drugs, while also making sure that researchers are fully able and capable to seek out new treatment?

Admiral GIROIR. Yes, ma'am. Special populations are a particular interest. I am a pediatric intensive care physician by training, and so taking care of children from newborns to 15- or 16-year-olds are what I do and what my passion is for. So let me say that we are investing an enormous amount of resources, for example, in children who are born dependent on opioids because their mothers were using opioids. We approach this as a treatment, right? We must keep the mother and child together. We want them both to recover. The NIH is investing literally \$50, \$60 million into their program for that.

I am personally very concerned. One of our big initiatives is also to not deny pain medications to special populations who need it. For example, patients with cancer, or I am a particular advocate for children and adults with sickle cell disease. In our reports, for example, our pain management task force, there is a whole section treating special populations, like people with sickle cell disease, like people with cancer or with other chronic illnesses, because we don't want to devastate people who are in real pain when they really need the drugs while we are achieving this. So, there are a number of special populations, and I would be happy to go through them with you, to make sure we get all of them because we want to treat everyone, not just the average person but everyone and their particular needs. We want to meet them where they are.

Mrs. MCBATH. Right. Thank you for that answer. Ms. Liskamm, we all want to keep these dangerous substances away from our communities, and especially away from our children, and some have recommended tough criminal penalties that actually do that. We also want to make sure that if these drugs do reach our communities, the emergency responders and medical professionals are able to intervene to prevent these tragedies. How can we make sure that these goals don't conflict?

Ms. LISKAMM. I don't believe that they do conflict. The Department is very much committed to outreach efforts targeting children to make sure that they are not getting involved in experimenting with opioids and getting addicted to them. One of the districts has an opioid youth summit where they send a youth ambassador from each high school to learn from victims' family Members, law enforcement, and public health officials about the dangers of opioid use, and then brings that back to their high schools to tell everyone about that, what they have learned. That is an incredibly important part of what the Department is doing, but it is separate and apart from the tools that we need to go after these transnational criminal organizations that are flooding our communities with this incredibly lethal poison. So, I think that we can sort of accomplish both of those through the Department's efforts.

Mrs. MCBATH. Thank you.

Admiral GIROIR. With your permission, I just want to highlight Drug Takeback Day is very important. Many children get first ex-

posed to opioids by leftover drugs in the cabinet, and this has been a tremendous national success. About 1 million pounds of pills are turned in for destruction multiple times per year, so getting rid of those excess drugs so they don't fall into the hands of your children or your relatives is still a very important thing that we do.

Mrs. MCBATH. Thank you.

Ms. BASS. Mr. Gohmert?

Mr. GOHMERT. Thank you, Madam Chair, and I appreciate having this hearing. I am glad we are having it before the expiration of the laws that restrict fentanyl and its analogues. I guess we could have had it last year, but time was of the essence. The President was a clear and a present danger. That was before the month we didn't take up impeachment after it was passed in the House. But eventually we got around to this hearing, and obviously it is important, as the Holmans know, having lost a son. We are talking about something that is extremely addictive, and I am glad, Admiral Giroir, to hear you say you are in favor of continuing the listing because I had concerns from your written testimony that you might want to see that eased up so it would be easier for researchers to get to fentanyl analogues. Clearly that is something we need to work on so it is easier for researchers to get it.

Fentanyl is used in some lawful medications, right? I mean, I tore my meniscus in the congressional baseball game, and when I had surgery, I said as I was about to go under, what is in this anesthesia, and he named a couple of things and said "fentanyl." I went "fentanyl," and that was the last thing I heard before I went out.

[Laughter.]

Mr. GOHMERT. Also, you had mentioned the DEA. I am surprised the majority did not want to hear from the DEA. They did not want to hear from the Office of National Drug Control Policy. From my experience as a felony judge, nobody knows more about the illegal drug situation in America than the DEA, would you all agree with that, from the law enforcement standpoint?

Ms. LISKAMM. I think that DEA is one of the preeminent experts on drug trafficking trends, both international and domestically.

Mr. GOHMERT. Admiral, have you had that experience?

Admiral GIROIR. Yes, sir, and literally every week, if not multiple times a week, the interagency, including DEA, ONDCP, DOJ, and myself, HUD, are all around a single table. So, we are pretty highly coordinated.

Mr. GOHMERT. I have here a letter from the national President of the National Fraternal Order of Police, Patrick Yoes, and he says he is "writing on behalf of the Members of the Fraternal Order of Police to advise you of our strong support for the swift consideration and passage of S. 3201"—that is the Senate bill—"Temporary Reauthorization and Study of Emergency Scheduling of Fentanyl Analogues Act, which the Senate passed by unanimous consent. The legislation would extend for 15 months the classification of fentanyl as a Schedule 1 drug, a classification which expires 6 February." Next week. "For this reason, the consideration and passage of this bill is a matter of some urgency as drug overdose deaths are surging across the country," although we know that actually since it has been listed, Ms. Liskamm, as you indicated,

17,000 contacts by our law enforcement have been reduced to 8,000. You know that has got to mean fewer deaths as a result. It seems to me, from what I have seen, if law enforcement is having half as much contact with the drug that normally can be projected, that there is probably half as much coming in as there was previously. Would you agree?

Ms. LISKAMM. I would, sir.

Mr. GOHMERT. Okay. Anyway, it just goes on to make the point that the police across the country, the National Order, they all agree this needs to be listed. Like I say, Admiral, we want to make it easier for researchers to get it, use it, and find answers, but I understand the problem here has been some in the majority were very concerned about mandatory minimums. In Texas, we call that a range of punishment. There is a low level, and then there is minimum and a maximum, and depending on the level of the crime, that determines the minimum and the maximum, and it is a good way to do things, as I found having sent someone to prison whose family hated my guts. They were extremely wealthy, but she had experimented with everything, and her mother says, thank you, you saved our daughter's life. It can help. We do need addiction centers to deal with some prisoners, and I hope we can work together on that. I yield back.

Ms. BASS. For the record, the Committee did invite the DEA, and we were honored that they recommended Ms. Liskamm to come.

Mr. GOHMERT. Madam Chair, could I offer or ask unanimous consent to—

Ms. BASS. Without objection. Ms. Jackson Lee wants to enter some articles.

Ms. JACKSON LEE. Yes, thank you so very much, Madam Chair. A letter from nearly 70 organizations that outline their concern about extending the DEA quickly; a statement for the record submitted by the American Psychological Association; a letter from the American Society for Pharmacology and Experimental Therapy; a letter from Charles P. France, Ph.D., professor, about concerns of this legislation; a letter from the Sentencing Project regarding today's hearing; a letter from the Drug Policy Alliance regarding today's hearing; a January 2020 report from the Drug Policy Alliance, titled, "Criminal Justice Reform in the Fentanyl Era"; and finally, a January 26th, 2020 Washington Post op-ed by Nancy Gertner, titled, William Barr's New War on Drugs. I ask unanimous consent that each of these be submitted to the record.

Ms. BASS. Without objection.

[The information follows:]

MS. JACKSON LEE FOR THE RECORD



Statement of the American Psychological Association

Submitted January 28th, 2020 to the
 United States House Committee on the Judiciary,
 Subcommittee on Crime, Terrorism, and Homeland Security
 The Honorable Karen Bass, Chairwoman

"Fentanyl Analogues: Perspectives on Classwide Scheduling"

Dear Chairwoman Bass, Vice-Chairwoman Demings, and Ranking Member Ratcliffe:

On behalf of the American Psychological Association (APA), we are writing to express our views on [H.R. 2935](#), Stopping Overdoses of Fentanyl Analogues (SOFA) Act and the class-wide Scheduling of fentanyl analogues. We share the concerns of the Judiciary Committee and sponsors of H.R. 2935 about the opioid epidemic and its devastating consequences for millions of Americans, their families, and their communities. According to the Centers for Disease Control and Prevention, an estimated [47,600 Americans died](#) in 2017 as a result of using opioids (mostly synthetic opioids other than methadone). One of the main reasons for that dramatic and disturbing increase is the spread of fentanyl, a synthetic opioid that is inexpensive and potent, as well as its analogues.

APA supports robust, science-based efforts to curb the illicit sale and use of synthetic fentanyl analogues. APA is the largest scientific and professional organization representing psychology in the United States, and works to promote the advancement, communication, and application of psychological science and knowledge to benefit society and improve lives. Our membership includes more than 121,000 researchers, educators, clinicians, consultants, and students. Two APA Divisions, Psychopharmacology and Substance Abuse ([Division 28](#)), and the Society of Addiction Psychology ([Division 50](#)) are dedicated to understanding the prevention, etiology, and treatment of substance use and substance use disorders.

APA agrees with the spirit of H.R. 2935 but we are concerned about the recent Senate vote to extend the temporary emergency scheduling of synthetic fentanyl analogues that was due to expire February 6, 2020. We support efforts to give the Drug Enforcement Administration (DEA) authority to control the importation and distribution of synthetic fentanyl analogues, but we also believe that any legislation to address this issue should include language reducing some of the barriers to research currently imposed by



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Schedule 1 registration requirements and we are concerned about the unintended negative consequences of including such a broad range of substances in the scheduling language.

Psychologists have played pivotal roles in the development of the three medications currently approved for the treatment of Opioid Use Disorder (methadone, buprenorphine and naltrexone) and for opioid overdose (naloxone). The barriers to research imposed by Schedule 1 requirements could limit the ability of scientists to conduct research on the behavioral and pharmacological properties of fentanyl analogues and develop medications to treat use of and overdose on these substances.

For example, the current language in the temporary emergency scheduling action of fentanyl analogues is overly broad and could result in a potential antidote to fentanyl overdose (e.g., a fentanyl antagonist with no abuse liability) inadvertently being placed in Schedule 1. Any further expansion of the language describing fentanyl analogues could have even greater negative implications for the development of therapeutically useful medications. The Department of Health and Human Services (HHS) detailed these potential negative consequences in a [letter to Senator Durbin](#) dated October 31, 2019. That letter further detailed several proposed steps that would alleviate at least some of the regulatory burden for scientists studying fentanyl analogues and other Schedule 1 compounds.

The chemical structure of a fentanyl analogue does not necessarily predict its pharmacologic activity. Several behavioral assays have been developed by psychologists to assess the [abuse liability](#) (e.g., conditioned place preference, self-administration and drug discrimination) and analgesic activity (e.g., tail flick, hot plate) of novel compounds in non-human animal models. We are aware that the National Institute on Drug Abuse, the Food and Drug Administration, and the DEA already collaborate through the Interagency Committee for Drug Control (ICDC) to review and prioritize compounds that require analysis for scheduling purposes. We understand that the ICDC uses a variety of existing techniques to characterize the behavioral pharmacology of novel compounds rather than inferring pharmacologic activity based on structure. As synthetic compounds continue to proliferate on the illicit drug market, we recommend that additional resources be devoted, as needed, for the rapid analysis of compounds under ICDC review.

In closing, we strongly urge you to consider both the unintended consequences of class-wide scheduling of fentanyl analogues and the steps outlined by HHS to reduce the regulatory burdens placed on scientists conducting research with Schedule 1 compounds. We thank you for holding today's hearing and for considering our position on these otherwise laudable efforts to address this serious public health issue. If you have any questions or need additional information, please contact Geoff Mumford, PhD, directly at 202.336.6067 or gmumford@apa.org.



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The Honorable Karen Bass
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January 27, 2020

Chairman Nadler and Ranking Member Collins,

The American Society for Pharmacology & Experimental Therapeutics (ASPET) is concerned about the impact to pharmacological research and human health of S. 3201, the Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act. This bill extends the expiration of the Drug Enforcement Administration's (DEA) Temporary Emergency Scheduling Order of fentanyl-related substances until May 2021. ASPET strongly believes that classwide scheduling inhibits the very research that will help solve the abuse potential of fentanyl analogues and possibly result in new therapeutic treatments for overdose and addiction.

ASPET is a 5,000-member scientific society whose members conduct essential basic and clinical pharmacological research and are employed by academia, government, large pharmaceutical companies, small biotech companies, and non-profit organizations. ASPET members work in a variety of different fields and their efforts help to develop new medicines and therapeutic agents to fight existing and emerging diseases.

While ASPET understands that the proliferation of fentanyl analogues compelled the DEA to invoke its temporary scheduling authority, using that authority to schedule an entire class of substances creates arbitrary, scientifically unjustified decisions with potentially adverse consequences. Classwide scheduling operates under the presumption that all members of the same chemical class will share the same properties. However, very minor rearrangement of the exact same molecule can change its properties. For instance, naloxone could be considered an analogue of morphine; under classwide scheduling, naloxone might have been placed into Schedule I, yet it is the very antidote to opioid poisoning. To ensure that such unintended consequences do not occur, it is imperative

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that the government rely on its scientific agencies (i.e., the Food and Drug Administration, the National Institute of Drug Abuse) to provide input on scheduling decisions.

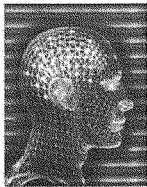
A Schedule 1 classification—even a temporary classification—increases the regulatory burden on researchers significantly. The cost of licensing, the extended wait time to receive approval, the limitations on supply, the storage requirements, and mandatory inspections all contribute to making research on Schedule 1 drugs burdensome and potentially prohibitively difficult. The delays that researchers face mean they are unable to rapidly respond to the emergence of new drugs of abuse and assist law enforcement and health practitioners by providing information on a substance such as its dependence liability and the scope and duration of its effects. Complicating and further compounding these impediments is the requirement that even with the addition of the DEA code for all fentanyl analogues (DEA Code 9850) onto a researcher's DEA Schedule I registration, they still have to separately apply for approval to conduct research with any fentanyl analogue that has been individually scheduled in order to obtain and conduct research with such a compound. Placing all fentanyl analogues into Schedule I will foreclose research opportunities for all but the small number of investigators that possess a Schedule I license and make it more difficult for those that do. An extension of a Schedule I classification will eliminate an important avenue of research that has the potential to ameliorate the effects of the ongoing opioid crisis, and possibly lead to more effective treatments for pain.

ASPET believes science has a role to play in protecting individuals from the harms caused by drug abuse. To do that, however, researchers need access to those drugs so that they may study the benefits and risks associated with their use. ASPET urges the committee to consider alternative methods to classwide scheduling.

Respectfully,



Wayne L. Backes, PhD
President



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FRIENDS of NIDA

July 25, 2019

The Honorable Lindsey Graham
Chairman
U.S. Senate Committee on the Judiciary
224 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Dianne Feinstein
Ranking Member
U.S. Senate Committee on the Judiciary
152 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman Graham and Ranking Member Feinstein,

On behalf of the Friends of NIDA we are writing to express our views on S.1622, Stopping Overdoses of Fentanyl Analogues (SOFA) Act. The Friends of NIDA represents hundreds of scientific organizations, service providers and patient advocate groups who collectively work to support funding for the National Institute on Drug Abuse and the application of that research to advance our understanding of the prevention, etiology and treatment of drug use, abuse and dependence.

We share the concerns of the Judiciary Committee and sponsors of S.1622 about the opioid epidemic and its devastating consequences for millions of Americans, their families, and their communities. According to the Centers for Disease Control, an estimated 28,466 Americans died in 2017 as a result of using synthetic opioids other than methadone. One of the main reasons for that dramatic and disturbing increase is the spread of fentanyl, a synthetic opioid that is inexpensive and potent, as well as its analogues. The Friends of NIDA support robust, science-based efforts to curb the sale and use of synthetic analogues.

The Friends of NIDA agree with the spirit of S.1622 but we are concerned about pending Senate Judiciary Committee action that would make the temporary emergency scheduling of synthetic fentanyl analogues permanent. We support efforts to give the Drug Enforcement Administration (DEA) authority to control the importation and distribution of synthetic fentanyl analogues, but we also believe that any legislation to address this issue should include language reducing some of the barriers to research currently imposed by Schedule 1 licensing requirements and we are concerned about the unintended negative consequences of including such a broad range of substances in the scheduling language.

The barriers to research imposed by Schedule 1 requirements could limit the ability of scientists to understand the pharmacology of these newer more powerful opioids and develop medications to treat use of and overdose on these substances. For example, the current language in the temporary emergency scheduling action of fentanyl analogues is broad and could result in a potential antidote to fentanyl overdose (e.g., a fentanyl antagonist with no abuse liability), inadvertently being placed in Schedule 1. Any further broadening of the language describing fentanyl analogues could have even greater negative implications for the development of therapeutically useful medications that have no opioid activity.

We strongly urge you to involve the National Institute on Drug Abuse and the Food and Drug Administration, in any decisions regarding scheduling of synthetic fentanyl analogues. We thank you for considering our position on these otherwise laudable efforts to address this serious public health issue. If you have any questions or need additional information, please contact Geoff Mumford, PhD, directly at gmumford@apa.org.

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Sincerely,

American Academy of Addiction Psychiatry
American Academy of Neurology
American College of Neuropsychopharmacology
American Psychological Association
AMERSA
College on Problems of Drug Dependence
Friends of the National Institute on Alcohol Abuse and Alcoholism
Friends of the National Institute on Drug Abuse
National Alliance for Medication Assisted Recovery
National Families in Action
Treatment Communities of America



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The Honorable Doug Collins
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The Honorable Karen Bass
Chairwoman
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The Honorable John Ratcliffe
Ranking Member
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27 January 2020

RE: Fentanyl Analogues: Perspective on Classwide Scheduling

I am Professor of Pharmacology and Psychiatry and the *Robert A Welch Distinguished University Chair in Chemistry* at the University of Texas Health Science Center in San Antonio Texas. For the past 40 years, my laboratory has studied drug addiction while supported predominantly by research grants from the National Institute on Drug Abuse, National Institutes of Health (NIH), and in collaboration with numerous pharmaceutical and biotechnology companies. We have contributed to the development of FDA-approved medications and we have terminated the development of compounds that displayed adverse effects in laboratory studies. I am also the President Elect of the *American Society for Pharmacology and Experimental Therapeutics*, a nearly 5,000-member scientific organization dedicated to the study of drugs and the discovery of new therapeutics.

I am writing to express my concerns regarding congressional efforts to legislatively add compounds to Schedule I of the Controlled Substance Act, in the absence of direct scientific evidence for potential harmful effects of those compounds. The third wave of the ongoing opioid crisis (first prescription opioids, then inexpensive heroin, and now synthetic opioids) is especially challenging because fentanyl and related analogs are exceptionally potent, inexpensive, and easy to synthesize. Small modifications in these molecules can have profound effects of their activity, changing an inactive compound to an exceptionally potent opioid with high abuse potential. On the other hand, this chemical class includes compounds that are or could be useful for treating pain, inflammation, gastrointestinal diseases, and addiction, among others. Putting all fentanyl-related molecules into DEA Schedule I will undoubtedly decrease the likelihood of researchers being able to identify and exploit the therapeutic potential of compounds in this chemical class. This situation poses a formidable challenge to Congress and the Drug Enforcement Administration (DEA) since there are literally thousands of (existing or potential) fentanyl analogs, some of which have high abuse and dependence potential. In the face of the opioid crisis, it is tempting to globally put all compounds that are chemically similar to fentanyl in Schedule I; however, I believe that such an action would have little impact on the manufacture, distribution, and abuse of fentanyl-related compounds, while severely limiting biomedical research and, in the long term, adversely impacting public health. The opioid crisis is a very challenging public health issue and, arguably, we are not winning that battle despite our current research efforts. To further restrict research by limiting access to potentially important compounds, based solely on chemical structure, is not likely to facilitate progress in this arena.

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Because I have had a DEA Schedule I license for nearly 30 years, I know first-hand the hurdles that researchers encounter when working with compounds in this scheduling category. Getting a Schedule I registration is complicated, burdensome, and can take a long time (e.g., more than a year), disincentivizing researchers in general and particularly young researchers (e.g., graduate students and postdoctoral fellows) who often need to complete their studies on strict academic schedules. Moreover, the additional security that is necessary for handling Schedule I substances can be prohibitively expensive, particularly for young investigators in the current climate when securing NIH funding is very challenging. Specialized safes, locking refrigerators and freezers, video surveillance, and renovations can be expensive, and institutions often are not willing to pay these costs. Each additional Schedule I compound that I want to study needs a protocol review that can take many months. Even for someone like me who has been conducting research in this area for many years and has an efficient, well-funded laboratory, the delay in obtaining Schedule I compounds for experiments is prohibitively long and significantly impedes progress. Moreover, despite having a DEA Schedule I registration, importation from outside the US of a Schedule I compound that proved to have significant therapeutic value and no abuse liability, required nearly two years. In fact, the conditions that apply to Schedule II substances, including very potent fentanyl analogs such as carfentanil, are comprehensive, appear adequate to protect public health, and are considerably less burdensome compared with Schedule I.

Investigators like me have dedicated our careers to research in this area because we want to make a difference in protecting individuals from the devastation caused by drug abuse. But we believe that more information, not less, is the most likely way we can achieve that goal. I encourage you and your colleagues to consider alternative approaches so that the potential benefits and risks of new chemical entities can be characterized before decisions are rendered regarding DEA scheduling.

Respectfully yours,



Charles P France, PhD

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The Honorable Jerrold Nadler
Judiciary Committee
U.S. House of Representatives
Washington, DC 20515

The Honorable Doug Collins
Judiciary Committee
U.S. House of Representatives
Washington, DC 20515

January 28, 2020

Re: Hearing - Fentanyl Analogues: Perspectives on Classwide Scheduling

Dear Chairman Nadler and Ranking Member Collins:

Thank you for holding this important hearing today regarding legislation to extend the Department of Justice's broad authority to classify fentanyl analogues as Schedule I substances and expose more people to harsh mandatory minimum sentences for drug offenses. The Sentencing Project opposes S. 3201, the Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act, and urge you to exclude the application of mandatory minimum sentences for cases prosecuted under this authority before it proceeds to a floor vote.

Just one-year after the president signed the First Step Act, the House of Representatives is preparing to approve S. 3201, a measure that would expose greater numbers of people to mandatory minimum penalties including in cases involving trace amounts of these substances. This effort contradicts the very premise of fairness and proportionality that led this Committee in a bipartisan way to support sentencing reforms just one year ago. I urge you to carefully consider the ramifications of this legislation which will exacerbate the already significant harm caused by the War on Drugs.

Indeed, the *Washington Post* on Sunday, January 26, published a column by retired U.S. District Court Judge Nancy Gertner that urged caution on this matter:

We must do everything we can to stop the opioid epidemic, but not with the failed policies of the past. The opioid epidemic persists despite decades of the punitive approach [Attorney General] Barr touts. Since 2014, federal prosecutions for fentanyl have increased more than 4,700 percent. In recent decades, such an approach has resulted only in mass incarceration — a nearly 790 percent increase in the federal prison population from 1980 to its peak in 2013, disproportionately impacting people of color.

According to the Sentencing Commission, most people sentenced for fentanyl trafficking in 2016 were deemed low-level, including mules or couriers (25.5 percent) and street-level sellers (23.5 percent). In 2018, 77 percent of those prosecuted for fentanyl were black or Hispanic. With passage of S. 3201 the trajectory of federal prosecutions in these cases, which overwhelmingly impact people who never knew a fentanyl analogue was present, will only get worse.

I am enclosing with this letter a copy of Judge Gertner's entire *Washington Post* [Op-Ed](#). I ask that it be included in the record of today's hearing.

Thank you for considering the concerns of The Sentencing Project. The organization looks forward to working with you to ensure our federal criminal justice policies are fair and effective.

Sincerely,

A handwritten signature in dark ink, appearing to read "Marc Mauer". The signature is fluid and cursive, with the first name "Marc" and last name "Mauer" clearly distinguishable.

Marc Mauer
Executive Director

January 28, 2020



The Honorable Karen Bass
 United States House of Representatives
 House Committee on the Judiciary
 Chairwoman, Subcommittee on Crime, Terrorism and Homeland Security
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 Washington, D.C. 20515

The Honorable John Ratcliffe
 United States House of Representatives
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 Ranking Member, Subcommittee on Crime, Terrorism and Homeland Security
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Dear Chairwoman Bass and Ranking Member Ratcliffe:

The Drug Policy Alliance is the nation's foremost organization promoting alternatives to current drug policy that are grounded in science, compassion, health and human rights. We appreciate the opportunity to submit comments on the topic of today's hearing entitled "Fentanyl Analogues: Perspectives on Classwide Scheduling."

In February 2018, the Drug Enforcement Administration (DEA) used its emergency scheduling authority to include fentanyl-related substances in Schedule I.ⁱ This "class-wide" emergency ban, effectively placed substances chemically similar to fentanyl—in *existence or not*—in Schedule I. The class-wide ban means that any substance in the future deemed by the DEA (either prior to or after interdiction) to have been produced by certain modifications to the fentanyl structure would be included in Schedule I. This emergency scheduling order expires on February 6, 2020.

As this expiration date has neared, the DEA and Department of Justice (DOJ) have requested Congress to pass legislationⁱⁱ to permanently extend the class-wide ban. We have grave concerns that making this class-wide ban permanent would exacerbate already disturbing trends in federal prosecutions for fentanyl trafficking, including racial disparities in sentencing, and relies on a flawed approach to scheduling, which may inadvertently exacerbate the overdose crisis. It may also set a dangerous precedent for scheduling and prosecuting substances where the DEA will have the ability to circumvent regular process, whereby scheduling a substance requires proving the substance has abuse potential.

Making permanent the class-wide ban could exacerbate disturbing trends in federal prosecutions for fentanyl trafficking.

Extending the life of the class-wide emergency ban would entail a huge increase in penalties by making substances currently prosecuted using the Analogue Act subject to Schedule I penalties. As an example, under the Analogue Act, possession with intent to distribute would generate a

20-year maximum sentence for a defendant.ⁱⁱⁱ Once the substance is classified as a Schedule I analogue of fentanyl under the class-wide ban a defendant with 100 grams or more of it would likely face a 10-year mandatory minimum sentence and a maximum of life in prison.^{iv} Evidence that the charged substance could have no effect on the human body would be irrelevant to the accused's defense.^v

Extending the class-wide ban would exacerbate fentanyl trafficking prosecutions that have disproportionately targeted low-level cases and communities of color. According to the United States Sentencing Commission, more than 50% of those sentenced for fentanyl trafficking in 2016 were defendants involved at the bottom of the distribution chain, couriers/mules (25.5%) and street-level sellers (23.5%).^{vi} In 2018, nearly half of individuals prosecuted for fentanyl cases were convicted of offenses carrying mandatory minimum penalties, and people of color comprised more than 77% of those prosecuted, indicating significant racial disparities in fentanyl sentencing. Of those sentenced, 15.3% received a decreased sentence for having a minor of minimal role in the offense; and 24.6% were safety valve eligible — meaning they were low-level, with minimal criminal histories.^{vii}

Moreover, the vast majority of those prosecuted in 2016 did not have clear knowledge that they were trafficking fentanyl. Only 15.7% reported even *knowing* they were trafficking fentanyl, raising mens rea concerns. This is a very common occurrence since most drug sellers and individuals involved in the lower rungs of the distribution chain have no way to know the composition of illicit substances. It also raises the question: how can tough sentences be a deterrent for behavior that people cannot prevent and may not even know they are engaging in?

Despite this lack of knowledge, people are subject to mandatory minimum sentences for fentanyl analogues under Schedule I when only a “detectable” amount is present in a substance of 10 grams - the weight of 10 paperclips. It takes only a trace amount of a fentanyl analogue to trigger a mandatory minimum. Yet, there is no available data about the average weight and purity in analogue cases involving a fentanyl-like substance. This is a factor to be taken under consideration in prosecutions that utilize a class-wide scheduling authority and applicable statutory penalties for controlled fentanyl-related substances.

Legislative proposals^{viii} that extend the class-wide ban fail to specifically prioritize high-level traffickers, but rather apply severe penalties, including mandatory minimums, indiscriminately across the distribution chain. The practical effect of these proposals, given sentencing trends, is to incarcerate people for even the most minor fentanyl trafficking crimes.

When these sentencing elements are taken together, the punitive response to fentanyl-related substances that is deployed by the class-wide ban is reminiscent of the harsh sentencing approach taken with crack cocaine in the 1980s. Earlier this month, the Drug Policy Alliance released a new report^{ix} entitled “*Criminal Justice Reform in the Fentanyl Era: One Step Forward, Two Steps Back*” that examines illicit fentanyl’s role in the overdose crisis and why punitive approaches to dealing with fentanyl-like substances will only exacerbate the harms caused by these substances. Key findings from the report include:

- Harsh penalties for fentanyl lead to more potent forms of fentanyl available for use, as underground chemists attempt to circumvent laws. This punitive approach also drives people who use drugs from seeking health services and instead encourages them to engage in riskier drug activity in an effort to avoid law enforcement but that can also increase overdose risk.
- Federal fentanyl laws are more likely to be used on individuals at the lowest levels of drug distribution chains who are often not even aware that the drugs they are selling contain fentanyl.
- Low-level drug sellers are often drug users too. Lawmakers must focus on public health approaches to fentanyl use rather than a punitive one that fails to account for drug sellers who are also drug users and could also benefit from greater access to life-saving treatments.
- The availability of illicit fentanyl in the drug supply has not decreased despite increased enforcement of fentanyl trafficking laws domestically and on our borders. Decades of research have demonstrated that increasing existing penalties for drugs does not dramatically reduce their use or sale or save lives. Lengthy sentences already exist for fentanyl and fentanyl analogues and have been on the books for decades. They have not stopped the spread of illicit fentanyl or its analogues.

The Drug Policy Alliance report warns “the proliferation of harsh penalties for fentanyl will lead to an increase in the prison population, subverting the fight to end mass incarceration” and “many legislators who support scaling back mass incarceration and the drug war are now supporting extremely harsh measures for fentanyl, undercutting the effectiveness of criminal justice reforms.”^x

The class-wide ban is a deeply flawed approach that exposes people to unjust incarceration, criminalizes harmless substances, and hinders research with helpful substances.

Under the class-wide ban approach, DEA can place a substance it deems to meet the statutory criteria into the Schedule I category, regardless of whether or not the substance has similar pharmacological effects to fentanyl, and reserves for itself the right to treat substances as Schedule I even if it has not specifically identified the substance prior to its interdiction.^{xi} The class-wide ban approach circumvents review of scheduling actions by the Department of Health and Human Services (HHS), which is essential to ensure substances that do not meet Schedule I criteria are not erroneously scheduled. There is no scientific basis for this approach, and no precedent for this sweeping grant of authority to DEA.

In order for the DEA to add a substance into the class-wide ban on fentanyl analogues, the agency need only demonstrate that the substance is chemically similar to fentanyl. This is very problematic as a substance can be chemically like fentanyl but behave very differently. It is not possible to predict the behavior of a fentanyl analogue on the central nervous system on its chemical structure alone or similarities in chemical structure to a controlled substance. In fact, many substances that do not have abuse potential, or could have therapeutic potential, could be scheduled just based upon similarities in chemical structure.

It is not clear how many substances the emergency class-wide order placed on Schedule I, although government estimates have cited “millions” or an “infinite number.”^{xii} The Department has not clarified how many substances it actually could control with the class-wide order. Before the Senate Judiciary Committee in June of last year, the Department of Justice testified that since 2011, the DEA has scheduled 17 fentanyl-related substances. Given this relatively low number of scheduling actions over a nine-year period, it is not clear why the Department needs such broad authority to indiscriminately schedule on a class-wide basis an infinite number of substances without HHS oversight.^{xiii}

Since the adoption of the modern-day Controlled Substances Act, the Department of Justice and the Department of Health and Human Services have worked together to determine whether a substance should be scheduled. The class-wide framework would take away the Department of Health Human Services’ input in these scheduling decisions. The DEA is a law enforcement agency that does not have the scientific or health expertise to schedule substances on its own. This is why HHS has always played an equal role in scheduling substances.

Indeed, in 2015, Congressman Charlie Dent (R-PA) introduced a bill containing DEA’s list of synthetic drugs to place in schedule I.^{xiv} The bill initially had more than 300 substances, but was reduced to 21 substances after HHS evaluated the wish list, determining that only 21 met the definition of a Schedule I substance, while the rest did not. Some of the substances that DEA wanted to schedule by way of the Dent bill were not even psychoactive.^{xv} This demonstrates the danger of allowing the DEA broad authority in proposing drugs for scheduling. The DEA could move to add substances that, although chemically similar to fentanyl, has no effect on the human body, thus exposing individuals to fentanyl analogue sentences for substances that are benign. Another consideration is the wide variation in potency among illicit fentanyl substances. In 2018 testimony before the United States Sentencing Commission Federal Public Defender Kevin Butler highlighted then that “(n)ot enough evidence is available regarding the comparative harms of fentanyl or its analogues, the typical dosage weight, its marketing forms, relative potencies, and other factors that are important to setting just punishments to support treating fentanyl analogues as a single class.”^{xvi}

Giving the DEA broad class-wide powers to schedule fentanyl analogues without HHS oversight could also undermine scientific research critical to finding solutions to the overdose crisis. Substances identified in the future that could be useful antagonists and medications for addressing the overdose crisis are at risk of being erroneously added to Schedule I through the class-wide approach. This could deter research looking into these potential therapies. The process of obtaining a Schedule I license and the regulations associated with maintaining that license, such as required protocols, storage, and security measures, deter both institutions and younger researchers from working with Schedule I substances. The barriers to research that are erected against studying a substance following its placement on Schedule I have been the subject of previous witness testimony before this Committee including that of Dr. David Nichols.^{xvii}

In a July 2019 letter to HHS, bipartisan members of the Senate Judiciary Committee warned that the same barriers to research that scientists encounter when attempting to study Schedule I drugs would apply to substances added by a class-wide ban. Senate Judiciary Committee members further warned that “the failure to engage necessary health experts vests far too much authority

to a law-enforcement agency and may result in action that will deter valid, critical medical research aimed at responses to the opioid crisis, including efforts to identify antidotes to fentanyl-analogue overdoses and improved treatment outcomes.”^{xviii}

The DEA emergency class-wide ban has been in place for nearly two years, yet fentanyl overdoses in the United States continue to increase,^{xix} and fentanyl and fentanyl analogues continue to be widely prevalent in the drug supply. The National Forensic Laboratory Information System, which tests drugs that have been seized by local, state and federal law enforcement, found that fentanyl was among the top five drugs present in samples that were seized by law enforcement in 2018 (found in 83,765 reports).^{xx} Lawmakers in the United Kingdom have had in place a class-wide approach to fentanyl-like substances but this has not stopped fentanyl-related deaths in the country, which have recently increased by nearly 30%.^{xxi}

Punitive approaches to the opioid crisis and fentanyl have not worked but only exacerbate the problem by incentivizing traffickers to increase the potency of illicit products or shift to entirely new classes of substances. In testimony before the Senate Judiciary Committee last June, an official with ONDCP stated: “[I]n addition to the threat posed by fentanyl analogues, we have seen the drug industry begin to produce a family of non-fentanyl synthetic opioids such as the U-series drugs. These non-fentanyl opioids may have the same qualitative effect on the human body as fentanyl or a fentanyl analogue, but they are not fentanyl-related in their chemical structure, and therefore are not controlled under DEA’s temporary scheduling order.”^{xxii} ONDCP has advocated adopting class-wide scheduling frameworks for classes of substances other than fentanyl-like substances.^{xxiii}

Punitive approaches to fentanyl can also exacerbate the overdose problem by deterring low-level sellers and users from seeking help during an overdose because they fear law enforcement involvement. For example, fear of increased penalties could reduce a bystander’s willingness to call 911 if they witness a fentanyl or other opioid-related overdose. There have been significant efforts on a bipartisan basis in Congress to address the stigmatization of people who struggle with addiction. However, punitive approaches and misinformation about fentanyl is creating and perpetuating stigma towards people at risk of fentanyl overdose that in turn can exacerbate the overdose crisis.

Department of Justice prosecutors have tools to prosecute fentanyl trafficking regardless of the status of the emergency scheduling order.

In a January 10th opinion piece in the *Washington Post*, Attorney General William Barr claimed that the expiration of the temporary order would result in a “tsunami of newly legalized fentanyl analogues.” He continued that “[w]ithout congressional action (to make permanent the temporary order), the Justice Department would not have the legal tools to prevent this onslaught.” This assertion is false. DOJ already has broad prosecutorial power under current federal law and has aggressively used this power to prosecute cases involving fentanyl and its analogues to pursue very severe penalties. Indeed, under the Controlled Substances Act, 10 or more grams of a mixture or substance containing a detectable amount of an analogue of fentanyl will trigger a five-year mandatory minimum for possession with intent to distribute.^{xxiv} There are additional sentencing enhancements too. For example, the United States Sentencing Commission revised its

guidelines in 2018, following lobbying by DOJ, to allow sentencing enhancements for fentanyl and fentanyl analogues, with one of the enhancements equating to a 50 percent increase in an individual's sentence.^{xxv} DOJ has effectively and aggressively used the Analogue Act to prosecute. A recent ONDCP report highlighted a 40-fold increase in federal fentanyl-related prosecutions since President Trump took office.^{xxvi} The United States Sentencing Commission also reported a 4,711% increase in fentanyl trafficking cases between 2014 and 2018.^{xxvii}

The emergency scheduling order notes that trafficking of fentanyl analogues is “actually illegal as persons who do so can be prosecuted using the controlled substance analogue provisions of the CSA.”^{xxviii} Moreover, in a June 2019 Senate Judiciary hearing, DOJ and the DEA acknowledged in sworn testimony that “if the temporary emergency scheduling order lapses without permanent scheduling, the Department would once again have to rely on the Analogue Act to bring fentanyl traffickers to justice” and “the government has a very good track record in Analogue Act prosecutions.”^{xxix} This testimony clearly identifies the legal standards by which fentanyl analogues would be evaluated, but these elements, which generally require the government to show that a substance actually has a psychoactive effect, are required by the Constitution's due process requirements.

Prosecution by way of the Analogue Act requires the government to show that a substance actually has a psychoactive effect, an evidentiary requirement and due process protection for defendants. These legal standards are compromised by the class-wide scheduling approach that remove the evidentiary requirement to prove a substance is an analogue of a controlled substance, increasing the risk of wrongful prosecutions.

We are concerned that removing the need for these steps will increase prosecutorial power, enabling prosecutors to coerce more guilty pleas from defendants even if the substance is not in fact an analogue of fentanyl. Giving the DEA such broad authority over scheduling will result in greater authority for the DOJ to increase prosecutions, depriving accused persons of the opportunity to mount a meaningful defense and undercutting the goals of criminal justice reform. Accordingly, this broad authority increases the risk of prosecutions involving substances that should not be illegal and individuals unjustly serving long prison terms.

In testimony before the Senate Judiciary Committee last year, the DOJ indicated that “a lapse in class scheduling” would impact prosecutions and make it difficult to charge substances scheduled by the class-wide order.^{xxx} But the DOJ has not provided data on the number of prosecutions it has charged under the authority provided by the temporary order nor information on how many of those prosecutions pursued high-level drug manufacturers or distributors.

Public health approaches, not punitive approaches, will effectively mitigate overdose and other harms from fentanyl-related substances.

Illicit fentanyl and fentanyl analogues pose an enormous public health challenge and the federal government should respond. But lawmakers should pursue evidence-based policies that will effectively mitigate the harms associated with fentanyl-related substances. Of grave concern is the massive amount of misinformation and fear-based rhetoric surrounding fentanyl in the media and from official sources and the degree to which policymakers lack evidence-based knowledge

of fentanyl and its risks. The push from the Department of Justice for class-wide scheduling of fentanyl-related substances is occurring amidst a drug panic that is persuading lawmakers who in recent years favored sentencing reform and compassionate approaches to opioid addiction to hastily approve punitive measures in response to fentanyl.

Although fentanyl is a more potent opioid, the same health-based approaches that Congress has taken steps to support to address demand, dependence and overdose risk involving prescription opioids and illicit opioids are effective at addressing harms caused by fentanyl-related substances. There are legislative measures and policy reforms that Congress can take now to effectively address fentanyl-related harms to public health including:

- Enact the Comprehensive Addiction Resources Emergency (CARE) Act, H.R. 2569. Modeled from the Ryan White Care Act, the CARE Act proposes \$100 billion over 10 years for treatment, harm reduction and recovery with much of the funding going directly to municipalities hardest hit by the crisis.
- Enact the Mainstreaming Addiction Treatment (MAT) Act, H.R. 2482. This legislation repeals the onerous requirement that health practitioners obtain a special waiver from the DEA and HHS to prescribe buprenorphine for treatment. The waiver has long served as an obstacle to expanding buprenorphine access in health care settings and perpetuates stigma against patients who present with opioid dependence.
- Remove barriers to methadone treatment, such as a long-standing federal rule that patients must demonstrate one year of dependence history before they can begin treatment. Mandate the DEA to release its hold on rulemaking that would lift restrictions on mobile methadone services.
- Provide federal support for drug checking interventions that enable individuals to detect fentanyl in the drug supply, including research evaluating new methods. Users are often unaware that the illicit substance they are purchasing - be it heroin or methamphetamine or cocaine - also contains fentanyl.
- Enact a federal Good Samaritan overdose prevention law to encourage individuals to seek emergency medical assistance during an expected overdose.

These health-based measures would be much more effective at targeting reductions in fentanyl related deaths than punitive measures such as extending the class-wide ban.

Thank you for considering our views,

Sincerely,



Grant Smith
Deputy Director, National Affairs
Drug Policy Alliance

ⁱ DEA, “U.S. Drug Enforcement Administration Emergency Schedules All Illicit Fentanyl In An Effort To Reduce Overdose Deaths,” February 7, 2018, available at <https://www.dea.gov/press-releases/2018/02/07/us-drug-enforcement-administration-emergency-schedules-all-illicit>

ⁱⁱ See for example: Stopping Overdoses of Fentanyl Analogues (SOFA) Act (H.R. 2935/S.1622/S.3148) and the FIGHT Fentanyl Act (S. 2701)

ⁱⁱⁱ Brian T. Yeh, “Drug Offenses: Maximum Fines and Terms of Imprisonment for Violation of the Federal Controlled Substances Act and Related Laws,” Congressional Research Service, January 20, 2015, available at <https://fas.org/sgp/crs/misc/RL30722.pdf>

^{iv} Brian T. Yeh, “Drug Offenses: Maximum Fines and Terms of Imprisonment for Violation of the Federal Controlled Substances Act and Related Laws,” Congressional Research Service, January 20, 2015, available at <https://fas.org/sgp/crs/misc/RL30722.pdf>

^v See 21 U.S.C. § 802(32)(A) (to prove that a substance is a controlled-substance analogue, the government must prove: 1) the chemical structure is substantially similar to the chemical structure of a controlled substance in Schedule I or II; 2) that the substance has a substantially similar stimulant, depressant, or hallucinogenic effect on the central nervous system as the analogous Schedule I substance, or 3) the person intends or represents that the substance would have a substantially similar effect on the central nervous system).

^{vi} United States Sentencing Commission, “Public Data Presentation for Synthetic Cathinones, Synthetic Cannabinoids, and Fentanyl and Fentanyl Analogues Amendments,” January 2018, available at https://www.uscc.gov/sites/default/files/pdf/research-and-publications/data-briefings/2018_synthetic-drugs.pdf

^{vii} United States Sentencing Commission, “Quick Facts: Fentanyl Trafficking Offenses,” available at https://www.uscc.gov/sites/default/files/pdf/research-and-publications/quick-facts/Fentanyl_FY18.pdf

^{viii} See for example: Stopping Overdoses of Fentanyl Analogues (SOFA) Act (H.R. 2935/S.1622/S.3148) and the FIGHT Fentanyl Act (S. 2701)

^{ix} Drug Policy Alliance, “Criminal Justice Reform in the Fentanyl Era: One Step Forward, Two Steps Back”, January 2020, read the full report at <http://www.drugpolicy.org/fentanylreport>

^x Drug Policy Alliance, “Criminal Justice Reform in the Fentanyl Era: One Step Forward, Two Steps Back”, January 2020, p.4, 8, available at: <http://www.drugpolicy.org/fentanylreport>

^{xi} See Department of Justice, Drug Enforcement Administration; Schedules of Controlled Substances: Temporary Placement of Fentanyl-Related Substances in Schedule I, 83 Fed. Reg. 25, 5,188 (Feb. 6, 2018) (codified at 21 CFR Part 1308) (“It bears emphasis, however, that even in the absence of a future publication by DEA specifically identifying such a substance, the substance is controlled by virtue of this temporary scheduling order if it falls within the definition of fentanyl-related substance.”).

^{xii} Sarah N. Lynch, “Trump administration drug officials clash over how to combat fentanyl copycats,” Reuters, July 9, 2019, available at <https://www.reuters.com/article/us-usa-congress-fentanyl/trump-administration-drug-officials-clash-over-how-to-combat-fentanyl-copycats-idUSKCN1U4105>

^{xiii} United States Department of Justice, “Statement of the Department of Justice Before the United States Senate Committee on the Judiciary For a Hearing Entitled “The Countdown: Fentanyl Analogues & the Expiring Emergency Scheduling Order,” June 4, 2019, p. 2, available at <https://www.judiciary.senate.gov/imo/media/doc/Liskamm-Cherundolo%20Joint%20Testimony.pdf>

^{xiv} United States Congress, “H.R.3537 – Dangerous Synthetic Drug Control Act of 2016,” available at <https://www.congress.gov/bills/114th-congress/house-bill/3537>

^{xv} United States Congress, “H.R.3537 – Dangerous Synthetic Drug Control Act of 2016,” available at <https://www.congress.gov/bills/114th-congress/house-bill/3537>

^{xvi} United States Sentencing Commission, “Statement of Kevin Butler Before the United States Sentencing Commission: Public Hearing on Synthetic Drugs March 14, 2018,” March 14, 2018, p. 28, available at <https://www.uscc.gov/sites/default/files/pdf/amendment-process/public-hearings-and-meetings/20180314/Butler.pdf>

^{xvii} United States House of Representatives Committee on the Judiciary, “Hearings: Synthetic Drugs, Real Danger,” May 17, 2016, available at <https://judiciary.house.gov/calendar/eventsingle.aspx?EventID=1878>

^{xviii} Sarah N. Lynch, “Lawmakers seek scientific review of plan to tightly regulate all fentanyl copycats,” Reuters, July 11, 2019, available at <https://www.reuters.com/article/us-usa-congress-fentanyl-letter/lawmakers-seek-scientific-review-of-plan-to-tightly-regulate-all-fentanyl-copycats-idUSKCN1U6217>

^{xix} U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Provisional Overdose Mortality, available at

https://public.tableau.com/shared/G25YDB43S7:toolbar=n&:tabs=n&:display_count=n&:origin=viz_share_link&:embed=y&:showVizHome=no

^{xxv} Drug Policy Alliance, “Criminal Justice Reform in the Fentanyl Era: One Step Forward, Two Steps Back”, January 2020, p. 12, available at: <http://www.drugpolicy.org/fentanylreport>

^{xxvi} See The Misuse of Drugs Act 1971 (Modification) Order 1986 (1986 No. 2230) and Frances Perraudin, “Fentanyl drug deaths rise by nearly a third in England and Wales,” The Guardian, August 6, 2018, available at <https://www.theguardian.com/society/2018/aug/06/fentanyl-drug-deaths-rise-nearly-third-england-wales>

^{xxvii} United States Senate Committee on the Judiciary, “Statement of Kemp L. Chester, Assistant Director of the National Opioids and Synthetics Coordination Group Office of National Drug Control Policy, Before the U.S. Senate, Committee on the Judiciary,” June 4, 2019, pp. 2-3, available at <https://www.judiciary.senate.gov/imo/media/doc/Chester%20Testimony.pdf>

^{xxviii} United States Senate Committee on the Judiciary, “Statement of Kemp L. Chester, Assistant Director of the National Opioids and Synthetics Coordination Group Office of National Drug Control Policy, Before the U.S. Senate, Committee on the Judiciary,” June 4, 2019, p. 6, available at <https://www.judiciary.senate.gov/imo/media/doc/Chester%20Testimony.pdf>

^{xxix} Families Against Mandatory Minimums, “Rejecting Fentanyl Penalty Increases in S. 2635 and Understanding Current Punishment for Fentanyl,” available at <https://famm.org/wp-content/uploads/Reject-S.-2635-Fentanyl-Changes.pdf>

^{xxx} United States Sentencing Commission, “News Release: U.S. Sentencing Commission Unanimously Adopts 2018 Guideline Amendments,” April 12, 2018, available at https://www.ussc.gov/sites/default/files/pdf/news/press-releases-and-news-advisories/press-releases/20180412_Press_Release.pdf

^{xxxi} The White House, “ONDCP Releases Report on the President’s Commission on Combating Drug Addiction and the Opioid Crisis,” May 8, 2019, available at <https://www.whitehouse.gov/briefings-statements/ondcp-releases-report-presidents-commission-combating-drug-addiction-opioid-crisis/>

^{xxxii} United States Sentencing Commission, “Quick Facts: Fentanyl Trafficking Offenses,” available at https://www.ussc.gov/sites/default/files/pdf/research-and-publications/quick-facts/Fentanyl_FY18.pdf

^{xxxiii} See Department of Justice, Drug Enforcement Administration, Schedules of Controlled Substances: Temporary Placement of Fentanyl-Related Substances in Schedule I, 83 Fed. Reg. 25, 5,188 (Feb. 6, 2018) (codified at 21 CFR Part 1308).

^{xxxiv} United States Department of Justice, “Statement of the Department of Justice Before the United States Senate Committee on the Judiciary For a Hearing Entitled “The Countdown: Fentanyl Analogues & the Expiring Emergency Scheduling Order,” June 4, 2019, available at <https://www.judiciary.senate.gov/imo/media/doc/Liskamm-Cherundolo%20Joint%20Testimony.pdf>

^{xxxv} United States Department of Justice, “Statement of the Department of Justice Before the United States Senate Committee on the Judiciary For a Hearing Entitled “The Countdown: Fentanyl Analogues & the Expiring Emergency Scheduling Order,” June 4, 2019, p. 5, available at <https://www.judiciary.senate.gov/imo/media/doc/Liskamm-Cherundolo%20Joint%20Testimony.pdf>

The Washington Post

Opinions

William Barr's new war on drugs

By Nancy Gertner | January 26

Nancy Gertner is a senior lecturer at Harvard Law School and a former U.S. district judge.

Attorney General William P. Barr's [support](#) for an expansion of mandatory minimum sentences for federal drug crimes involving fentanyl analogues should come as no surprise given his [long record](#) of hawking incarceration as a solution to our drug crisis. We have seen this movie before; it does not end well.

Illicit analogues are synthetic compounds that are substantially similar to Schedule I or II substances in chemical structure. Some analogues are dangerous substances with a substantial potential for misuse. Others are benign or helpful. For example, naloxone, a life-saving antidote to opioid overdoses, is an analogue of morphine, a powerful opioid. Scientists believe that an antidote for fentanyl overdoses could well be within the substances scheduled under a proposal pending in Congress.

The only way to tell how a drug will act in the body is through pharmacological research to measure its effect. Barr's proposal omits that crucial step, enabling federal prosecutions in cases involving substances with no scientific research confirming the drug's physiological effect.

Barr recently warned that if his request were not granted, illicit fentanyl analogues would be "legal." That is false. Dangerous fentanyl analogues have long been illegal and will continue to be under existing laws. One such tool, the Federal Analogue Act, exposes defendants to [sentences](#) of up to 20 years, and, if death or serious injury results, 20-year mandatory minimums.

But the analogue act is limited; it requires the government to prove a substance is actually harmful or intended to be harmful. Barr wants to eliminate that hurdle — thereby paving the way to potentially prosecute harmless substances — by pushing legislation, known as the Stopping Overdoses of Fentanyl Analogues Act (SOFA). Earlier this month, the Senate [granted](#) some of Barr's wishes, passing a temporary measure that adopts SOFA's broad approach and enabling the Justice Department to seek severe punishments for a potentially limitless set of fentanyl analogues.

That means a person dealing in one of these analogues — even one that is harmless — could be subject to mandatory-minimum penalties with no opportunity to prove the analogue is benign. For any offense involving 10 grams of a substance that contains a detectable amount of a SOFA substance, the Justice Department could

seek a five-year mandatory minimum. (In contrast, [100 grams or more of heroin](#) is required to trigger the same mandatory minimum.) Judges will have no choice but to impose mandatory minimums, even though street-level dealers — many of whom are users themselves — have no idea that the drugs they are selling contain fentanyl.

According to the Sentencing Commission, most people sentenced for fentanyl trafficking in 2016 [were at the bottom](#) of the drug distribution ladder, including mules or couriers (25.5 percent) and street-level sellers (23.5 percent). In 2018, [77 percent](#) of those prosecuted for fentanyl were black or Hispanic.

We must do everything we can to stop the opioid epidemic, but not with the failed policies of the past. The opioid epidemic persists despite decades of the punitive approach Barr touts. Since 2014, federal prosecutions for fentanyl have increased more than [4,700 percent](#). In recent decades, such an approach has resulted only in mass incarceration — a nearly [790 percent increase](#) in the federal prison population from 1980 to its peak in 2013, disproportionately impacting people of color.

Republican Sens. Rob Portman (Ohio) and Shelley Moore Capito (W.Va.), who represent states among the most devastated by the opioid epidemic, deserve praise for introducing language intended to exclude the application of mandatory minimums for fentanyl analogues. The House should follow their lead.

It is ironic that Barr's proposal comes only one year after enactment of the First Step Act, when Congress agreed that mandatory minimums have failed, and six years after the National Research Council [wrote](#) that “the successive iterations of the war on drugs ... are unlikely to have markedly or clearly reduced drug crime over the past three decades.”

The low-level people disproportionately burdened with federal drug sentences are easily replaced on the street. Their incarceration does not stop addiction and will not protect users from overdose deaths. They are not the ones creating these analogues and often don't even know what is in the drugs they possess or sell. The real target here should not be mules, couriers or street-level sellers but rather high-level importers.

Barr is waging the same failed war, what Yogi Berra might describe as, “*déjà vu* all over again.” He seeks to extend mandatory minimums without regard to their impact on people of color, let alone whether they will make our communities safer. They will not.

Ms. JACKSON LEE. Thank you.

Ms. BASS. Mr. Reschenthaler?

Mr. RESCHENTHALER. Thank you, Madam Chair. I do ask for unanimous consent to enter a letter from the Addiction Policy Forum.

Ms. BASS. Without objection.

[The information follows:]

MR. RESCHENTHALER FOR THE RECORD



ADDICTION POLICY FORUM

January 27, 2020

The Honorable Nancy Pelosi
Speaker
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Kevin McCarthy
Minority Leader
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Jerrod Nadler
Chair
Committee on the Judiciary
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Doug Collins
Ranking Member
Committee on the Judiciary
U.S. House of Representatives
Washington, D.C. 20515

Dear Speaker Pelosi, Minority Leader McCarthy, Chairman Nadler, and Ranking Member Collins,

The Addiction Policy Forum (APF) writes to express support for S. 3201, the Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act, which would extend the classification of fentanyl-like substances under Schedule I of the Controlled Substances Act (CSA) for 15 months. On behalf of patients and the families of those who have died as a result of fentanyl and related substances, we urge the House of Representatives to pass this critical, bipartisan legislation forthwith.

APF has been on the front lines of the opioid epidemic since our founding five years ago. We are a national nonprofit organization dedicated to eliminating addiction as a major health problem. Our headquarters are located in Washington, D.C., and we have resources and services in every state. We lead the fight against the deadly consequences of addiction and help patients, families, and communities affected by the disease.

As patient advocates, we see the destruction that fentanyl and fentanyl analogues wreak on individuals and communities. Tragically, we lose 192 people to overdose daily, the equivalent of a plane crashing every single day. In 2017, there were 70,237 drug overdose deaths in the United States.¹ Importantly, the Centers for Disease Control and Prevention found that “[t]he

¹ Holm, Hedebrand MD, Arnold M. Minato, M.T.R., and Margaret Warner, Ph.D., *Drug Overdose Deaths in the United States, 1999–2017*, Centers for Disease Control and

Prevention. <https://www.cdc.gov/nchs/data/databriefs/db329-h.pdf> (accessed January 27, 2020). The CDC will be releasing updated statistics on overdose deaths later this week.

Unfortunately, we expect the number to continue to increase.

age-adjusted rate of drug overdose deaths involving **synthetic opioids other than methadone (drugs such as fentanyl, fentanyl analogs, and tramadol) increased by 45% between 2016 and 2017, from 6.2 to 9.0 per 100,000** (emphasis added).

APF believes that it takes a comprehensive approach to combat the opioid epidemic, and S. 3201 is an important tool in law enforcement's tool box. While we also believe in, and have advocated for, robust prevention and education programs, expanded treatment services, and alternatives to incarceration, we appreciate the vital role that law enforcement plays in the fight to eradicate addiction.

It is difficult to convey the overwhelming grief and devastation that opioids and, specifically fentanyl and its analogues, cause families and communities. We urge you to ensure that these substances remain on Schedule I of the CSA by taking up S. 3201 and not allowing the temporary ban to expire on February 6th.

Sincerely,

A handwritten signature in black ink, reading "Jessica Hulsey Nickel". The signature is written in a cursive, flowing style.

Jessica Hulsey Nickel
President

Mr. RESCHENTHALER. Thank you. Thank you, again, Chairwoman Bass. Thank you for our witnesses for being here today. I am incredibly disappointed that my colleagues across the aisle are dragging their feet on legislation to combat the flow of fentanyl substances into our communities. This is an extremely lethal drug. It only takes 3 milligrams of fentanyl to kill an average-sized adult. By comparison, a fatal dose of heroin is 30 milligrams.

The opioid crisis is an issue that hits every single congressional district, Republican or Democrat. It is a pandemic. We should not play partisan politics when it comes to people's lives. In 2017, my home State of Pennsylvania was ranked 3rd in the United States for drug overdose deaths, and fentanyl was present in roughly two-thirds of those fatalities. Speaking bluntly, people are dying, and my Democrat colleagues are sitting on their hands. The House should have approved the Senate bill, which passed the other chamber unanimously without opposition. We should have been working on this instead of wasting all our time on this sham impeachment. This is absolutely shameful.

But thankfully, we have a President who is treating this crisis with the seriousness it deserves. In 2018, President Trump secured a commitment from China to address the flow of fentanyl into the United States. The following year, China permanently scheduled fentanyl, making fentanyl drugs illegal for manufacture, possession, and sale. President Trump's actions are working. If you look at the stats, in 2019, the amount of fentanyl and fentanyl analogues smuggled in from China decreased. So, it is critical that the House follow the Senate's lead to pass legislation and extend the temporary scheduling of fentanyl-related substances before the February 6th deadline. American lives are at risk. Admiral Giroir?

Admiral GIROIR. Yes, sir.

Mr. RESCHENTHALER. I have heard pushback from the other side that scheduling fentanyl hinders important medical research. Can you briefly outline steps that HHS has taken to provide researchers with access to study these substances?

Admiral GIROIR. So, thank you for that, and I want to be absolutely clear that in an ideal world we would like it permanently scheduled and the research protections to be at the same time, but we have to schedule these drugs or else we are going to have thousands more deaths this year. The emergency rooms are not going to be able to detect it. Some of the harm reduction measures have not been effective. So, we do support it being scheduled.

The kinds of research protections we talked about, again, are the ability to rapidly de-schedule or reduce the schedule of drugs, and, again, this is not something just from HHS. This is something that the interagency has decided is very important because, look, they want reversal agents and better treatment as well as we do, as well as some activities that would, for example, if you are approved to do work on one substance, you have to go back through the whole process if you want to go through another analogue. That just doesn't make, you know, sort of common, logical sense.

So, these kind of simplified procedures, we think, are very consistent with scheduling, but also achieving our goals. They are not mutually exclusive. We think we can do both.

Mr. RESCHENTHALER. Thank you, Doctor. I appreciate it, and I would yield the remainder of my time to my colleague from Arizona, Mrs. Lesko.

Mrs. LESKO. Thank you. I have a question. Ms. Liskamm, can you repeat what you said about to get a 5-year minimum sentence, what has to happen, because we heard, at least I heard, that Chairman Nadler, this was one of the reasons for the holdup because of the concern over this minimum mandatory sentencing.

Ms. LISKAMM. So, in order to trigger a 5-year mandatory minimum, there needs to be the equivalent of 5,000 lethal doses of a fentanyl analogue. To trigger a 10-year mandatory minimum, you need the equivalent of 50,000 lethal doses of a fentanyl analogue.

Mrs. LESKO. What does that mean? They have to be dealing it, possessing it? What does that mean?

Ms. LISKAMM. So, under the statute, it could be possession, possession with intent to distribute, manufacturing, distribution, importation, conspiracy of all of these different crimes as well. We need every tool that we can to go after these criminals.

Mrs. LESKO. Thank you.

Ms. BASS. Thank you. I would like, one, to thank the panelists. Thank you, witnesses, for being here today. I would like call forward the next panel: Dr. Comer, Mr. Butler, Mr. Holman, and Dr. Ciccarone. Before you sit down—thank you—I want to swear everyone in.

We welcome our second set of witnesses and thank them for participating in today's hearing. Now, if you would please—well, you have already risen—I want to begin by swearing you in. Raise your right hand.

Do you swear or affirm under penalty of perjury that the testimony you are about to give is true and correct to the best of your knowledge, information, and belief, so help you God?

[A chorus of ayes.]

Ms. BASS. Let the record show the witnesses answered in the affirmative. Thank you, and please be seated.

We will now proceed with introductions, starting with the panel. Dr. Comer is professor of neurobiology in the department of psychiatry at the Columbia University, and a research scientist at the New York State Psychiatric Institute. She is also director of the opioid laboratory in the Division on Substance Use Disorders and runs a very active research program devoted to examining various aspects of the abuse liability of opioids. Mr. Butler is the Federal public defender for the Northern District of Alabama. Prior to his appointment, Mr. Butler served as the chief deputy defender and chief trial attorney for the Office of the Federal Defender for the Middle District of Alabama.

Mr. Holman is a father who lost his son, Garrett, to overdose from a synthetic opioid called U-47700. Since his family's loss, he has been an advocate to help address the opioid crisis. He has attended roundtable meetings with Governor Christie and First Lady as well as testified in Pennsylvania for Senator Jay Costa. Through his advocacy, he works to ensure other families do not lose loved ones to addiction.

Dr. Ciccarone is a Board-certified clinician in family medicine and addiction medicine. In his position as professor of family and

community medicine at the University of California—San Francisco, he has been principal or co-investigator on numerous NIH-sponsored public health research projects, including his current heroin and transition study. He is also the associate editor for the *International Journal of Drug Policy* and has recently edited a special issue on the triple-wave crisis of opioids, heroin, and fentanyl in the United States.

Dr. Comer, you can begin.

TESTIMONY OF SANDRA D. COMER

Ms. COMER. Chair, Ranking Member, and Members of the subcommittee, thank you for holding today's hearing on class-wide scheduling of synthetic fentanils. I am Dr. Sandra Comer, public policy officer of the College on Problems of Drug Dependence, a Membership organization with over 1,000 Members that has been in existence since 1929. CPDD is the longest-standing organization in the U.S. addressing problems of drug dependence and abuse. For over 2 decades, my research has focused on the development and testing of novel approaches to the treatment of opioid use disorder.

The U.S. is experiencing an unprecedented increase in the illicit use of opioids and its associated morbidity and mortality. In 2017, opioid overdoses claimed more than 47,000 lives in the U.S. Many of these deaths have been linked to illicitly manufactured fentanyl and its analogues. Fortunately, several medications are available and have been used successfully for treating opioid use disorder, including methadone, buprenorphine, and naltrexone. One concern with the introduction of fentanyl and its analogues to the street supply of illicit opioids is whether the approved treatment medications can effectively reduce use of these drugs.

Further research on the ability of the approved as well as new medications for treating opioid use disorder in patients who are predominantly using fentanyl is clearly needed to address the fentanyl crisis. Naloxone is an antagonist that is used therapeutically to reverse opioid overdose. Recent reports suggest that higher or repeated dosing with naloxone may be required to reduce fentanyl-induced respiratory depression. The reason that higher doses of naloxone may be required is not entirely clear. Additional studies are needed to assess the effectiveness of naloxone and other antagonists in reversing fentanyl-related overdoses.

Fentanyl and its analogues are exceptionally potent, inexpensive, and easy to synthesize. Small modifications in these molecules can have profound effects on their activity, changing an inactive compound to an exceptionally potent opioid with high abuse potential. However, similarity in chemical structure does not necessarily translate to similarity in abuse liability. For example, oxycodone is a potent mu opioid receptor agonist with high abuse potential, while naltrexone and naloxone are opioid antagonists that have saved thousands of lives. All 3 medications share the same core chemical structure.

This example illustrates how the antidote to a toxic substance and the toxic substance itself can share core structures, but the chemical structure of a compound alone cannot tell us whether it will have agonists or antagonist activity. Basic pharmacological studies must be performed to make this determination. Science-

based agencies, specifically the Food and Drug Administration and the National Institute on Drug Abuse, should review the pharmacological activity, not just the chemical structures of these compounds. The Committee should consider adding a role for HHS subjecting compounds to limited tests of pharmacological activity through animal models using a rapid process that could be undertaken by NIDA, and a designated pre-screened team of extramural scientists.

The current fentanyl crisis poses a formidable challenge to Congress and the DEA since there are literally thousands of fentanyl analogues, some of which have high abuse potential. CPDD supports efforts to control the distribution, sales, and use of these synthetic fentanils. However, to globally put all compounds that are chemically similar to fentanyl in Schedule 1 is likely to severely limit biomedical research and, in the long term, adversely impact public health.

Obtaining a DEA schedule on registration is complicated, burdensome, and can take a long time, sometimes more than 1 year, disincentivizing researchers in general, and, particularly, young researchers. To ensure more research on synthetic fentanils, Congress should consider instituting legislation procedures for streamlining the process for obtaining a Schedule 1 license. I can expand on these specific recommendations during the question-and-answer session following my testimony.

Scientists have dedicated their careers to research to save lives and protect individuals from the devastation caused by drug abuse. More information, not less, is the best way we can achieve that goal. I encourage you and your colleagues to consider alternative approaches so that the potential benefits and risks of new chemical entities can be characterized before decisions are rendered regarding DEA scheduling.

[The statement of Ms. Comer follows:]

U.S. House of Representatives
Committee on the Judiciary
Subcommittee on Crime, Terrorism, and Homeland Security

"Fentanyl Analogues: Perspectives on Classwide Scheduling"

28 January 2020

Testimony Submitted by

Sandra D. Comer, Ph.D.

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Columbia University Irving Medical Center
New York State Psychiatric Institute

Public Policy Officer
The College on Problems of Drug Dependence

Introduction

Chair, Ranking Member, and members of the Subcommittee, thank you for holding today's hearing on classwide scheduling of synthetic fentanyl and for inviting me to testify. My name is Dr. Sandra Comer and I am the Public Policy Officer of the College on Problems of Drug Dependence (CPDD), a membership organization with over 1000 members that has been in existence since 1929. It is the longest standing organization in the United States (U.S.) and the world addressing problems of drug dependence and abuse. The organization serves as an interface among government, industry, and academic communities maintaining liaisons with regulatory and research agencies as well as educational, treatment, and prevention facilities in the field of substance use disorders (SUDs).

I am also a Professor of Neurobiology in the Department of Psychiatry at the Columbia University Irving Medical Center, and a Research Scientist at the New York State Psychiatric Institute. My research focus for over 2 decades has been on the development and testing of new approaches to the treatment of opioid use disorder (OUD).

Scope of the Problem

Approximately 31 million people worldwide have a substance use disorder related to controlled substances, but across all of the illicit drug classes, non-therapeutic use of opioids is associated with the most harm: 76% of deaths associated with SUDs have been attributed to opioids¹. The U.S. in particular is experiencing an unprecedented increase in illicit use of opioids and its associated morbidity and mortality. In 2017, opioid overdoses (OD) claimed more than 47,000 lives in the U.S., more than 28,000 of which were attributed to synthetic opioids other than methadone². OD deaths are the tip of the iceberg as research suggests 20-30 non-fatal ODs occur for every OD death³. In addition, the majority of people who use opioids either have experienced a non-fatal OD or have witnessed an OD during their lifetime⁴⁻⁶. These numbers are likely to be underestimates because the data on non-fatal overdoses were collected prior to the introduction of illicitly manufactured fentanyl. ***Of great concern to the research community is that our tools for treating OUD and reversing opioid OD were developed before the emergence of highly potent illicit fentanyl so new approaches may be needed to address this challenge.***

Research Gaps

Fortunately, several medications are available and have been used successfully for treating OUD, including methadone, buprenorphine⁷⁻⁹, and naltrexone¹⁰⁻¹⁵. Despite the clear clinical utility of these medications, approximately half of the patients who initiate medication relapse and/or drop out of treatment within 6 months^{11,15,16}. Thus, there is a substantial need for improving the effectiveness of these medications, given the high relapse rates.

The introduction of fentanyl and its analogues to the street supply of illicit opioids complicates an already difficult-to-treat disorder because it is not clear whether the approved treatment medications can reduce use of these drugs as effectively as they reduce the use of heroin and prescription opioids such as oxycodone. A number of

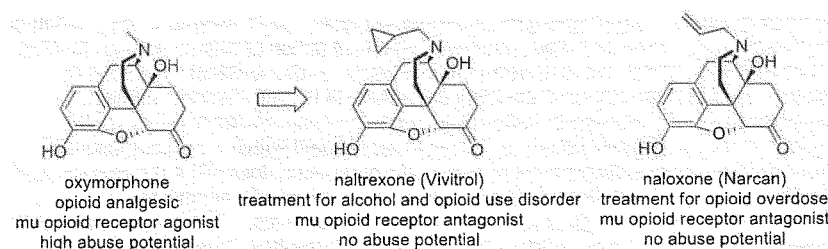
preclinical studies have demonstrated that fentanyl is a highly potent opioid with a receptor pharmacology that differs from other opioids¹⁷. Multiple studies conducted in several different species have demonstrated that opioid agonist maintenance or irreversible antagonist administration was less effective in blocking the effects of higher efficacy agonists, like fentanyl, compared to intermediate efficacy agonists, like heroin or morphine¹⁸⁻²⁹. **Further research on the ability of the approved medications for treating OUD in patients who are predominantly using fentanyl is clearly needed. The development of alternative medication approaches is also critically needed to address the shift in the illicit opioid supply toward fentanyl.**

Naloxone is a potent, short-acting medication that blocks opioid receptors. While it binds to opioid receptors, it does not activate them (that is, it doesn't produce a "high" or other desirable effect), so the risk of abusing the medication is non-existent. Naloxone is effective in both preventing and reversing the effects of heroin and other opioids, including respiratory depression, which is the primary cause of death due to opioid overdose³⁰. The antagonist effects of naloxone are evident within 5 minutes following administration and its effectiveness at commonly prescribed doses (0.4-0.8 mg) can last 45 to 90 minutes. It is relatively ineffective orally, so it is typically administered intravenously or intramuscularly and more recently, intranasally³¹⁻³³. Originally approved by the Food and Drug Administration (FDA) in 1971 for treating opioid overdose, naloxone is traditionally used in both emergency room and non-hospital settings, where it is administered by medically trained personnel.

Non-fatal and fatal opioid overdoses have increased substantially over recent decades. While provisional data suggest that the number of opioid overdoses has leveled off, they remain at alarming levels. Naloxone is now being used by individuals with little or no medical training in order to broaden our ability to address the opioid overdose crisis. Recent reports suggest that fentanyl and its analogues have contributed to the sharp increase overdose deaths and that higher and/or repeated dosing with naloxone may be required to reverse fentanyl-induced respiratory depression³⁴⁻³⁶. **The reason that higher doses of naloxone may be required for fentanyl overdoses is not entirely clear.** Possibilities are that a large dose of naloxone is needed simply because a large dose of fentanyl was used, a fentanyl analogue was used that is not sensitive to naloxone, or a post-receptor or non-opioid-receptor cascade of effects is initiated that is not sensitive to reversal by naloxone. Another possible explanation for the apparent lack of effectiveness of naloxone in some overdose situations is that fentanyl and naloxone may share a site that allows drug entry into the brain and when high doses of fentanyl are used, the ability of naloxone to pass into the brain is impeded^{35,37}. Emerging preclinical research suggests that other opioid antagonists may be more effective than naloxone in reversing fentanyl over-intoxication³⁸. **Clearly, additional studies are needed to understand the mechanisms by which fentanyl and its analogues produce severe respiratory depression. Furthermore, studies are needed to assess the effectiveness of naloxone and other opioid antagonists in reversing fentanyl-related OD because naloxone may not be the ideal compound for reversing the respiratory depressant effects of fentanyl-like drugs.**

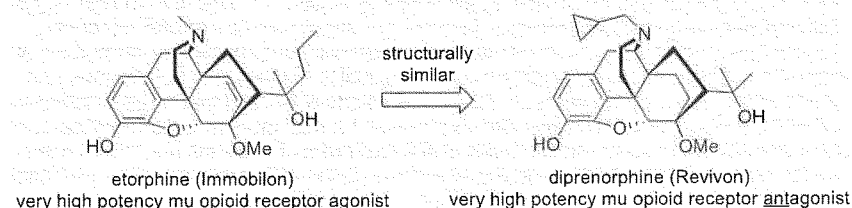
Classwide Scheduling of Fentanyl Analogues from a Research Perspective

Fentanyl and related analogues are exceptionally potent, inexpensive, and easy to synthesize. Small modifications in these molecules can have profound effects on their activity, changing an inactive compound to a potent opioid with high abuse potential. **A critical point is that similarity in chemical structure does not necessarily translate into similarity in abuse liability.** Below is an example of how small modifications to a core chemical structure can result in large differences in pharmacological activity.



Oxycodone is a potent mu opioid receptor agonist with high abuse potential, while naltrexone and naloxone are opioid antagonists that have saved thousands of lives. Naltrexone is approved for treating both alcohol and opioid use disorder and naloxone is approved for treating opioid overdose. All three of these medications share the same core chemical structure (shown in red).

Another example of compounds that share similar structures but not pharmacological activity is etorphine and diprenorphine (below):



Etorphine is a very potent opioid used in veterinary medicine to tranquilize large animals and diprenorphine is an antagonist used as an antidote for etorphine. These examples illustrate how **the antidote to a toxic substance and the toxic substance itself can share core chemical structures. However, the chemical structure of a compound alone cannot tell us whether it will have agonist or antagonist activity. Basic pharmacological studies must be performed in order to make this determination.**

- Science-based agencies, specifically the FDA and the National Institute on Drug Abuse (NIDA) at the Department of Health and Human Services (HHS), should review the pharmacological activity, not just the chemical structures, of these compounds.

- The role of HHS need not be as robust as the 8-factor analysis currently mandated by the Controlled Substances Act. Instead, ***the Committee should consider adding a role for HHS in subjecting compounds to more limited tests of pharmacological activity through animal models using a rapid process that could be undertaken by NIDA and a designated, pre-screened team of extramural scientists.*** In fact, NIDA, FDA, and the Drug Enforcement Administration (DEA) currently participate on the Interagency Committee for Drug Control, which reviews and prioritizes compounds that need analysis. NIDA issues grants and contracts for such analyses, as does the DEA.

The current fentanyl crisis poses a formidable challenge to Congress and the DEA since there are literally thousands of (existing or potential) fentanyl analogues, some of which have high abuse and dependence potential. ***CPDD supports efforts to control the distribution, sales, and use of these synthetic fentanyls.*** In the face of the opioid crisis, it is tempting to globally put all compounds that are chemically similar to fentanyl in Schedule 1; however, such an action is likely to severely limit biomedical research and, in the long term, adversely impact public health. The opioid crisis is a very challenging public health issue and, arguably, we have yet to significantly turn the tide in this battle despite our current efforts. To restrict research by limiting access to potentially important compounds, based solely on chemical structure, is not likely to facilitate progress in this arena.

For a research scientist, obtaining a DEA Schedule 1 registration is complicated, burdensome, and can take a long time (e.g., more than a year), disincentivizing researchers in general and particularly young researchers (e.g., graduate students and postdoctoral fellows) who often need to complete their studies on strict academic schedules.

- The additional security that is necessary for handling Schedule 1 substances can be prohibitively expensive, particularly for young investigators in the current climate when securing NIH funding is very challenging. Specialized safes, locking refrigerators and freezers, video surveillance, and renovations can be expensive, and institutions often are not willing to pay these costs.
- Each additional Schedule 1 compound that might be of interest to study requires a protocol review that can take many months. Even for seasoned investigators who have been conducting research in this area for many years and who have efficient, well-funded laboratories, the delay in obtaining Schedule 1 compounds for experiments is prohibitively long and significantly impedes progress. For example, one investigator reported that despite having a DEA Schedule 1 registration, importation from outside the U.S. of a Schedule 1 compound that proved to have significant therapeutic value and no abuse liability required nearly two years.
- Part of the difficulties in obtaining licenses to study Schedule 1 compounds stems from differing interpretations of registration requirements at both the state and federal levels, as well as at the academic administrative level.

Some suggestions for streamlining the process for obtaining a DEA registration to study fentanyl analogues are to:

- Require the Attorney General to register researchers unless it is not in the public interest, and further require researchers to submit their research protocols for review and approval by the Secretary of HHS, the National Institutes of Health, or pursuant to DEA's existing approval process. This streamlines the process compared to the current requirement for multi-agency approvals.
- Mandate that the Attorney General approve a complete application for Schedule 1 registration or request supplemental information within 60 days. If supplemental information is provided, the application must be granted or denied within 30 days of receipt. If the application is denied, the Attorney General must provide a written explanation.
- Permit researchers holding a Schedule 1 license to conduct research on all Schedule 1 drugs and allow a registrant to amend or supplement their research protocol without additional approvals required (subject to the next bullet).
- Expedite the process to make changes to the quantity, type, source, or conditions of storage, tracking, or administration of controlled substances. Require the registrant to submit an amended protocol to the Secretary and the Attorney General. Unless explicitly denied, the request is considered approved within 30 days of submission.
- Allow researchers to make limited modifications to the substances they are researching, such as processing them into extracts, solutions, or derivatives, without having to obtain a separate manufacturing license.
- Allow qualified research institutions and research laboratories to receive a blanket registration that would allow scientific investigators at the institution and laboratories to research Schedule 1 substances under a single license. The registrant will be required to notify DEA if it seeks to research a new Schedule 1 substance, and DEA to modify the registration appropriately. This allows qualified research institutions and research laboratories to engage in limited manufacturing of covered substances for research.
- Establish a 120-day grace period for newly designated Schedule 1 substances or analogues. If an applicant already has a registration to conduct research on a controlled substance, they may continue their research on the newly designated substance while waiting for their new application to be approved - while requiring researchers without an existing registration to submit one (as they continue to conduct their studies).
- Require that a practitioner, qualified research institution, or research laboratory to store Schedule 1 substances in securely locked, substantially constructed cabinets, eliminating the requirement to store each substance in a separate cabinet, other onerous cost-prohibitive measures, and arbitrary enforcement.
- Create a partnership between the Attorney General and members of the research community to expeditiously research newly discovered fentanyl-related substances.

Investigators have dedicated their careers to research in this area because we want to make a difference in protecting individuals from the devastation caused by drug abuse. But we believe that more information, not less, is the most likely way we can achieve that goal. I encourage you and your colleagues to consider alternative approaches so

that the potential benefits and risks of new chemical entities can be characterized before decisions are rendered regarding DEA scheduling.

Summary

We share the concerns of the Subcommittee about the opioid epidemic and its devastating consequence to millions of Americans, their families, and their communities. One of the main reasons for the dramatic and disturbing increase in illicit opioid use is the spread of fentanyl, a synthetic opioid that is inexpensive and potent, as well as its analogues. The College supports robust, science-based efforts to curb the sale and use of synthetic analogues.

CPDD supports efforts to give the DEA authority to control the importation and distribution of synthetic fentanyls, but we also believe that any legislation to address this issue should include language reducing some of the barriers to research currently imposed by Schedule 1 licensing requirements and must address the unintended consequences of including such a broad range of substances in the scheduling language.

We strongly recommend that any legislation on scheduling synthetic opioids – either by extending the current temporary scheduling order, making permanent scheduling of these compounds, or requiring rapid tests of their pharmacological activity – should involve the Department of Health and Human Services' science-based agencies, specifically NIDA and the FDA.

We thank you for considering our position on how these decisions may have a potentially negative impact on our shared efforts to address this serious public health issue.

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APPENDICES

U.S. House of Representatives
Committee on the Judiciary
Subcommittee on Crime, Terrorism, and Homeland Security

"Fentanyl Analogues: Perspectives on Classwide Scheduling"

28 January 2020

How Regulating Fentanyl Structure Impacts Science

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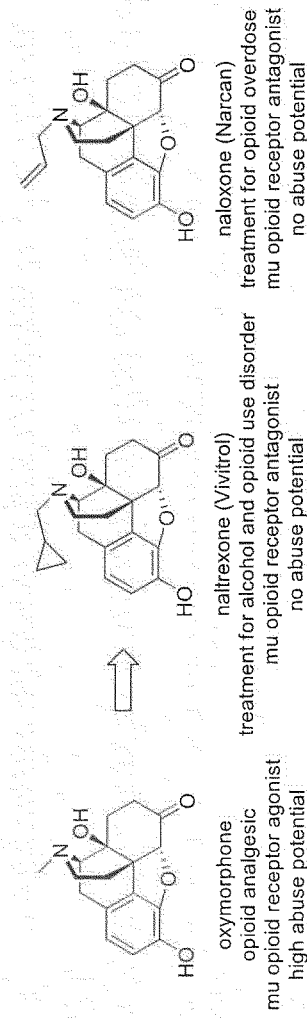
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12800 N. Lake Shore Drive

Mequon, WI 53097 USA

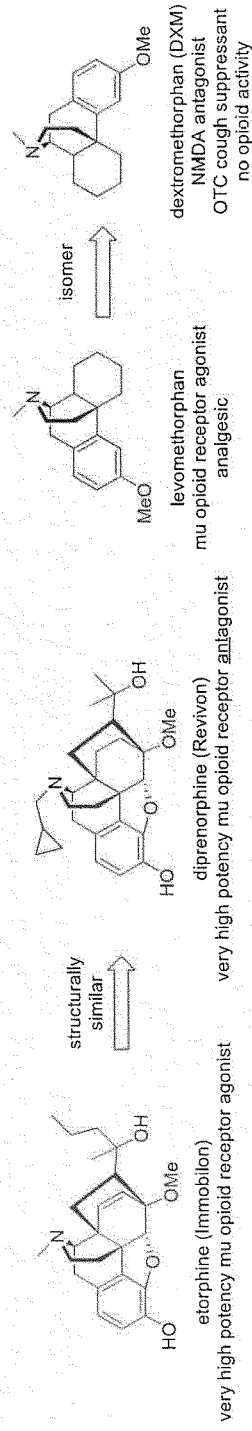
Blanket scheduling a class based on chemical structure is problematic: Very small changes to a chemical structure makes a potent agonist into an antagonist



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- Oxycodone is an opioid receptor agonist with high abuse potential. The portion of the molecule shown in red is called a *4,5-epoxymorphinan*.
- Naltrexone (Vivitrol®) and naloxone (Narcan®) are also 4,5-epoxymorphinans (in red), but are opioid receptor antagonists that have saved millions of lives.

Blanket scheduling a class based on chemical structure is problematic



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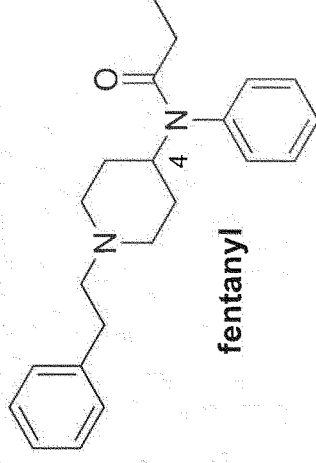
Compounds that have similar structures, or that are isomers, do not always share activity.

- Etorphine is a tranquilizer, whereas diprenorphine is its antidote.
- Levomethorphan is an analgesic, whereas DXM is an OTC cough suppressant.

Scheduling the isomer of levomethorphan would ban DXM.

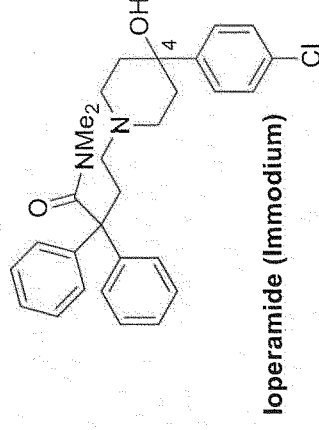
Structure of fentanyl

- Fentanyl is a 4-anilidopiperidine.
 - This group is shown in *red*.
- 4-Anilidopiperidine is not a common structural feature of current OTC medications or other pharmaceuticals.
- Piperidines with substitutions to the *N*- and 4-positions *are* common, however.



Will the proposed language identify other OTC or pharmaceutical products?

- Loperamide (Immodium®) is an anti-diarrheal.
- It *does not* have an anilide group at the 4-position of the piperidine.
- Like fentanyl, it *is* an agonist of the mu opioid receptor (MOPr).
- Unlike fentanyl, it *does not* get into the brain when taken as directed, so it has low abuse liability.



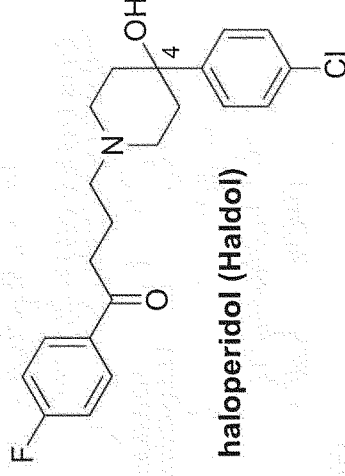
loperamide (Immodium)

Loperamide would not be covered under this language.

Will the proposed language identify other OTC or pharmaceutical products?

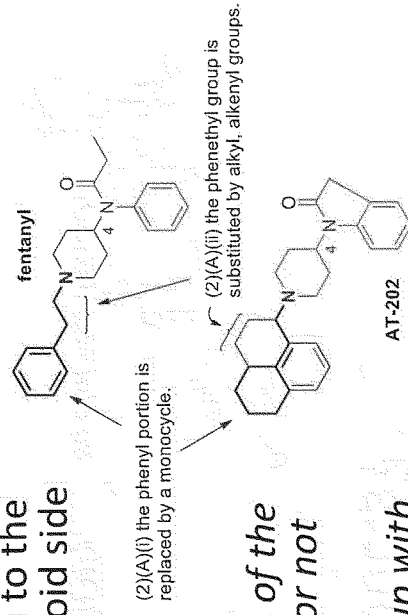
- Haloperidol (Haldol®) is an antipsychotic.
- It *does not* have an anilide group at the 4-position of the piperidine.
- Though its structure is very similar to loperamide, it has negligible affinity for MOPr.

Haloperidol would not be covered under this language.



Will the proposed language cause problems for legitimate medication development?

- AT-202 is in development as an analgesic lacking abuse liability (Astraea Therapeutics). It contributed to the discovery of AT-121, which generates few opioid side effects in non-human primates.

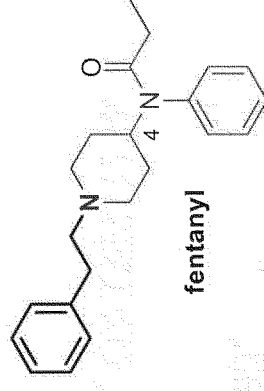


AT-202 would be covered under this language:

- (2)(A)(i) By replacement of the phenyl portion of the phenethyl group by any monocycle, whether or not further substituted on the monocycle.
- (ii) By substitution in or on the phenethyl group with alkyl, alkenyl, alkoxy, hydroxy, halo, haloalkyl, amino or nitro groups.

Will the proposed language cause problems for legitimate medication development?

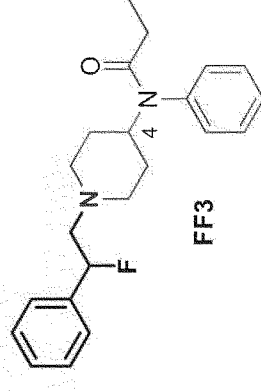
- FF3 was designed to selectively activate MOPr in inflamed tissues. Though opioid side effects were seen at high doses, this constitutes a potentially exciting new route to making safer analgesics.
- Dockendorff, et al., improved on FF3 (RR-49).



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FF3 and RR-49 would be covered under this language:

- (2)(A) (ii) *By substitution in or on the phenethyl group with alkyl, alkenyl, alkoxy, hydroxy, halo, haloalkyl, amino or nitro groups.*



References

- Reviews: Cunningham et al., *Neuropharmacology*, 2019, 151: 195-207. Burns et al., *ACS Chem. Neurosci.*, 2018, 9: 2428-2437.
- AT-121: Ding et al., *Sci. Transl. Med.* 2018, 10: eaar3483.
- FF3: Spahn et al., *Sci. Rep.* 2018, 8: 8965.
- RR-49: Dockendorff et al., *ACS Med. Chem. Lett.* 2019, 10: 1353-1356.

Ms. BASS. Mr. Butler?

TESTIMONY OF KEVIN L. BUTLER

Mr. BUTLER. Chairwoman Bass, Ranking Member Ratcliffe, Members of the subcommittee, thank you for inviting my perspective as you consider how to best respond to the opioid episode. Before I begin, I would like to pause and recognize Mr. Holman and your family. I am so sorry for your loss.

This is a complex issue. I do not pretend to have all the answers, but DOJ's proposal will simply repeat what does not work: Policies that are trumpeted as targeting kingpins that instead severely punish low-end offenders and users. My testimony here today is based on my personal experience and on behalf of the National Association of Federal Defenders. What we fear is that history is repeating itself.

I grew up in Toledo, Ohio, just south of Detroit. By the time I graduated high school in 1984, crack addiction and War on Drug laws had devastated my community. Friends and relatives with little or no criminal history who were abusing crack and selling it to support their habit were going to prison to serve long mandatory sentences with no relief. Meanwhile, drug kingpins, who had information prosecutors wanted, could cooperate, and earn reduced sentences. As a young public defender in 1992, I'll never forget the devastation on my client's face when I told him he was facing a mandatory minimum 10-year sentence. He was a young Black man my exact age. He had no criminal history, had a severe crack addiction. He was arrested for crack found in a car he was driving. Year after year, my colleagues and I fought for sentence reductions, but it was more of the same: Young minorities charged with non-violent drug offenses being sent to prison for long mandatory sentences.

Over the past decade, I've been encouraged by laws moving away from these failed and disruptive approaches. The Fair Sentencing Act of 2010 reduced the unjust crack cocaine disparity, and about 1 year ago, the First Step Act became law. Both passed with overwhelming bipartisan support, and both recognized that sentencing nonviolent drug dealers to oversized prison terms does not cure our problems. We must focus on education, treatment, and reducing overdose deaths. We have 30 years of evidence showing that a drug policy predicated on severe one-size-fits-all punishments does not work. Class-wide scheduling is not the solution. Fear and misinformation are being used to support the call for class-wide scheduling. Make no mistake: A class-wide ban will silence health experts and ignore science. I urge you to cast a critical eye on calls for this ban.

Let me first address the misinformation. To be clear, harmful fentanyl analogues are illegal now with or without class-wide scheduling. If the class-wide ban expires, no harmful fentanyl analogue will become legal. I was glad to see Judge Nancy Gertner's article this Sunday, and that has been entered into the record. This addresses that. The article addressed that. The government already, too, has powerful tools to ban and prosecute fentanyl and its analogues. The first tool is scheduling. With HHS, the Department of Justice can schedule any substance that meets certain criteria,

and DOJ can use its broad authorities under the Controlled Substances Act to temporarily schedule and then prosecute fentanyl analogues on a substance-by-substance basis without even going through the HHS process. Many fentanyl analogues have already been scheduled this way.

The second tool is the Analogue Act. This allows DOJ to criminalize substances that are chemically similar and have similar biological effects compared to drugs that are already scheduled. DOJ has used these tools to wage aggressive and successful prosecutions. Between 2014 and 2018, the number of individuals sentenced for fentanyl-related offenses has increased by 4,711 percent. Who is DOJ prosecuting? In 2018, the GAO found that DOJ was “targeting street-level and mid-level distributors rather than focusing more heavily on traditional targets, such as cartels. Less than 6 percent of prosecutions involve leaders or supervisors, more than 40 percent had little or no criminal history, and over three-quarters of the people were people of color. This is the War on Drugs Part 2.”

Currently, if DOJ wants to schedule a substance quickly, it can, but before substances are permanently scheduled, the law requires health experts at HHS to confirm that the drug is actually harmful and check for any potential beneficial uses. The class-wide ban would remove this expertise from the process. We don’t even know how many substances the ban would schedule, let alone their effects on the human body.

Ms. BASS. Thank you.

Mr. BUTLER. Thank you.

[The statement of Mr. Butler follows:]

STATEMENT OF KEVIN L. BUTLER

Mr. Chairman and Members of the Subcommittee:

Thank you for holding this hearing and for inviting me to testify. At any given time, Federal Public and Community Defenders and other appointed counsel under the Criminal Justice Act represent 80 to 90 percent of all federal defendants because they cannot afford counsel.

I have spent 27 years as a public defender on the front lines of the War on Drugs. From this vantage point, I have watched the implementation of law enforcement policies adopted in the name of ending drug addiction, reducing supply, and making streets safer. I have watched as harsh mandatory minimums and the unjust discriminatory 100-to-1 crack cocaine penalties sent my clients—many young men of color—to crowd our prisons. I have seen the broken families and communities left behind. I’ve witnessed through my clients that the policies adopted in this War on Drugs have failed.

Tens of millions of Americans continue to struggle with addiction and its consequences.¹ Near-daily headlines reporting large scale seizures of a variety of drugs prove that our nation’s choice to address drug dependence through sweeping and severe law enforcement efforts, rather than public health responses, has failed to alleviate the addiction that fuels demand.²

¹ Substance Abuse and Mental Health Services Administration, *Key Substance Use and Mental Health Indicators in the United States: Results from the 2018 National Survey on Drug Use and Health*, at 2 (2019), <http://www.samhsa.gov/data/sites/default/files/cbhsq-reports/NSDUH-NationalFindingsReport2018/NSDUH-NationalFindingsReport2018.pdf> (“In 2018, approximately 20.3 million people aged 12 or older had a substance use disorder (SUD) related to their use of alcohol or illicit drugs in the past year”).

² See e.g., Kelly McCarthy, *\$377 Million Drug Bust Includes Almost 40,000 Combined Pounds of Cocaine and Marijuana*, ABC News (Oct. 29, 2019), <https://abcnews.go.com/US/377-million-drug-bust-includes-40000-combined-pounds/story?id=66611327> (U.S. Coast Guard seizes 28,000 pounds of cocaine and 11,000 pounds of marijuana at a Florida port); *U.S. Customs and Border Control, U.S. Customs and Border Protection Seizes Over 17.5 Tons of Cocaine in Philadelphia*

We can and must do better for the individuals, families and communities impacted by addiction and its consequences. I have been encouraged by the last decade's bipartisan movement toward reform. In 2010, Congress enacted the Fair Sentencing Act to reduce the unjust disparity between crack and cocaine from 100-to-1 to 18-to-1.³ President Obama granted clemency to almost 2,000 individuals serving lengthy sentences for drug offenses, and during his Administration the Department of Justice (Department) curtailed its use of mandatory minimums.⁴ Just over a year ago, Congress passed the First Step Act of 2018 with overwhelming bipartisan support, reducing sentences for certain drug offenses and making the Fair Sentencing Act of 2010 retroactive.⁵ To date, more than 2,400 individuals serving unduly long sentences imposed under the discriminatory 100-to-1 ratio have seen reductions in their sentences.⁶ And recent government efforts to emphasize treatment instead of incapacitation, such as the SUPPORT Patients and Communities Act,⁷ show a hopeful commitment to reverse our past missteps and respond to this public health problem deliberately and humanely.

Since 2015, fentanyl has replaced heroin and crack as the face of drug addiction in our country.⁸ Fentanyl is a potent, fast-acting, synthetic opioid. There are also fentanyl analogues: substances with chemical structures and effects substantially similar to fentanyl. Fentanyl and its analogues have increasingly emerged in the illegal drug market, most often added to heroin or sold in counterfeit opioid prescription pills.⁹ In 2018, 30,000 overdose deaths involved synthetic opioids.¹⁰ Fentanyl is now present in most heroin in the Midwest and Northeast and its prevalence is spreading West.¹¹

There are troubling signs that Congress's response to fentanyl threatens to erase the gains of the past decade by returning to the failed and unjust strategies of the drug war. Some legislators who have supported the bipartisan movement away from the War on Drugs are nevertheless endorsing a harsh and punitive response to fentanyl.¹² Classwide scheduling of fentanyl-related substances, as proposed by the Department and Drug Enforcement Agency (DEA),¹³ and in several pending bills in the House and Senate,¹⁴ is part and parcel of this devolution. Classwide scheduling of fentanyl-related substances would grant the DEA broad and unilateral authority

(June 21, 2019), <https://www.cbp.gov/newsroom/national-media-release/us-customs-and-border-protection-seizes-over-175-tons-cocaine> (reporting largest cocaine seizure in the 230-year history of Customs and Border Protection, valued at \$1.1 billion); Joel Shannon, *Frozen Strawberry Shipment from Mexico Contained \$12.7 Million Worth of Meth, Authorities Say*, USA Today (Feb. 20, 2019), <https://www.usatoday.com/story/news/nation/2019/02/20/meth-worth-12-7-million-found-frozen-strawberries-mexico/2931988002/> (Customs and Border Protection seized 906 pounds of methamphetamine, worth \$12.7 million concealed in a commercial shipment of frozen strawberries).

³Fair Sentencing Act of 2010, Pub. L. No. 111-220, 124 Stat 2372 (Aug. 3, 2010).

⁴Sari Horwitz, *Obama Grants Final 330 Commutations to Nonviolent Drug Offenders*, Wash. Post (Jan. 19, 2017), https://www.washingtonpost.com/world/national-security/obama-grants-final-330-commutations-to-nonviolent-drug-offenders/2017/01/19/41506468-de5d-11e6-918c-99ede3c8c9a_story.html (granting a total of 1,715 clemencies); United States Dept of Justice, In Milestone for Sentencing Reform, Attorney General Holder Announces Record Reduction in Mandatory Minimums Against Nonviolent Drug Offenders (Feb. 17, 2015).

⁵First Step Act of 2018, Pub. L. No. 115-391, 132 Stat 5194 (Dec. 21, 2018).

⁶Federal Bureau of Prisons, *First Step Act*, <https://www.bop.gov/inmates/fsa/> (Jan. 24, 2020).

⁷See, e.g., Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT for Patients and Communities Act), Pub. L. No. 111-271, 132 Stat 3894 (Oct. 24, 2018).

⁸Drug Policy Alliance, *Criminal Justice Reform in the Fentanyl Era: One Step Forward, Two Steps Back*, at 6 (2020), http://www.drugpolicy.org/sites/default/files/dpa-cj-reform-fentanyl-era-v.3_0.pdf (One Step Forward).

⁹*Id.* See also, Centers for Disease Control and Prevention, *Synthetic Opioid Overdose Data*, <https://www.cdc.gov/drugoverdose/data/fentanyl.html>.

¹⁰*One Step Forward*, at 3; Overdose deaths resulting from these substances are grouped together with other synthetic opioids, like Tramadol. See Centers for Disease Control and Prevention, *supra* note 9.

¹¹*One Step Forward*, at 7.

¹²*Id.* at 8.

¹³*The Countdown: Fentanyl Analogues & the Expiring Emergency Scheduling Order*, Hearing Before the Committee on the Judiciary, United States Senate (2019) (statement of Amanda Liskamm, Director of Opioid Enforcement and Prevention Efforts, Office of the Deputy Attorney General and Greg Cherundolo, Chief of Operations, Office of Global Enforcement, Drug Enforcement Administration) (*DOJ Statement*).

¹⁴See, e.g., Federal Initiative to Guarantee Health by Targeting Fentanyl Act, S. 2701, 116th Cong. (1st Sess. 2019); Stopping Overdoses of Fentanyl Analogues Act, S. 1622, 116th Cong. (1st Sess. 2019); Extend Act, H.R. 5233, 116th Cong. (1st Sess. 2019); Stopping Illicit Trafficking Act of 2019, H.R. 5421, 116th Cong. (1st Sess. 2019).

to place any existing or future substance it deems to have a certain chemical structure on Schedule I, the highest restriction, with no further health or scientific justification required.¹⁵

Classwide scheduling would facilitate broader prosecutions, with harsher penalties and fewer Constitutional Due Process protections. The Department has indicated that it will use classwide scheduling to pursue severe mandatory minimums for anyone trafficking in an undefined and potentially limitless set of substances,¹⁶ without having to prove these substances harm, or were intended to harm, the human body.¹⁷ I urge you to reject this approach.

Classwide scheduling would disrupt the careful balance of drug policy authority between enforcement and public health authorities. The campaign in support of this radical shift rests on misinformation.¹⁸ To be clear: Harmful fentanyl analogues are illegal *with or without* classwide scheduling. The Department has a long history of prosecuting crimes involving fentanyl analogues, and successfully pursues stringent penalties for possessing and trafficking in these substances under existing law.

We have been here before: Over 30 years ago, reacting to alarmist rhetoric and media coverage of drug abuse in America, Congress responded by passing harsh sentencing laws replete with mandatory minimums and one-size-fits-all penalties.¹⁹ Decades later, these policies have destroyed communities, but they haven't reduced drug supply or demand. I urge this Committee to resist the misguided and rhetorically simple approach of a drug policy predicated on penalties. Evidence shows it will not work, and we will soon again be seeking inadequate remedies for the missteps of the past. Opioid addiction has devastated too many lives to respond with a false antidote. Congress must focus on evidence-based approaches directed at education, treatment, and reducing overdose deaths. We cannot incarcerate our way out of this health crisis.

I. Classwide Scheduling Would Repeat Past Mistakes

In 1971, President Nixon declared drug abuse as “America’s public enemy number one.”²⁰ “In order to fight and defeat this enemy,” he said, “it is necessary to wage a new, all-out offensive.”²¹ Fifteen years later, Ronald Reagan warned that “illegal drugs were every bit as much a threat to the United States as enemy planes and missiles.” We must “do all we can to defeat the drug menace threatening our country.”²² Congress heeded this command, enacting sweeping and severe penalties like the Comprehensive Crime Control Act of 1984 and the Anti-Drug Abuse Act of 1986.²³ A decade later, on the eve of his reelection, Bill Clinton reported “we passed ‘three strikes and you’re out’ and the death penalty for drug kingpins and cop killers,” touting the accomplishments of the Violent Crime Control and Law Enforce-

¹⁵ See, e.g., Schedules of Controlled Substances: Temporary Placement of Fentanyl-Related Substances in Schedule I, 83 Fed. Reg. 5188, n.4 (Feb. 6, 2018) (*2018 Scheduling Order*); Stopping Overdoses of Fentanyl Analogues Act, S. 1622, 116th Cong. (1st Sess. 2019) (proposing codification of *2018 Scheduling Order*).

¹⁶ United States Dept’t of Justice, Drug Enforcement Administration, *2018 National Drug Threat Assessment*, at 25 (2018), <https://www.dea.gov/sites/default/files/2018-11/DIR-032-18%202018%20NDTA%20final%20low%20resolution.pdf>. (Explaining that classwide scheduling “signifies criminals who possess, import, distribute, or manufacture any [fentanyl-related substance] is subject to criminal prosecution in the same manner as for fentanyl and other controlled substances. This action will make it easier for law enforcement officers and federal prosecutors to arrest and prosecute traffickers of all forms of FRS without having to rely on the Analogue Act.”).

¹⁷ See 21 U.S.C. § 802(32)(A).

¹⁸ See, e.g., William P. Barr, *William Barr: Fentanyl Could Flood the Country Unless Congress Passes This Bill*, Wash. Post, (Jan. 10, 2020), https://www.washingtonpost.com/opinions/william-barr-congress-pass-this-bill-so-we-can-attack-the-onslaught-of-illegal-fentanyl/2020/01/10/cbb8ccdc-33cb-11ea-a053-dc6d944ba776_story.html; Drug Enforcement Administration (@DEAHQ), Twitter (Jan. 11, 2020), <https://twitter.com/DEAHQ/status/1216094432648409090>.

¹⁹ See Lucius Outlaw III, *We Have a Growing Fentanyl Problem So Let’s Not Repeat Past Mistakes*, The Hill (Jul. 29, 2019), <https://thehill.com/opinion/criminal-justice/455213-we-have-a-growing-fentanyl-problem-so-lets-not-repeat-past-mistakes>.

²⁰ Richard Nixon, *Remarks About an Intensified Program for Drug Abuse Prevention and Control* (Jun. 17, 1971), <https://prhome.defense.gov/Portals/52/Documents/RFM/Readiness/DDRP/docs/41%20Nixon%20Remarks%20Intensified%20Program%20for%20Drug%20Abuse.pdf>.

²¹ *Id.*

²² *Remarks on Signing the Just Say No To Drugs Week Proclamation*, Ronald Reagan Presidential Library & Museum (May 20, 1986), <https://www.reaganlibrary.gov/research/speeches/52086a>.

²³ See, *Comprehensive Crime Control Act of 1984*, Pub. L. No. 98–473, tit. II, 98 Stat. 1976 (Oct. 12, 1984); *Anti-Drug Abuse Act of 1986*, Pub. L. No. 99–570, 100 Stat. 3207 (Oct. 27, 1986).

ment Act of 1994.²⁴ The laws from this era imposed harsh mandatory minimums for a variety of offenses, including drug offenses, and introduced the now-discredited 100-to-1 ratio between crack and powder cocaine.²⁵

What in 1971 was “public enemy number one,” is now in 2020 “a tsunami” of “legalized poison.”²⁶ Trafficking in fentanyl, says the Attorney General (AG), “amounts to outright murder.”²⁷ But while the rhetoric of today is the same of that from the past, we know our actions must be different. We have three decades of evidence proving that increasing sentences does not make communities safer and it does not drive down drug supply or demand.²⁸ A 2014 report commissioned by the Department “found that lengthy prison sentences are not the best way to deter crime,”²⁹ and data indicate that long sentences can actually be criminogenic and increase recidivism.³⁰ To avoid detection, users are less inclined to seek treatment and instead more likely to engage in risky drug-use behaviors.³¹

These lessons apply to fentanyl and its analogues. A 2019 Rand study reviewed fentanyl’s presence in domestic and international drug markets to create a framework for the response to fentanyl and other synthetic opioids.³² It concluded that “[t]here is little reason to believe that tougher sentences, including drug-induced homicide laws for low-level retailers and easily replaced functionaries (e.g., couriers) will make a positive difference.”³³

Our missteps in the War on Drugs are clear. Congress enacted harsh mandatory penalty laws with the goal of incapacitating high-level traffickers, “managers of drug enterprises,” and “king-pins,”³⁴ but it had no evidence from experts that higher sentences would achieve that goal in practice. Once on the books, the draconian sentencing laws impacted a broader population than Congress intended.³⁵ Indeed, only 14% of all people incarcerated federally are the managers, leaders, and organizers Congress intended to capture.³⁶ Because Congress legislated without evidence or the advice of experts, more than 2.2 million people are behind bars in America and 1 in 3 adults possess a criminal record.³⁷ We cannot repeat these mistakes.

²⁴ *The President’s Radio Address*, 32 Weekly Comp. Pres. Doc. 2282 (Nov. 2, 1996), <https://www.govinfo.gov/content/pkg/WCPD-1996-11-11/pdf/WCPD-1996-11-11-Pg2282.pdf#page=1>; *Violent Crime Control and Law Enforcement Act of 1994*, Pub. L. No. 103-322, 108 Stat. 1796 (Jan. 25, 1994).

²⁵ See Rachel E. Barkow, *Categorical Mistakes: The Flawed Framework of the Armed Career Criminal Act and Mandatory Minimum Sentencing*, 133 Harv. L. Rev. 200, 212 (2019) (*Categorical Mistakes*); see also Ranya Shannon, *3 Ways the 1994 Crime Bill Continues to Hurt Communities of Color*, Center for American Progress (May 10, 2019), <https://www.americanprogress.org/issues/race/news/2019/05/10/469642/3-ways-1994-crime-bill-continues-hurt-communities-color/>.

²⁶ Barr, *supra* note 18.

²⁷ *Id.* See also Attorney General William P. Barr Delivers Remarks at the Grand Lodge Fraternal Order of Police’s 64th National Biennial Conference, Dept. of Justice (Aug. 12, 2019), <https://www.justice.gov/opa/speech/attorney-general-william-p-barr-delivers-remarks-grand-lodge-fraternal-order-police-64th> (“A tsunami built up and has been crashing over the country, bringing death and destruction.”).

²⁸ See, e.g., Rachel E. Barkow, *Prisoners of Politics: Breaking the Cycle of Mass Incarceration*, 42–44 (2019) (*Prisoners of Politics*) (collecting studies); see also Pew Charitable Trusts, *More Imprisonment Does Not Reduce State Drug Problems* (Mar. 8, 2018), https://www.pewtrusts.org/-/media/assets/2018/03/pspp_more_imprisonment_does_not_reduce_state_drug_problems.pdf; Drug Policy Alliance, *Rethinking the “Drug Dealer,”* 12–13 (2019), http://www.drugpolicy.org/sites/default/files/dpa-rethinking-the-drug-dealer_0.pdf (*Rethinking the Drug Dealer*); Letter from FreedomWorks, Prison Fellowship, R Street Institute, et al., to the Hons. Lindsey Graham & Dianne Feinstein, at 1 (Jul. 2, 2019), <https://www.rstreet.org/2019/07/02/letter-in-opposition-to-the-stopping-overdoses-of-fentanyl-analogues-act-sofa/>.

²⁹ *Prisoners of Politics*, at 43 (citing National Research Counsel, *The Growth of Incarceration in the United States: Exploring Causes and Consequences*, ed. Jeremy Travis and Bruce Western (2014)).

³⁰ See *Id.* at 44.

³¹ See, *Rethinking the Drug Dealer*, at 13.

³² See Bryce Pardo, et al., *The Future of Fentanyl and Other Synthetic Opioids*, Rand Corp. (2019), https://www.rand.org/content/dam/rand/pubs/research-reports/RR3100/RR3117/RAND_RR3117.pdf.

³³ *Id.* at 161.

³⁴ See e.g., *United States v. Dossie*, 851 F. Supp. 2d 478, 479–80 (E.D.N.Y. 2012) (collecting legislative history).

³⁵ See *Categorical Mistakes*, at 217.

³⁶ See *Id.* at 217, n.138.

³⁷ See *Prisoners of Politics*, at 2.

II. The Department Can and Does Prosecute Harmful Fentanyl Analogues Without Classwide Scheduling

In recent months, the Department has claimed that failure to enact classwide scheduling will *legalize* harmful fentanyl analogues. “[T]he legal prohibitions on the various forms of fentanyl expire next month unless Congress reauthorizes them,” the AG wrote in the Washington Post earlier this month. Without classwide scheduling, he claimed, fentanyl analogues would become “newly legalized.”³⁸

These claims are untrue.

With or without classwide scheduling, the Department is armed with powerful tools it currently uses to successfully and aggressively prosecute fentanyl and its analogues. First, the Department can use its broad authorities under the Controlled Substances Act (CSA) to temporarily schedule—and then prosecute—fentanyl analogues on a substance-by-substance basis. Second, the Department can use the Analogue Act to immediately prosecute new substances that have not been scheduled. In contrast to classwide scheduling, both of these existing authorities include essential checks to confirm the accuracy of DEA’s designation of a substance as harmful.

First, the CSA. Many fentanyl analogues, such as carfentanil and acetyl fentanyl have already been scheduled on a substance-by-substance basis.³⁹ Fentanyl analogues that are scheduled controlled substances can be prosecuted as any other controlled substance would be prosecuted. The CSA also equips the DEA to swiftly add new substances to the schedule by providing it with temporary scheduling authority. Temporary designation becomes permanent only if the AG asks the Secretary of Health and Human Services (“Secretary”) to confirm the accuracy of the designation and the Secretary so confirms.

The second avenue that has been available to the Department since 1986 for the prosecution of unscheduled analogues—fentanyl or not—is the Analogue Act. Congress passed the Analogue Act to criminalize the harmful unscheduled chemical variants of controlled substances “that otherwise would escape the reach of the drug laws.”⁴⁰ Under the Act, a “controlled substance analogue shall, to the extent intended for human consumption, be treated, for the purposes of any Federal law as a controlled substance in Schedule I.”⁴¹ Congress listened to and relied on evidence from experts when it defined a “controlled substance analogue” to require two things: First, a chemical structure which is substantially similar to a schedule I or II controlled substance, and second, a physiological effect on the central nervous system that is substantially similar to or greater than the effect of a schedule I or II controlled substance, or a particular person must represent or intend to have a physiological effect on the central nervous system that is substantially similar to or greater than the effect of a schedule I or II controlled substance.⁴²

Whether the government would be required to prove that an unscheduled substance had both a substantially similar chemical structure, and an actual or intended substantially similar effect was carefully considered by Congress in enacting the Analogue Act. Although the Department argued for an approach that would look only to structure, Congress ultimately accepted the views of the American Chemical Society. The Society testified before the Senate Judiciary Committee that it “believe[d] it necessary to require that designer drugs meet both of these tests”—that it must “be specifically designed to have . . . a chemical structure substantially similar to that of a controlled substance” and “a biological effect substantially similar to that of a controlled substance”—“in order to protect the legitimate production of drugs that are intended for human consumption and that have similar chemical structures to those of designed drugs, but that are designed to have the opposite or dissimilar biological effects,” such as naloxone and other analogs designed with

³⁸ Barr, *supra* note 18; see also Drug Enforcement Administration (@DEAHQ), Twitter (Jan. 11, 2020, 3:28 PM), <https://twitter.com/DEAHQ/status/1216094432648409090> (“Without the emergency scheduling of the entire class of fentanyl-related substances, all non-scheduled fentanyl substances will no longer be illegal. This scheduling expires in 26 days.”).

³⁹ 21 C.F.R. 1308.12 Schedule II (2019) (carfentanil); 21 C.F.R. 1308.11 Schedule I (2019) (acetyl fentanyl).

⁴⁰ *United States v. Hodge*, 321 F.3d 429, 437 (3d Cir. 2003) (quoting 131 Cong. Rec. 19114 (1985) (statement of Sen. Thurmond) (“This proposal will prevent underground chemists from producing dangerous designer drugs by slightly changing the chemical composition of existing illegal drugs.”); 131 Cong. Rec. 27311 (1985) (statement of Sen. D’Amato) (stating that the Analogue Act “closes the loophole in present law that allows the creation and distribution of deadly new drugs without violating Federal law”); 131 Cong. Rec. 32950 (1985) (statement of Rep. Lungren) (“The focus of this proposal is clearly to impact on the designer drug phenomena by making it illegal for the clandestine chemists to manufacture and distribute these substances.”)).

⁴¹ 21 U.S.C. 813(a).

⁴² 21 U.S.C. 802(32)(A)(i)–(iii).

the purpose of countering drug abuse.⁴³ So long as an unscheduled substance is proven to be a “controlled substance analogue,” it can be treated and prosecuted as if it was a schedule I controlled substance.

Despite these authorities, and the Department’s history of prosecuting fentanyl traffickers under them, the Department now claims that it is unable to effectively prosecute fentanyl traffickers and that, without classwide scheduling, it would enter “relatively unknown territory.”⁴⁴ Other statements by the DEA and the Department, however, confirm that they know well how to use existing scheduling and prosecuting methods.⁴⁵ The Department has acknowledged its “very good track record in Analogue Act cases.”⁴⁶ As of May 2019, the Trump Administration reported a 40-fold increase fentanyl prosecutions from 2016 to 2018.⁴⁷ Data from the United States Sentencing Commission confirms that between 2014 and 2018, fentanyl trafficking offenders have increased by 4,711.1%.⁴⁸ These cases often involved mandatory minimums: In 2018, 44.6% of fentanyl traffickers were convicted of an offense carrying a mandatory minimum.⁴⁹ Such prosecutions are felt most harshly by minority defendants. In 2018, 77% of those prosecuted for fentanyl-related substances were people of color.⁵⁰

Despite claims to the contrary by proponents of classwide scheduling,⁵¹ the Department has not shown an intent to only target high-level traffickers. Available information indicates that most of the Department’s prosecutions have not been of high-level importers or traffickers but rather of couriers, mules, street-level dealers, and users. In 2018, only 5.7% of prosecutions involved individuals who were given increased sentences for having a leadership/supervisory role in the offense.⁵² Almost half—41.1%—of those prosecuted had little or no criminal histories.⁵³ Indeed, the Department has made explicit that low-level dealers and addicts are exactly whom they intend to target. In 2018, former AG Sessions initiated an “enforcement surge,” directing prosecutors in ten regions of the United States to “prosecute every readily provable case involving the distribution of fentanyl, fentanyl analogues and other synthetic opioids, regardless of drug quantity.”⁵⁴ That same year, the Government Accountability Office issued a report that recognized that federal drug enforcement agencies are “target[ing] street-level and mid-level distributors, rather than focusing more heavily on traditional targets, such as cartels.”⁵⁵

These enforcement statistics are particularly troubling in light of testimony from the Acting Chief of the DEA’s Synthetic Drugs and Chemicals section that, most often, people do not know that the substances they are selling contain fentanyl.⁵⁶

⁴³ *Controlled Substance Analogs Enforcement Act of 1985: Hearing on S. 1437 Before the S. Comm. on the Judiciary*, 996th Cong. 79 (1985) (American Chemical Society Responses to Questions from Senator Biden); see also *United States v. Roberts*, No. 01 CR 410 RWS, 2001 WL 1646732, *5 (S.D.N.Y. Dec. 17, 2001).

⁴⁴ *DOJ Statement*, at 6.

⁴⁵ See *2018 Scheduling Order*, at n.4 (noting that trafficking in fentanyl related substances is “actually illegal as persons who do so can be prosecuted using the controlled substance analogue provisions of the Controlled Substances Act”); see also *DOJ Statement*, at 5 (“In terms of investigations and prosecutions, if the temporary emergency scheduling order lapses without permanent scheduling, the Department would once again have to rely on the Analogue Act to bring fentanyl traffickers to justice.”).

⁴⁶ *DOJ Statement*, at 5.

⁴⁷ See *An Update on the President’s Commission on Combating Drug Addiction and the Opioid Crisis: One Year Later*, <https://www.whitehouse.gov/wp-content/uploads/2019/05/Opioid-Commission-Report-One-Year-Later-20190507.pdf> (last accessed Jan. 24, 2020).

⁴⁸ See USSC, *Quick Facts on Federal Fentanyl Trafficking Offenses 1* (2019).

⁴⁹ See *Id.*

⁵⁰ See *Id.*

⁵¹ See Editorial, *Congress Should Act to Allow a Ban on Fentanyl Indefinitely*, Wash. Post, Jan. 5, 2010, https://www.washingtonpost.com/opinions/congress-should-act-to-allow-a-ban-on-fentanyl-indefinitely/2020/01/05/432b94b2-2e67-11ea-bcb3-ac6482c4a92f_story.html (“there is little evidence that the Justice Department plans to target individual users rather than traffickers”).

⁵² See *Quick Facts*, *supra* note 48.

⁵³ See *Id.*

⁵⁴ Dept. of Justice, *Attorney General Jeff Sessions Announces the Formation of Operation Synthetic Opioid Surge* (S.O.S.), July 12, 2018, <https://www.justice.gov/opa/pr/attorney-general-jeff-sessions-announces-formation-operation-synthetic-opioid-surge-sos>. AG Barr has confirmed his intention of “ratchet[ing] up” this initiative. See Attorney General William P. Barr Delivers Remarks at the Grand Lodge Fraternal Order of Police’s 64th National Biennial Conference, *supra* note 27.

⁵⁵ *Illicit Opioids: While Greater Attention Given to Combating Synthetic Opioids, Agencies Need to Better Assess Their Efforts*, Government Accountability Office, March 29, 2018, <https://www.gao.gov/assets/700/690972.pdf>.

⁵⁶ See Transcript of Public Hearing before the United States Sentencing Commission, Washington, D.C., at 28 (December 5, 2017) (Joe Schleigh, Acting Chief, Synthetic Drugs and Chemi-

Sentencing Commission data supports this testimony: in 2016, only 16% of defendants sentenced in fentanyl-related cases clearly knew they had fentanyl.⁵⁷ And, more recently, the DEA agreed that: “It is highly likely many distributors do not know what exactly they are selling when it comes to differentiating between heroin, fentanyl, and fentanyl-laced heroin, as well as differentiating between diverted pills and fentanyl-containing counterfeit pills. This probably means many distributors are not intentionally deceiving customers; instead, suppliers do not always inform distributors specifically what substances or combinations of substances they are selling.”⁵⁸

Indeed, distinguishing between users and low-level dealers is simply not possible because “many people do both.”⁵⁹ Drug users sell drugs to support their habits and many low-level actors in the supply chain are not paid in money, but rather in drugs.”⁶⁰ “People who use drugs often sell them in small quantities to their friends, leaving little daylight between the role of the user and seller.”⁶¹

A client of one of my federal defender colleagues illustrates this point. The client, a 30-year old man with no criminal history, was charged with conspiracy to distribute fentanyl and fentanyl analogues, distribution of fentanyl and fentanyl analogues, and attempted distribution of fentanyl and fentanyl analogues. The client had suffered a serious back injury in high school but went on to play football in college before reinjuring his back and transferring to a school closer to home. While the client gave up football, his debilitating back pain persisted. He suffered a divorce, grew increasingly depressed and isolated, and moved away from his family. He was introduced to fentanyl by a girlfriend who was selling fentanyl online. He became addicted. Dependent upon his girlfriend for housing, finances, and fentanyl, he agreed to assist her with mailing and receiving packages and was subsequently arrested. While on bond, he successfully completed an inpatient treatment program and mental health counseling where he obtained the skills and resources to stay sober. He also addressed the root cause of his back pain. He has had two spinal fusions, which his surgeon described as “long” overdue. This individual, like so many of the clients I represent, did not sell drugs for a profit. He did not have a weapon. He was not a “king-pin,” manager, or organizer. He distributed drugs to feed his own addiction. And now he is a felon, with all of the collateral consequences that status carries, who will spend over a year in prison because his addiction was treated too late. Unfortunately, cases like this one are not outliers.

While the Department claims a permanent classwide ban of fentanyl-related substances is necessary to effective enforcement—and despite confusion regarding its use of these authorities to date⁶²—the Department has not identified any case where it has relied on the classwide ban to prosecute any major manufacturing or importation cases. Instead, it has made effective use of its substance-by-substance controls and the Analogue Act, which allows the Department to prosecute unscheduled fentanyl analogues.⁶³

cals Section, Diversion Control Division (DEA). <https://www.ussc.gov/sites/default/files/pdf/amendment-process/public-hearings-and-meetings/20171205/transcript.pdf>.

⁵⁷ See USSC, Public Data Presentation for Synthetic Cathinones, Synthetic Cannabinoids and Fentanyl and Fentanyl Analogues Amendments (January 2018), https://www.ussc.gov/sites/default/files/pdf/research-and-publications/data-briefings/2018_synthetic-drugs.pdf; see also Letter from Freedomworks, *supra* n. 28 at 2; Letter from American Civil Liberties Union (ACLU), Drug Policy Alliance, FARM, The Leadership Conference on Civil and Human Rights, *et al.*, at 3–4 (Dec. 11, 2019), https://www.aclu.org/sites/default/files/field_document/sofa_and_class_wide_ban_extension_opposition_letter_final.pdf.

⁵⁸ DEA 2018 Threat Assessment at 25, *supra* note 16.

⁵⁹ *Rethinking the Drug Dealer*, at 13; see also Zachary A. Siegel, *How to Rethink Drug Dealing and Punishment*, The Appeal (Dec. 17, 2019), <https://theappeal.org/how-to-rethink-drug-dealing-and-punishment/>.

⁶⁰ See *Rethinking the Drug Dealer*, at 36.

⁶¹ See *How to Rethink Drug Dealing and Punishment*, *supra* note 59.

⁶² In July, ABC News reported, after a Department of Justice briefing with reporters about the classwide scheduling request, that the classwide scheduling had “assisted prosecutors in cases, such as an August 2018, 43-count indictment against two Chinese Citizens who were charged with shipping fentanyl analogues to 37 U.S. states over a decade, linked to at least two deaths of Americans in Ohio.” See Alexander Mallin, *DOJ Issues Plea to Congress in Battle Against Fentanyl Copycats*, ABC News, Jul. 1, 2019. But none of the charges in that case—*United States v. Zheng*, 18-cr-00474 (E.D. Ohio)—depended on the classwide scheduling. Instead, each fentanyl-analogue related charge was for analogues that had been scheduled on a substance-by-substance basis by the DEA. 10 substances were charged under the Analogue Act, but none were fentanyl analogues.

⁶³ See 21 U.S.C. § 813.

III. Classwide Scheduling Would Be a Radical Shift in the Current Balance of Drug Policy Authority Between Enforcement and Health

The Department asserts that Congress must enact classwide scheduling to preserve an uncontroversial status quo. This elides the unprecedented and radical nature of the DEA's placement of an entire class of drugs onto Schedule I.

Congress originally decided in the CSA that the authority to schedule substances should be shared between the AG and the Secretary of Health and Human Services.⁶⁴ "This division of decisionmaking responsibility was fashioned in recognition of the two agencies' respective areas of expertise. Members of the House repeatedly stated that the Department of Justice should make judgments based on law enforcement considerations, while [the Department of Health, Education, and Welfare] should have the final say with respect to medical and scientific determinations."⁶⁵ Although Congress originally gave the ultimate decision to control to the AG, it chose to bind that decision-making by the medical and scientific findings of the Secretary. Typically, both the AG and the Secretary must evaluate eight separate factors to determine whether and where to classify a substance.⁶⁶

Thus, in its original form, no drug could be "placed in any schedule unless the findings required for such a schedule [were] made."⁶⁷ But in 1984, in response to the emergence of synthetic drugs, Congress created an exception by granting the AG temporary scheduling power, allowing the Department to skip formalized review to more quickly control new substances.⁶⁸ For that control to become permanent, however, the AG must ask the Secretary to initiate a period of scientific study to assess the scientific and medical necessity of the AG's control.⁶⁹ Congress enacted the temporary scheduling authority to "allow the Attorney General to respond quickly to protect the public from drugs of abuse that appear in the illicit traffic too rapidly to be effectively handled," but still required that the more "extensive scheduling procedures required under current law . . . be met."⁷⁰ Once that analysis is complete, and if the Secretary agrees with DEA's designation, the control is made permanent.⁷¹

In February 2018, the DEA announced it would temporarily schedule any substance with one of five modifications to the fentanyl structure in Schedule I—whether the substance is in existence or not.⁷² Prior to the order, approximately 220 individual drugs were listed on Schedule I.⁷³ The number of substances that fall within the class are unknown, but estimates have ranged from a thousand to "nearly infinite."⁷⁴ The Department did not follow the statutorily provided path to permanent scheduling which calls for initiating a scientific and medical review of its scheduling action by the Secretary. By turning to Congress instead, the Department has cut health experts out of the decision-making process. This temporary authority will expire on February 6, 2020.⁷⁵

⁶⁴ See 21 U.S.C. 811; see also Thomas M. Quinn & Gerald T. McLaughlin, *The Evolution of Federal Drug Control Legislation*, 22 Cath. U. Law. Rev. 586, 607–608 (1973).

⁶⁵ *Natl' Org. for Reform of Marijuana Laws (NORML) v. Drug Enforcement Admin.*, U. S. Dep't. of Justice, 559 F.2d 735, 745–46 (D.C. Cir. 1977).

⁶⁶ See 21 U.S.C. 811(c).

⁶⁷ 21 U.S.C. 812(b).

⁶⁸ See Comprehensive Crime Control Act of 1984, at § 508, *supra* note 23.

⁶⁹ See 21 U.S.C. 811.

⁷⁰ S. Rep. 98–225 at 264–265 (1984).

⁷¹ See 21 U.S.C. 811(h)(1) and (2).

⁷² See *2018 Scheduling Order*, at 5189 ("As indicated, the temporary scheduling order includes all substances that fall within the above definition—even if such substances have not yet emerged on the market in the United States. As a result, DEA cannot currently specify the chemical name of every potential substance that might under this new definition.").

⁷³ See 21 C.F.R. 1308.11 (2017).

⁷⁴ *The Administration's estimates have varied from "hundreds to maybe a thousand,"* see Sarah Lynch, *Trump Administration Officials Clash Over How to Combat Fentanyl Copycats*, Reuters, Jul. 9, 2019, <https://www.reuters.com/article/usa-congress-fentanyl/corrected-trump-administration-drug-officials-clash-over-how-to-combat-fentanyl-copycats-idUSL2N248062>, to "over 3,000," Kemp Chester, Associate Director, National Heroin Coordinate Group, Office of National Drug Control Policy, *Response to Questions for the Record Following Hearing Entitled, The Countdown: Fentanyl Analogues & the Expiring Emergency Scheduling Order to S. Comm. on the Judiciary* (June 4, 2019 (Chester QFRs), to "millions" to "an infinite" number, see Lynch.

⁷⁵ See *2018 Scheduling Order*. Two weeks ago, the Senate passed a measure that would temporarily extend SOFA's codification by 15-months, the *Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act*, S. 3201, 116th Cong. 2 (2020), but Senator Graham has nevertheless indicated he hoped "in the coming days we can reach an agreement that will allow fentanyl analogues to be listed as a Schedule I drug permanently," Press Release, *Feinstein, Graham, Durbin, Colleagues Pass Bill to Keep Fentanyl-Related Substances Schedule*

The CSA does not allow the DEA to do what it did here: place an undefined and potentially limitless class of “fentanyl-related substances” on Schedule I.⁷⁶ The Department has expressly acknowledged this. In testimony before the Senate Judiciary Committee, the Department described classwide scheduling—in contrast to substance-by-substance scheduling—as an “untested approach.”⁷⁷ The Department warned of “legal uncertainty surrounding the authority of the Attorney General, through DEA, to schedule fentanyl-like substances,” because it is “[i]mplicit in the structure and text of the CSA’s scheduling authority” that substances “are scheduled one at a time.”⁷⁸

In its quest for classwide scheduling, DEA seeks to permanently and exclusively vest scheduling authority for these substances with the DEA at the expense of scientific evidence and research.⁷⁹ Abandoning the expert advice of HHS should trouble the Committee. In July, a bipartisan group of Senators raised concerns that this “failure to engage necessary health experts vests far too much authority to a law-enforcement agency and may result in action that will deter valid, critical medical research aimed at responses to the opioid crisis.”⁸⁰ But DEA’s effort to cut Health and Human Services out could also have devastating consequences for public health and participants in the federal criminal system by sweeping a potentially limitless set of substances onto Schedule I.

A class-based approach is certain to criminalize substances that have no place in Schedule I. The chemical composition of different fentanyl-related substances can cause vastly different physiological effects. The Administration has acknowledged that “[t]hese analogues have a wide variance in potency. Some analogues, like acetyl fentanyl, are less potent than fentanyl; others like carfentanyl, are many times more potent; and still others, like benzylfentanyl, are believed to be essentially biologically inactive.”⁸¹

The incredible breadth of this request, in combination with the wide variance in potency of these substances, makes one fact certain: Benign, helpful, and harmful drugs alike will be swept onto Schedule I.⁸² Once placed on Schedule I, any research into these substances must flow through the DEA.⁸³ Researchers have warned that this will raise unnecessary barriers to critical research into, *inter alia*, life-saving antidotes, and warned that “the Department of Health and Human Services’ science-based agencies, specifically the National Institute on Drug Abuse and the Food and Drug Administration,” must be involved in “any decisions regarding scheduling of synthetic analogues.”⁸⁴

There are troubling signs that the Administration views a class-based approach that abandons science and evidence as the new framework for all new synthetic drugs—fentanyl or not. Kemp L. Chester, the Assistant Director of the National Opioids and Synthetics Coordination Group Office of National Drug Control Policy,

⁷⁶ (Jan. 16, 2020), <https://www.feinstein.senate.gov/public/index.cfm/press-releases?id=A4344756-7857-4160-964E-73A14E6B232D>.

⁷⁷ See 21 U.S.C. 811(h) (permitting the Attorney General to only schedule drugs on a substance-by-substance basis).

⁷⁸ DOJ Statement, at 6.

⁷⁹ *Id.*

⁸⁰ See Freedomworks Letter, *supra* n. 28 at 1 (warning that SOFA would grant the Department the “unilateral authority to add substances to the federal schedule and pursue harsh penalties”).

⁸¹ Letter from Senators Richard J. Durbin, Michael S. Lee, Sheldon Whitehouse, Amy Klobuchar, Christopher A. Coons, Mazie Hirono, Cory A. Booker, Kamala D. Harris to The Hon. Alex M. Azar II, Secretary, United States Department of Health and Human Services (Jul. 10, 2019), <https://www.durbin.senate.gov/imo/media/doc/Letter%20to%20DOJ%20HHS%207.10.pdf>.

⁸² Chester QFRs, at 3; see also Statement of Kevin L. Butler Before the U.S. Sentencing Comm’n, Washington, DC, at 28–29 (Mar. 14, 2018) (“[T]he relative potency of fentanyl and fentanyl analogues varies widely.”), <https://www.ussc.gov/sites/default/files/pdf/amendment-process/public-hearings-and-meetings/20180314/Butler.pdf>.

⁸³ See Letter from the College of Problems of Drug Dependence (CPDD) to the Hons. Lindsey Graham & Dianne Feinstein, Senate Judiciary Comm. at 2 (Dec. 13, 2019) (on file with author); see also Letter from the Friends of NIDA to the Hons. Lindsey Graham & Dianne Feinstein, Senate Judiciary Comm. (Jul. 2, 2019) (on file); Letter from the American Psychological Association to the Hons. Lindsey Graham & Dianne Feinstein, Senate Judiciary Comm. (Jul. 8, 2019) (on file); Statement of Patrick M. Beardsely, Ph. D., Re: S. 2701: *Federal Initiative to Guarantee Health by Targeting Fentanyl*, (Nov. 27, 2019) (“Harm could be caused by this bill in that it will inevitably inhibit research with fentanyl-related substances.”) (on file); Statement of Charles B. France (Nov. 29, 2019) (writing to “express my concerns regarding congressional efforts to legislatively add compounds to Schedule I of the Controlled Substance Act, in the absence of direct scientific evidence for potential harmful effects of those compounds”) (on file).

⁸⁴ See 21 C.F.R. 1301, *et seq.*

⁸⁵ Letter from CPDD, *supra* note 82.

explained that classwide scheduling provides “a framework for us to better address rapid and emerging changes in the dynamic illicit drug market, seize the initiative from illicit drug producers and traffickers and set the United States on a path to better preventing these drugs from entering the country before they kill Americans.”⁸⁵ Congress must be wary of setting a precedent that will cut health agencies out of drug policy decisions.

Moreover, the Administration has recognized that classwide scheduling will be, at best, a short term solution. Mr. Kemp has acknowledged that “scheduling an entire class of fentanyl related substances may drive illicit drug manufacturers to begin developing non-fentanyl synthetic opioids that would not be included in class-based scheduling.”⁸⁶ There are already a growing number of emerging non-fentanyl synthetic opioids—like the U-Series of drugs—that are not captured under the classwide ban and are causing overdose deaths.⁸⁷ Indeed, Mr. Chester has warned that “[G]iven what we know about the dynamism and rapid pace of illicit drug production we see today, the synthetic opioid that will be killing Americans in 2021 or 2022 has not yet been invented.”⁸⁸

There is growing recognition that, based on evidence, the only way to stop the demand for drugs is through prevention and treatment.⁸⁹ Yet an outsize proportion of federal resources is still allocated towards enforcement. It is time for the government to adjust its drug policy to catch up. It is more important than ever to maintain—and increase—the distribution of power in drug control policy to the Secretary and prioritize evidence-based strategies to effectively fight this critical public health issue.

IV. Conclusion

Classwide scheduling is a step in the wrong direction and would mark a return to the failed approaches of the War on Drugs. The Department has used existing tools to successfully and aggressively prosecute harmful fentanyl analogues and those tools do not disrupt the balance between, on one hand, enforcement, and on the other, science, prevention and public health. Again, I thank the Committee and appreciate the invitation to share my perspective on this issue.

Ms. BASS. Mr. Holman?

TESTIMONY OF DONALD A. HOLMAN

Mr. HOLMAN. Chairwoman Bass, Ranking Member Ratcliffe, and Members of the subcommittee, thank you for inviting me to testify today. My name is Don Holman. My son, Garrett’s, 21st birthday was on February 17th, 2017, but he never saw it. He died on February the 9th, just 8 days prior, from his 3rd synthetic opioid overdose in less than 2 months.

Garrett grew up in Lynchburg, Virginia, where he established friendships in grammar school that carried through high school. Growing up, he spent endless hours playing sports and spending time with family and friends. Garrett was diagnosed at an early age with ADHD and took medication to help him concentrate in school, but as Garrett grew older, he resisted taking the medication and started self-medicating with marijuana.

As parents, we were not aware until he started having disciplinary schools at school. Our focus then became to make sure he graduated from high school and hopefully go to college. We went through many different scenarios from trying to set down reasoned rules to trying to get him treatment for anxiety and depression. We would make excuses for Garrett’s behavior to friends, family, and

⁸⁵ Statement of Kemp L. Chester, Assistant Director of the National Opioids and Synthetics Coordination Group Office of National Drug Control Policy, Before the U.S. Senate, Committee on the Judiciary, at 6 (June 4, 2019).

⁸⁶ *Id.*

⁸⁷ *See Id.* at 2.

⁸⁸ *Id.* at 3.

⁸⁹ *See supra* note 7.

co-workers, but never revealed the extent to which his illness had progressed. I never gave up hope, and I was proud of my son. He needed medication for anxiety, but due to his tendency to abuse, he was never diagnosed or treated properly. Finally, someone told him about a synthetic opioid that would not show up on a drug test, so some time in November 2016, he ordered U-47700 online, and it was delivered to the house by the U.S. Postal Service.

Garrett overdosed the first time in December 2016 where I had to perform CPR until the paramedics arrived to administer naloxone and transport him to the hospital. Once he awakened in ICU, it was obvious that this was not the wakeup call we had hoped, so he was forced into a mental health evaluation. From there, he reluctantly went into a 30-day in-house treatment program, but a week after he got out, he overdosed the 2nd time. I forced him into a 2nd evaluation, but the judge decided he did not belong in a mental health facility, and released him on February the 6th, 2017. His final overdose was 3 days later, on February the 9th.

You're never prepared to lose a child. Garrett's death has pulled our family apart, and we work to deal with our loss in a different way, each in a different way. My son's synthetic opioid exposure was less than 2 months, and at 20 years old, I do not believe he deserved to die for his initial bad choices. I understand that today's session is to hear testimony on extending the temporary class-wide scheduling on fentanyl analogues. By extending the ban, in my opinion, we continue to control what is coming into the U.S. killing Americans and allow time to finalize the permanent solution that allows for research access and ensures the punishment fits the crime.

Garrett's struggles were not a death sentence until he discovered synthetic opioids. I have learned that before the temporary ban, analogues were a challenge to schedule, and so each slight variation was identified and scheduled individually. Class-wide scheduling allows for an urgent response to this fast-moving global crisis. Since that time, law enforcement has been able to aggressively bring high-tech criminal drug traffickers to justice, and China is now with the United States in similar scheduling for fentanyl analogues. If we back off, China and other countries may follow, and the result will be catastrophic because criminals are counting on this. Sadly, there are people in the world that see unscheduled fentanyl analogues as an opportunity to make a tremendous amount of money with absolutely no regard for human life. Without class-wide scheduling, they can produce, distribute, and kill with less risk of being held accountable.

I'm also sensitive to situations where mandatory minimums may need to be considered, but not today, not here, and not in relation to fentanyl. Today, someone using or selling fentanyl or one of the analogues for any reason is very likely to kill themselves or someone else. I went from fighting to keep my son out of jail to fighting to get him into jail to save his life. I failed both times. Instead, let's continue to focus on jail and prison reform so individuals are treated like human beings, and the goal is rehabilitation and a permanent return to society.

My friend, Sheriff Cocchi, in Hamden County, Massachusetts, has this type of rehabilitation program in place. He even allows adult males not charged with a crime into his facility for treatment. If my son would have gone to jail for an extended period of time, I would at least be able to visit him. If he were receiving treatment for mental health and substance abuse issues, I feel sure he would be here today.

Because of the bipartisan support in fighting the opioid crisis, politics do not play a role in the decision to approve the extension. Additionally, I have also not read any scientific studies that indicate a person's gender, race, religion, or political affiliation makes them exempt from the tragic effects of the opioid crisis.

In conclusion, I ask that you please extend class-wide scheduling as soon as possible, but also let's continue to work towards a permanent solution that will continue to give law enforcement an effective tool while also minimizing any concerns. Please allow the opioid crisis to be the issue that encourages everyone to reach across the aisle and put Americans and American lives first. I'd also like to thank this committee, Congress, the White House, ONDCP, HHS, CBP, HIS, DOJ, and DEA for everything you do to combat the opioid crisis. Each step forward is a step closer to resolving this issue, which will not only save thousands of American lives, but will also ensure that other parents will not have to bear the pain of losing a child to overdose. Thank you.

[The statement of Mr. Holman follows:]

STATEMENT OF DONALD A. HOLMAN—DAD AND IMPACTED PARENT

Donald A. Holman—Bio

On February 9th, 2017, I lost my son Garrett to an overdose from a synthetic Opioid called U-47700. Since that time, I have been working to do my part to help fight the Opioid Crisis on every front. I have attended round table meetings with Gov. Christie and the First Lady as well as testified in PA for Senator Jay Costa. I attend HIDTA meetings when possible and make myself available to support efforts at the Federal level when needed. I have shared information with HSI and CBP PA to help identify the source of the Opioids that caused Garrett's death.

Garrett ordered Synthetic Opioids online that were shipped through the mail from China and delivered to the House by the Mail carrier. When I first shared this story almost three years ago no one believed it.

I firmly believe that my role is to support those at the Federal level when I can so together, we can stop this crisis and stop losing our children and other loved ones to this disease. My mission is not specific and covers a broad range of issues and solutions to combat the Opioid Crisis. I will not stop until Americans stop dying from overdose.

Chairman Nadler, Ranking Member Collins of the House Judiciary Committee and Chairwoman Bass, Ranking Member Ratcliffe, and Members of the Subcommittee on Crime, Terrorism, and Homeland Security, thank you for inviting me to testify today and share my personal story as well as my perspective on Classwide Scheduling for Fentanyl Analogues.

My Name is Don Holman.

I am not a Scientist, Politician, Lawyer, or Doctor ... I am just a Dad who wants to share my personal story with you of my son Garrett.

Garrett's 21st birthday was on February 17, 2017, but he never saw it. He died on February 9th just 8 days prior from his third synthetic overdose in 2 months. Garrett is a statistic of the current Opioid Crisis and makes up less than 1% of the victims that died that day from Overdose in the U.S.

Garrett was born and grew up in Lynchburg, VA living in the same house most of his life with my wife, Bobbie and I and his sister Kristen. He established friendships in Grammar school that carried through High school and spent endless hours

playing Football, Basketball, and lacrosse as well as Wake boarding in the summer and snowboarding in the winter.

I would prefer to spend time talking about all the good qualities and the person Garrett really was but that would take a long time. Garrett was diagnosed at an early age with ADHD and took medication to help him concentrate in school. One of the side effects of ADHD medication is loss of appetite which presented an issue for someone athletic that enjoyed playing sports. As Garrett grew older, he resisted taking the medication part because he didn't like the way it made him feel, and part because emotionally he felt it was what everyone else wanted not

what he needed. I now know that Garrett started self-medicating early in High School and like so many he was introduced to Marijuana and convinced that it was a natural alternative to the ADHD Medication. As parents, we were not aware, and it wasn't until the 11th Grade that his behavior really started to concern us due to several incidents of him getting into trouble.

However, he had many more good days than bad, and it seemed to be just a rebellious stage or at least we hoped.

Our focus was to make sure he kept his grades up so he could graduate High School and hoping he would mature so he could go to college. With constant pressure and push he was able to graduate and even get accepted to Liberty University for the Fall Semester.

Once he got out of High School, he struggled with the transition from child to Young adult. He never adapted to College and ended up dropping his classes that semester. As parents we went through so many different scenarios, trying to set boundaries and rules to trying to get him treatment for Anxiety and Depression. He was very strong minded and as a result of defiance and bad decisions started to get into legal trouble. He quickly fell into a downward spiral and soon the focus was on keeping him from a felony conviction and going to jail.

Like so many parents, we would make excuses for Garrett's behavior to friends, family, and coworkers but never reveal the extent on which his illness had progressed. This is where the Stigma plays a tough role in the person afflicted as well as the Family that supports them. Mental Illness, Substance Abuse, and Addiction are not things that people want to talk about or other people want to hear. I never gave up hope and I was proud of my son. I did not want to imply that he was any more than a little wild and would settle down soon and be on track.

Unfortunately, meeting legal obligations took precedence over any treatment for Mental Health or Substance Abuse. He was under a lot of pressure but the whole time still struggling with the need to escape reality. He needed medication for Anxiety but due to his legal issues and his tendency to abuse, he was never diagnosed or treated properly. Finally, someone told him about a Synthetic Opioid that would not show up on a drug test and that is all he heard.

Sometime in November 2016 he ordered a synthetic Opioid U-47700 online and it was delivered to the apartment by the mail carrier. So today, the mail carrier can inadvertently be the new drug dealer.

This Was the Beginning of the End

Garrett overdosed the first time in early December 2016, and I had to perform CPR until the paramedics arrived to administer Naloxone and transport him to the Hospital. Once he awakened in ICU it was obvious that this was not the wakeup call, we had hoped, so he was forced into a mental health evaluation by his Mom and me. He was only required to stay 5 days. From there he reluctantly went into a 30-day in-house treatment program but a week after he got out, he overdosed the second time and once again I called 911 then performed CPR until Paramedics arrived and revived him. I forced him into a second evaluation, but the judge decided he did not belong in a mental health facility and released him on Feb 6, 2017. His final overdose was three days later on Feb 9, 2017. His cause of death was determined accidental as a result of mixed drug use. He had taken the synthetic Opioid U-47700 and Xanax.

You will never be prepared to lose a child. Garrett's death has pulled our whole family apart and we are each working to deal with his loss a different way. I am not sharing my story because I have all the answers, I am sharing because I am sure I am not alone, and I would like to do my part to make it easier to have the conversation. You may read a headline about the opioid epidemic and see information about Heroin, or Fentanyl laced Heroin or maybe over prescribing of Pain medication. All of which are relevant and still carry the negative stigma and in many cases the opinion that a person addicted made a choice and deserves what they got. My son's Synthetic Opioid exposure was less than 2 months. He did not have time

to hit bottom. At 20 years old, I do not believe my son deserved to die for his initial bad choices.

I do not have all the answers, I just think everyone needs to be asking the questions and working together to fight this Crisis.

Looking back, when I first saw my son in the funeral home, I became enraged and all I could think was that this is unacceptable, and I am angry! I immediately exclaimed I needed to talk to the President and let him know what happened because I felt it was a case of National Security that needed attention at the highest level of our Government. That fire I felt from that day until now has not diminished and I don't think it ever will.

In the last three years I have become very close friends with several Parents that have also lost a child to Overdose. I have participated in Round table meetings with Gov Christie, the First Lady Melania Trump and have talked with the US Surgeon General. I have a close relationship with the Director of the ONDCP and continue to communicate with DEA, CBP, and HSI.

I truly believe that everyone has something, and I constantly meet people that for some reason will share their story with me. There is no one solution or silver bullet but if we all work together and listen to each other, we can establish tools and resources that will collectively save lives.

My understanding of this hearing is a focus on testimony to help determine if the temporary Classwide Scheduling on Fentanyl Analogs should be extended for an additional 15 months. The simple, only answer to that is YES it should, and we should not be here at the last hour debating it. Also, within the next 15 months we need to pass SOFA or something similar to make it permanent.

Garrett was a good looking, bright, intelligent, and athletic young man who had dreams and hopes just like everyone else his age. His struggles were not a death sentence until he was made aware of a synthetic Opioid that he could order online from China and have delivered to the house by mail. Since then I have learned that because of Synthetic Analogues both Fentanyl and other Synthetics, were a challenge to declare illegal until each slight variation was identified and scheduled.

Since that time with the temporary ban on all Fentanyl like analogues, DEA and Law enforcement have been able to aggressively bring these high-tech criminal drug traffickers to justice. The most important accomplishment and the one that makes me feel like Garrett's death may not have been in vain, is that China is now with the U.S. in similar scheduling for Fentanyl Analogues. If we back off our stance against Fentanyl Analogues, then China and other countries may follow, and the result will be catastrophic because criminals are watching and waiting for this to happen. Instead of reducing the current ban, my hope is that we not only extend the current Scheduling ban for Fentanyl Analogues, but we make it permanent and do the same thing for all Synthetic Opioids.

We hear a lot about the Health issues around Substance abuse and efforts to increase Treatment and Recovery which are so important and do save lives and give those struggling the chance for a future. However, the reality we hear less about is that there are people in this world that see Fentanyl and especially the unscheduled Fentanyl Analogues as an opportunity to make a tremendous amount of money with absolutely no regard for human life. Without the classwide scheduling, they are able to produce, distribute, and kill with less risk of being caught and held accountable.

I have tried to look at any justifiable reason that might make sense to not make this Classwide Scheduling permanent or at a minimum approve the 15-month extension. I refuse to believe that Politics play any role in the decision not to approve the extension. No matter what the political climate is in DC, first and foremost we are all Americans and we are all human beings. So far, I have not read any scientific studies that indicate being of a certain sex, race, religion, or political party makes you or anyone in your family exempt from tragedy as a result of the Opioid Crisis.

In the case of mandatory minimums, I am sensitive to the fact that there may be situations where they need to be considered but not today, not here, and not in relation to Fentanyl. I went from fighting to keep my son out of jail to two days before I lost him, fighting to get him into jail to save his life, I failed both times and now he is gone.

If someone is arrested and charged with distribution of Fentanyl or a Fentanyl Analogue, I understand there are provisions to evaluate the person to be sure they are not someone using and selling to support an addiction as opposed to someone selling solely for profit. In my opinion, instead of debating this issue, let's continue to focus on jail and prison reform where anyone being arrested is treated like a human being and efforts are in place to rehabilitate and return to society as a proud person with the skills to succeed and not return to prison. I have recently visited

a correction facility in Mass where Sheriff Cocchi has a program to do this. He even allows adult males not charged with a crime into his facility for treatment if it is determined they are a danger to themselves.

If my son would have been caught and because of mandatory minimums, put in jail for an extended period of time, he may have had a chance and could be alive today. I would be fine visiting him in jail and if he was receiving treatment for mental Health and Substance Abuse, his chances of fulfilling his dreams would be a reality. Today, someone using or selling Fentanyl or one of the Analogues is very likely to kill themselves or someone else.

Conclusion

I ask that you please extend Classwide Scheduling ASAP and let's continue to work towards a permanent solution that will continue to give law enforcement an effective tool while also minimizing any concerns.

Please allow this to be the issue that everyone reaches across the aisle and puts Americans and American lives First.

I would like to thank the Committee, the White House, ONDCP, HHS, CBP, HSI, DOJ and DEA for everything you do to combat the Opioid Crisis. Each step forward is a step closer to resolving this issue which will not only save thousands of American lives but will also ensure family and friends of those lost will not have to bear the pain and loss of losing a loved one to overdose. I would also like to remind you that myself along with other parents and siblings like me that have lost a loved one, are here to help in the fight. Take advantage of that resource so we can beat this together. Thank You!



Garrett and his sister Kristen



Garrett



Garrett High School Graduation



Garrett doing what he loved!



Image of envelope mailed to the house from China with Synthetic Opioids

Ms. BASS. Dr. Ciccarone?

TESTIMONY OF DANIEL CICCARONE, M.D.

Dr. CICCARONE. Mr. Holman, my condolences for your loss.

Mr. HOLMAN. Thank you.

Dr. COMER. It is good to see you again today.

Mr. HOLMAN. Thank you, Dan.

Dr. COMER. Chair Bass, Ranking Member Ratcliffe, and other distinguished Members of this subcommittee, thank you for the opportunity to speak in front of you today. My name is Dan Ciccarone. I am a professor of family and community medicine at UCSF, and I am an addictions medicine specialist, an academic researcher, and drug policy expert. I know the current overdose crisis firsthand. I have witnessed it at the ground level in my research, and my team and I have published extensively on it.

Here are my thoughts on how the Class 1 schedule of fentanyl derivatives might work counter to the goals of public health.

Point 1: The class of fentanils is a large number of unexplored compounds, over 1,400, some of which have been identified already as partial agonists and antagonists at the opioid mu receptor. Because of the potency of illicit fentanyl, it is important to explore new antagonists to reverse overdose and new treatments to address greater dependency, and these may come from the fentanyl class. Based on my research, users and low-level dealers typically do not know if the drug they are selling or using contain fentanyl.

Piont 2: Making a class ban on fentanyl permanent will likely increase trends in fentanyl trafficking and prosecution, which disproportionately affect those at the bottom of the supply chain.

Point 3: Class 1 scheduling has not been shown effective in reducing the number of overdose deaths, nor reducing fentanyl availability. The latest provisional data from the CDC as of June 2019 shows synthetic opioid overdoses continuing to rise at a rate of 8.3 percent over the year prior. This is despite 15 months of emergency scheduling. In an analysis of 10 years of drug seizure data from Ohio, which my team and I have just published this month, we found a steady rate of novel synthetics, of novel fentanils being introduced through the end of 2018. Now, I know that only includes 10 months of emergency scheduling, so we need more data on that. However, I do want to point out a drug policy metaphor, and that is, squeezing the drug supply balloon often causes supply to pop out in unexpected places. We've already seen the U series, the AH series, the other series of non-fentanyl synthetics coming out. We do not know what happens next.

Point 4: despite decades of strong prohibitionist efforts, drug mortality is increasing exponentially. A report in the Journal of Science found an exponential growth in overdose deaths from 1978 to 2016. This exponential increase in drug overdose deaths was not defined by any specific class of drugs. The triple-wave fentanyl opioid is just the last phase of this 38-year phenomenon. The reasons for this worse-case public health scenario involves 2 failures: First, that of drug prohibition to stop the drug supply balloon from morphing, and, secondly, the failure to address the underlying or root causes of problematic drug use. There's growing evidence that we need to address the social and economic determinants of health,

the root causes of drug demand, and the overdose crisis if we are to fill in the cracks of society that the waves of drug supply fall into.

Overdose deaths due to illicit fentanyl represent a historic crisis, one full of challenges, but this era is also one of historic opportunity to rebalance our drug policies more in favor of demand reduction, including treatment, and away from failed prohibitionist policies, and to reorient to a healthier society resilient to problematic drug use. Specifically, we need to offer treatment of punishment. We need to expand treatment, reduce the barriers to buprenorphine, for example, with the Mainstreaming Addiction Treatment Act of 2019, which has House and Senate versions. We need greater support for prevention. Harm reduction's goal is to reduce deaths and other harms from drug use. Because it is person-centric, it can reduce stigma and engage folks where they're at. It can even serve as a bridge to treatment.

One could argue that HIV/AIDS was a similar crisis in the 1990s, one with stigma and a head-in-the-sand approach at first, but one which was eventually addressed with a comprehensive plan of prevention and treatment. Likewise, now, we need a grand piece of legislation, like the Ryan White CARE Act, to address the current crisis. In my small way, I've helped envision and promote such a comprehensive and balanced plan, including treatment, harm reduction, demand reduction, and supply reduction. Its implementation could signal the end of this unfortunate era.

I thank you all for your time, and we're willing to answer any questions you have.

[The statement of Dr. Ciccarone follows:]

No Moral Panic: Public Health Responses to Illicit Fentanyl

Testimony of Daniel Ciccarone, M.D., M.P.H.
Professor, Department of Family and Community Medicine,
University of California San Francisco

Before the House Committee on the Judiciary,
Subcommittee on Crime, Terrorism and Homeland Security
United States House of Representatives

Hearing: Fentanyl Analogues: Perspectives on Class Scheduling
January 28, 2020

Chair Bass, Vice-Chair Demings, Ranking Member Ratcliffe and other distinguished members of the House Subcommittee on Crime, Terrorism and Homeland Security, thank you very much for the opportunity to testify before you today. It is indeed an honor to be here. My name is Dan Ciccarone. I am professor of family and community medicine at the University of California, San Francisco. I have been a clinician for over 30 years and an academic researcher in the area of substance use with a focus on the medical and public health consequences of heroin use for the past 20 years. I have been asked to speak on my perspective on the class scheduling of fentanyl analogues and how these regulations might work counter to the goals of public health.

My research and that of my team is multidisciplinary and multi-level. We use the tools of epidemiology, anthropology, statistics, economics, clinical and basic sciences. I am appreciative of my funder, which is the National Institutes of Health, National Institute on Drug Abuse, as well as my team, which includes Dr. Jay Unick, University of Maryland, Dr. Sarah G. Mars, UCSF, Dr. Dan Rosenblum, Dalhousie University, and Dr. Georgiy Bobashev from RTI, North Carolina.

I know the current overdose epidemic first hand. I have witnessed it at the ground level in my street-based ethnographic research. My team and I have published extensively on the opioid overdose crisis. In this testimony I will discuss the public health dimensions of the triple wave opioid overdose crisis, give a primer on the fentanyl class of opioids, and present the challenges of drug supply control esp. as they relate to fentanyls, as well as the opportunities presented by drug policy reform and demand reduction.

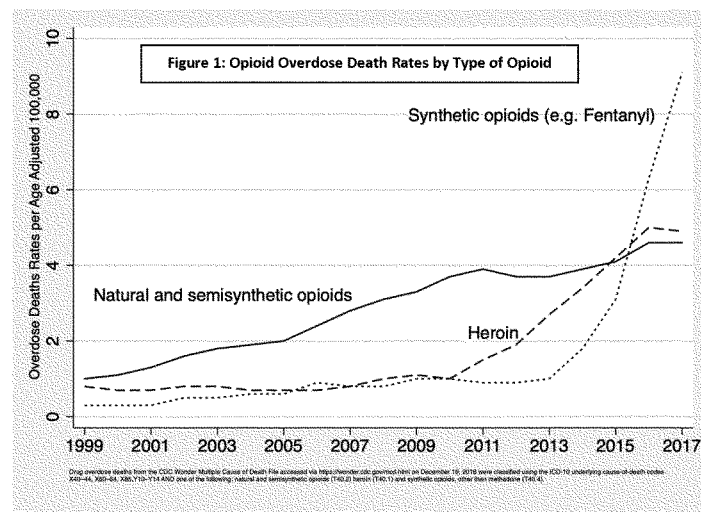
Overdose deaths due to illicit fentanyl represent a historic crisis; one full of challenges. But, this era is also one of historic opportunity: to rebalance our drug policies more in favor of demand reduction, including treatment, and away from failed prohibitionist policies; and to reorient to a healthier society resilient to problematic drug use.

A Drug Crisis of Historic Proportions

For the first time in 100 years, life expectancy at birth has gone down in the US three years in a row from 2014 to 2017.¹² In 1919, mortality rates shot up because of the ravages of WW1 and the great influenza pandemic. And because these events disproportionately affected young people, correspondingly life expectancy went down. While we don't have a war of similar scale or infectious epidemic affecting young people today we do have another scourge: drug poisoning which is disproportionately affecting young people and driving down life expectancy. According to the latest formal data from the US Centers for Disease Control and Prevention (CDC), deaths due to drug poisoning exceeded 70,000 in 2017; with a 9.6% increase in drug mortality rate from 2016.³ Since the beginning of the opioid epidemic 700,000 Americans have died from drug poisoning. Annual deaths due to drug overdoses now exceed deaths due to car accidents, gun violence, and even HIV at the height of the 1990's HIV epidemic.³

The triple wave epidemic

The triple wave epidemic of overdose deaths stems from three classes of opioids: prescription opioid pills ("semi-synthetic opioids" in Figure 1), heroin and synthetic opioids other than methadone.⁴ Figure 1 shows three waves of opioid mortality, each wave cresting on top of the one



¹ Murphy SL, Xu JQ, Kochanek KD, Arias E. Mortality in the United States, 2017. NCHS Data Brief, no 328. Hyattsville, MD: National Center for Health Statistics. 2018

² Woolf SH, Schoomaker H. Life expectancy and mortality rates in the United States, 1959–2017. JAMA, 2019;322(20):1996–2016. <https://doi.org/10.1001/jama.2019.16932>

³ Hedegaard H, Miniño AM, Warner M. Drug overdose deaths in the United States, 1999–2017. NCHS Data Brief, no 329. Hyattsville, MD: National Center for Health Statistics. 2018

⁴ Ciccarone, D. The triple wave epidemic: Supply and demand drivers of the US opioid crisis. International Journal of Drug Policy, <https://doi.org/10.1016/j.drugpo.2019.01.010>

before it. In the first wave, overdoses related to opioid pills, started rising in the year 2000 and have steadily grown through 2016. The second wave saw overdose deaths due to heroin, which started increasing clearly in 2007, surpassing the number of deaths due to opioid pills in 2015. The third wave of mortality has arisen from fentanyl, fentanyl analogues and other illicit synthetic opioids in the drug supply, climbing slowly at first, but dramatically after 2013. Data from 2017 show synthetic opioid deaths continuing to rise, reaching a peak of over 28,000, while opioid pill and heroin overdose deaths leveled off, albeit at very high levels of approximately 15,000 deaths in each category.⁵ **It is important to note that the latest provisional data from the US Centers for Disease Control and Prevention (CDC) shows the third wave – deaths due to fentanyls – continuing to rise with 32,299 deaths attributed to synthetic opioids in the 12-months period through June of 2019; an 8.3% increase from the 12-month period prior to June 2018.⁶**

Understanding fentanyls

Opioids are put into three classes based on their relationship to opium: Natural, semi-synthetic and synthetic. Natural opioids are derived from opium, a gum extract of the poppy ovary; examples include morphine and codeine. Semisynthetics are derived from opium derivatives e.g. morphine or thebaine; examples include well known pharmaceutical opioids e.g. hydromorphone or oxycodone. Synthetics have no relationship to opium-based products and are produced in pharmaceutical facilities. Examples include fentanyl and methadone. Another way to classify opioids is by their mechanism of action at the mu-receptor of the nervous system: agonist, partial agonist and antagonist. Many pain medications as well as most opioids with abuse potential are full mu agonists. By triggering the mu-receptor they induce pain relief as well as euphoria. Partial agonists are just that, weaker stimulators of the mu-receptor. A good example of a partial agonist is the medication buprenorphine which is considered an excellent choice in treating opioid use disorder aka opioid addiction. Antagonists are essentially blockers of the mu-receptor and thus trigger no effect, except perhaps dislocating an agonist from mu binding and reversing its effect; the overdose reversal agent naloxone is a good example.

Fentanyl and its chemical cousins, the fentanyl analogues, are synthetic opioids. Mother chemical fentanyl is a powerful agonist with potency by volume 100 times that of morphine, 40 times that of heroin.⁷ As a licit medication fentanyl is successfully used in surgery, obstetrics and end-of life care; it has both short-acting and long acting forms which when applied correctly are tremendously useful. The street fentanyl that is causing the overdose crisis is illicitly manufactured product. According to the US Drug Enforcement Administration (DEA), illicit fentanyl is mostly coming from China.⁸ There is Estonian and Russian production, but those products do not come to the US. There have been waves of fentanyls into the US for three decades, the last one in 2006 in the Chicago region; however the recent wave, beginning in 2014 is the longest lasting.

⁵ Hedegaard H, Miniño AM, and Warner M, Drug overdose deaths in the United States, 1999-2017, in NCHS Data Brief no 329. Hyattsville, MD: National Center for Health Statistics. 2018.

⁶ <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>. Accessed 1.22.20

⁷ Ciccarone D. Fentanyl in the US heroin supply: A rapidly changing risk environment. *Int J Drug Policy*. 2017 08; 46:107-111. PMID: 28735776. PMCID: PMC5742018

⁸ US Drug Enforcement and Administration (2016). 2016 National Drug Threat Assessment Summary. Washington, DC: Domestic Strategic Intelligence Unit, Special Strategic Intelligence Section.

Most of the illicit fentanyl is agonists and thus have abuse potential. **It is important to note, however, that researchers have identified fentanyl analogues which are partial agonists and antagonists. In addition, importantly, one cannot predict which fentanyl analogue is going to be an agonist or an antagonist based on chemical structure alone.**

My team and I have the privilege of doing some of our research in street-based settings talking to folks who use drugs and observing heroin, fentanyl and other drug use. This research helps gain a deep cultural understanding of drug use along with gaining the perspective of those most affected by the vicissitudes in supply and the structural risks that are imposed on them. From a public health perspective we are interested in understanding both imposed risk as well as behavioral risk taking. These understandings better inform interventions to reduce the negative health outcomes. We have written extensively on fentanyl supply, risk and perception.^{9,10,11,12,13,14,15,16} Among our findings: Fentanyl is a supply side phenomenon that was not driven by demand from heroin users; most street-based fentanyls are not sold as is, they are sold as fentanyl-adulterated or -substituted heroin (FASH); fentanyl adulteration is occurring unbeknownst to users and low-level dealers; FASH is the norm in the areas of the country with the highest overdose rates i.e. Midwest and New England regions; the fentanyl component of FASH is unpredictable and under constant change; as fentanyl supply changes, overdose risk changes. **It is important to note that the cryptic nature of FASH and the resultant vicissitudes in heroin and fentanyl potency are likely driving overdose (more so than sheer potency alone). In addition, it appears likely that fentanyls appear to be here to stay; for a deadly chemical to stay around for 5 years says something about its durable supply.**

PARADOXES OF PROHIBITION

The failure of drug prohibition

Drug policy is roughly divided into two poles: demand reduction and supply reduction. I have just stated that FASH is a supply side imposition into the US drug market. Since it is supply-sided then why not simply “turn off the tap”? It’s not that I don’t believe in drug supply as problematic – I do and have written a number of papers on supply and the downstream problems it creates – it’s just that the reverse, i.e. attempting to decrease the problem by curtailing supply doesn’t work as

⁹ Mars S, Bourgois P, Montero F, Karandinos G, Ciccarone D. "The Textures of Heroin: User Perspectives on "Black Tar" and Powder Heroin in Two US Cities." *J of Psychoactive Drugs*. 2016 Sep-Oct;48(4):270-8. doi: 10.1080/02791072.2016.1207826. Epub 2016 Jul 20 PMID:27440088

¹⁰ Ciccarone D, Ondocsin J, Mars SG. Heroin uncertainties: Exploring users' perceptions of fentanyl-adulterated and -substituted 'heroin'. *Int J Drug Policy*. 2017 08; 46:146-155. PMID: 28735775. PMCID: PMC5577861

¹¹ Ciccarone D. Fentanyl in the US heroin supply: A rapidly changing risk environment. *Int J Drug Policy*. 2017 08; 46:107-111. PMID: 28735776. PMCID: PMC5742018

¹² Mars SG, Ondocsin J, Ciccarone D. Sold as Heroin: Perceptions and Use of an Evolving Drug in Baltimore, MD. *J Psychoactive Drugs*. 2017 Dec 06; 1-10. PMID: 29211971. PMCID: PMC6114137

¹³ Mars SG, Ondocsin J, Ciccarone D. Toots, tastes and tester shots: user accounts of drug sampling methods for gauging heroin potency. *Harm Reduct J*. 2018 May 16; 15(1):26. PMID: 29769132. PMCID: PMC5956544

¹⁴ Mars SG, Rosenblum D, Ciccarone D. 'Illicit fentanyls in the opioid street market: desired or imposed?' *Addiction*. 2018 Dec 4. doi: 10.1111/add.14474.

¹⁵ Ciccarone D. The triple wave epidemic: Supply and demand drivers of the US opioid overdose crisis. *Int J Drug Policy*. 2019 Feb 1. pii: S0955-3959(19)30018-0. doi: 10.1016/j.drugpo.2019.01.010.

¹⁶ Rosenblum D, Unick J, Ciccarone D. The Rapidly Changing US Illicit Drug Market and the Potential for an Improved Early Warning System: Evidence from Ohio Drug Crime Labs, Drug and Alcohol Dependence 208 (2020) 107779. <https://doi.org/10.1016/j.drugalcdep.2019.107779>

well as we want it to and in fact having an excessive supply focus can have paradoxical results.

Supply control, including prohibition of drugs, and with the corollary penalization of drug use, has been the leading force in US drug policy for over a hundred years. The founding father of these prohibitionist efforts, beginning in the 1920s, was Henry Anslinger. President Richard Nixon famously coined the term “war on drugs” to highlight his efforts to curb the drug problem in the early 1970s. There is an extensive critical literature on the societal outcomes of this so-called war on drugs. I want to focus on one paper that is highly relevant to today’s discussion.

The journal *Science*, published by the American Association for the Advancement of Science (AAAS), is the most highly respected publication reporting on advances in scientific understandings in the world. Hawre Jalal and colleagues, reported in the September 21, 2018 issue of *Science* the results of their analysis of 38 years (1978 – 2016) of drug mortality data.¹⁷ **They found an exponential growth in overdose deaths over this time period (Figure 2).** This exponential increase in drug overdose deaths was not defined by any specific class of drugs. **Each era has its**

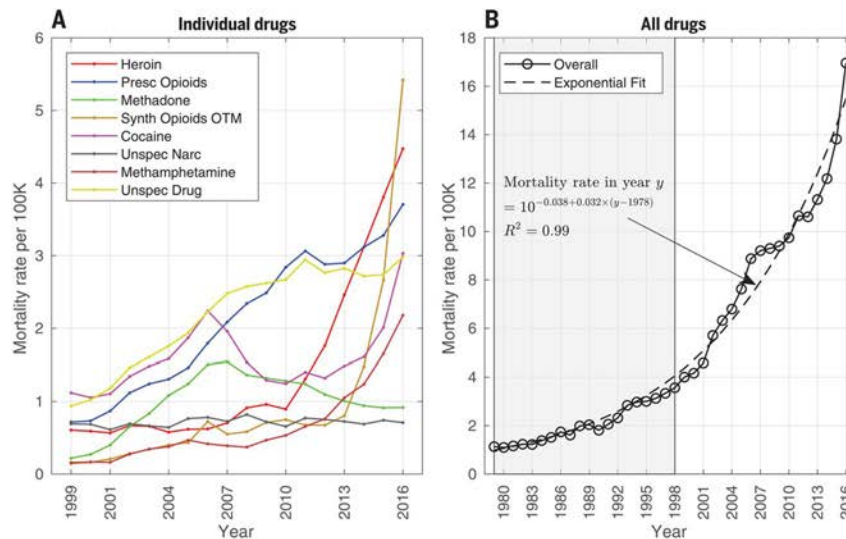


Figure 2. Mortality rates from unintentional drug overdoses. (A and B) Mortality rates for (A) individual drugs and (B) all drugs. Detailed data for individual drugs are only available from 1999 to 2016, although additional data for all drugs are available since 1979 (this area is grayed out). The exponential equation and fit are shown for all drugs. (Synth Opioids OTM: synthetic opioids other than methadone. This category includes fentanyl and its analogs.) From Jalal H, Buchanich J, Roberts MS, Balmert LC, Zhang K, Burke DS. Changing dynamics of the drug overdose epidemic in the United States from 1979 through 2016, *Science* 21 Sep 2018;Vol. 361, Issue 6408, eaau1184. DOI: 10.1126/science.aau1184. Reprinted with permission from AAAS.

¹⁷ Jalal H, Buchanich J, Roberts MS, Balmert LC, Zhang K, Burke DS. Changing dynamics of the drug overdose epidemic in the United States from 1979 through 2016, *Science* 21 Sep 2018;Vol. 361, Issue 6408, eaau1184. DOI: 10.1126/science.aau1184

problematic drug defined by supply or by cultural desire, but the underlying driver of problematic drug use leading to death is independent of the type of drug and getting worse over time. Deaths due to opioids, including fentanyl, is only the latest manifestation of this multi-decade phenomenon. There is no doubt however that the triple wave has made the situation much worse.

The reasons for this ‘worse case’ public health scenario involves two failures: firstly, that of drug prohibition to curb the problem and secondly, the failure to address the underlying, root, causes of problematic drug use.

There is a metaphor we use in drug policy when discussing the paradoxical effects of many supply interventions: that of the ‘balloon’, i.e. attempts to restrict supply are like squeezing a balloon and, as we all know, that leads to the balloon popping out in an unexpected place. There are historical examples of supply control events with paradoxical effects. I’ll give just one example from my own research. In the 1990s and 2000s, the US led or supported intense efforts to reduce cocaine production in Colombia and export to the US. These efforts included crop spraying and supply route interdiction as well as arrest, extradition and supported killing of drug cartel leaders. These efforts led to reduced coca crops but unfortunately did not immediately affect the historically high cocaine production at the time – at the height of which approximately 1,000 metric tons were estimated to be produced each year. **One unforeseen result of this downward pressure on coca/cocaine was the novel introduction of poppy and heroin production – for the first time in Colombian history.** In a 2009 publication on this issue I stated; “The diversification of Colombian drug production and export to include heroin in addition to cocaine, with the resultant increase in heroin availability in the US, despite reduced supply from traditional sources, highlights a paradoxical effect of interdiction.”¹⁸ The influx of new Colombian-sourced heroin into the US led to a nationwide decrease in heroin price to historically low levels.¹⁹ The DEA’s metric for success in controlling a drug’s supply is increased price. Despite multi-decade efforts to control heroin into this country, whether from Afghanistan, Colombia or Mexico, heroin prices have remained at relative historically low levels.

The under-recognized driver of drug mortality is demand and the under-treated root causes of drug demand. A demand-side argument has been introduced examining the structural factors that might be driving the triple wave overdose epidemic.²⁰ (Indeed they may be driving the 38-year exponential increase in overdose mortality.) The “diseases of despair” analyses highlight the extraordinary rise in death rates, among middle aged Whites without a college degree, in three related categories: drug poisoning, alcohol-related disease and suicide. The most compelling structural determinants include an aging population with rises in reported pain and disability, economic distress, declining social cohesion and rising psychological malaise that may have led an at-risk population to seek opioids in the first place [17]. In this line of reasoning increased opioid

¹⁸ Ciccarone D. Heroin in brown, black and white: structural factors and medical consequences in the US heroin market. *Int J Drug Policy*. 2009 May; 20(3):277-82. PMID: 18945606

¹⁹ Ciccarone D, Unick GJ, Kraus A. Impact of South American heroin on the US heroin market 1993-2004. *Int J Drug Policy*. 2009 Sep; 20(5):392-401. PMID: 19201184

²⁰ Dasgupta N, Beletsky L, Ciccarone D. Opioid Crisis: No Easy Fix to Its Social and Economic Determinants. *Am J Public Health*. 2018 Feb; 108(2):182-186. PMID: 29267060. PMCID: PMC5846593

prescribing is a “vector” of the opioid overdose epidemic with more proximal root causes being worsening structural forces accompanied by generational hopelessness and despair [19].

The futility of fentanyl prohibition

The current issue is whether the emergency scheduling of fentanyl derivatives as a class in schedule 1 should be continued, perhaps permanently. There are a number of problems with a permanent class-wide fentanyl ban:

- The class of fentanyls has a large number of unexplored compounds, some of which are theoretically beneficial for treatment or as overdose antagonists. Schedule one classification will inhibit basic science and clinical research
- Emergency scheduling has not been shown effective in reducing fentanyl availability nor reduced the number of overdose deaths
- The ‘Iron Law’ of prohibition predicts stronger chemicals, more potent by volume, to be trafficked under greater supply control
- The high potency and low volume of fentanyl already strain the potential successfulness of interdiction. The supply control challenge is worsened by the move from agricultural-based to lab-based illicit drug manufacturing
- Making the class-ban on fentanyl permanent will likely increase trends in federal prosecution from fentanyl trafficking; countering the goals of public health as well as trends in sentencing reform for drug possession

More than 1400 fentanyl analogues have been synthesized as research chemicals and two hundred of these analogues have been studied pharmacologically.²¹ The DEA’s National Forensic Laboratory Information Service is actively tracking over 16 analogues which have entered the illegal drug market.²² The public health concerns center on the illicit fentanyl agonists which have abuse potential and overdose risk due to their potency, but research into fentanyls has identified potential antagonists, like naloxone, and partial agonists, like buprenorphine, which may be useful in treatment. **Why is this important? Because of the potency of illicit fentanyl we need to explore new antagonists to reverse overdose and new treatments to address greater dependency. So we need better, perhaps stronger, perhaps longer lasting, antagonists and partial agonists – and they may come from the fentanyl class.** This class ban will also potentially inhibit: 1, clinical trials of novel beneficial fentanyls and 2, clinical understandings of how fentanyls adversely affect health e.g. why overdose events are so severe.

It is important to note: as of the latest data, the currently active class-wide ban hasn’t yet shown effective. For example, my team and I have analyzed drug seizure data from the Ohio Bureau of Criminal Investigation’s (BCI) crime lab from 2009 to 2018 (204,951 samples across 87 counties, providing 8,352 county-month observations) to examine trends and the relationship between drug seizures (type, amount) and overdose at the county level.¹⁶ Ohio has been exceptional hard-hit by the third wave – fentanyls – of the opioid crisis which began in 2014. **Our analysis**

²¹ Misailidi N, et al. Fentanyls continue to replace heroin in the drug arena: the cases of ocfentanil and carfentanil. *Forensic Toxicol* (2018) 36:12–32 <https://doi.org/10.1007/s11419-017-0379-4>

²² U.S. Drug Enforcement Administration, Diversion Control Division. (2017). NFLIS Brief: Fentanyl and Fentanyl-Related Substances Reported in NFLIS, 2015–2016. Springfield, VA: U.S. Drug Enforcement Administration.

shows the number of fentanyl analogues by year: The only fentanyl analogue detected in 2015 was acetyl fentanyl; eight new analogues appeared in 2016, six more appeared in 2017 and seven new analogues appeared in 2018. Other non-fentanyl synthetic opioids emerged as well: U-47700 in 2016 and U-48800, U-49900, and U-51754 in 2017. No decline in novel opioids over time was seen and the spill-over to non-fentanyl synthetics is concerning. However, it is important to note that the DEA class-wide scheduling took effect in Feb., 2018 so additional study is needed.

In a Commentary I published in the International Journal of Drug Policy, stemming from a testimony I gave in 2018 to a House subcommittee, I argued that synthetic opioids may represent the “end of interdiction.”²³ One paradox of supply control that comes out of examining alcohol prohibition in 1920s America is termed the “Iron Law of Prohibition.” This ‘law’ predicts that drug weight and volumes go down while potencies go up due to supply control. During Prohibition the illicit alcohol trade shifted from beer to high alcohol content liquors to avoid detection. We see evidence of this effect in the current triple wave opioid crisis as supply pressures on opioid pills, esp. those illicitly marketed, shifted the street market to higher potency heroin to even higher potency fentanyl.¹⁴ **The “Iron Law” suggests that highly potent-by-volume drugs like fentanyl are expected due to the honing effects of interdiction.**²⁴

Interdiction will be challenging given the size of illicit fentanyl flows. In 2016, a mere 668 kg of fentanyl was seized in the US, a fraction of the estimated 11 metric tons of cocaine seized in 2016 at the US Southwest Border alone. Fentanyl’s high potency allows shipment in small volumes. Considering a seizure to importation ratio of 1:4, a total of 2.6 metric tons of fentanyl may have been distributed in the US in 2016. This would fit into approximately 10 industrial drum barrels – a tiny volume that if divided up over the huge trade that occurs across the Pacific Rim constitutes a proverbial needle in a haystack.¹⁴

Why is it so hard to get the fentanyl supply genie back in the bottle? In their recent publication, *The Future of Fentanyl*, Bryce Pardo and colleagues discuss the drivers of the synthetic opioid market in the US: increased profitability, lack of regulatory capacity in the main source country, China, as well as technological advancements in purchasing (i.e. cryptocurrencies) and routing.²⁵ The change in source-country of our imported illicit opioids is important: from known drug-producing countries, e.g. Afghanistan, Colombia and Mexico to new source-countries i.e. China. In addition, moving from agricultural based drugs, e.g. poppy and heroin, to lab-based drugs, e.g. fentanyl, makes the sourcing and routing more challenging to detect. The technology to produce fentanyls is mobile; if China were able to crack down on domestic production, the supply balloon could squeeze production to a novel source-country.

Making the class-ban on fentanyl permanent will likely increase trends in federal prosecution from fentanyl trafficking. Sentencing commission data show dramatic increases in fentanyl trafficking offenders, disproportionately among persons of color; with 41% having no prior criminal

²³ Ciccarone D. The triple wave epidemic: Supply and demand drivers of the US opioid overdose crisis. *Int J Drug Policy*. 2019 Feb 1. pii: S0955-3959(19)30018-0. doi: 10.1016/j.drugpo.2019.01.010.

²⁴ Beletsky, L. and C.S. Davis, Today’s fentanyl crisis: Prohibition’s Iron Law, revisited. *International Journal of Drug Policy*, 46 (2017): 156-159. <http://dx.doi.org/10.1016/j.drugpo.2017.05.050>

²⁵ https://www.rand.org/content/dam/rand/pubs/research_reports/RR3100/RR3117/RAND_RR3117.pdf

record and 50% at the bottom of distribution chain. The vast majority did not know they are selling fentanyl.^{26,27}

Sociologists and anthropologists talk about “moral panics” when society collectively acts out of instinct or fear. This notion often fits when we respond to problematic drug waves. The moral panic over fentanyl leads to irrational claims and responses e.g. the fear that fentanyl cannot be touched or that fentanyl is being deliberately put into all substances, not just heroin. These myths are being debunked as we learn about fentanyl. We saw the same fear based reaction when HIV became epidemic in the 1990’s and folks with that disease were shunned and treated prejudicially. **Fear, moral panic, penalization of drug use – all lead to stigma and marginalization of the affected population. And this is counter to the goals of public health which wants folks not to run and hide but to come forth for prevention and treatment services.**

SUMMARY

- The third wave of the opioid overdose crisis continues to grow with increasing numbers of deaths in 2019 – despite the past two-year all-class fentanyl scheduling
- The class of fentanyls is very large with untapped research and clinical potential. Possible future therapeutic agents including antagonists and partial agonists are known to be present
- Fentanyls appear to be here to stay; illicit fentanyl represents a historic shift from agricultural based to lab-based illicit drug production – from an new illicit drug source country – China
- Users and low level dealers typically don’t know if the drug they’re selling/using contains fentanyl. Making the class-ban on fentanyl permanent will likely increase trends in federal prosecution from fentanyl trafficking which are disproportionately affecting those at the bottom of the supply chain
- The currently active class-wide ban has not yet shown effective examining data as of late 2018; the numbers of new fentanyl analogues – and non-fentanyl synthetic opioids e.g. the U-series – shows steady growth in hard-hit Ohio; more study is needed
- The “Iron Law” suggests that highly potent-by-volume drugs like fentanyl are expected due to the honing effects of interdiction
- Despite decades of strong prohibitionist efforts, drug mortality is increasing exponentially. The under-recognized driver of drug mortality is demand and the under-treated root causes of drug demand

²⁶ "Public Data Briefing: Synthetic Drugs - United States Sentencing" https://www.ussc.gov/sites/default/files/pdf/research-and-publications/data-briefings/2018_synthetic-drugs.pdf

²⁷ "Public Data Briefing: Synthetic Drugs - United States Sentencing" https://www.ussc.gov/sites/default/files/pdf/research-and-publications/data-briefings/2018_synthetic-drugs.pdf; https://www.ussc.gov/sites/default/files/pdf/research-and-publications/quick-facts/Fentanyl_FY18.pdf

- **Fear, moral panic and penalization of drug use – leading to stigma and marginalization of the affected population – run counter to the goals of public health**

THE WAY FORWARD

I've lost too many colleagues, patients and research participants to overdose. I understand the desire to act, the need to do something to reduce the carnage. But I also know the danger of moral panic and the stigmatizing effects of excessively punitive approaches and exuberant supply reduction approaches. By increasing stigma – a very powerful force in human nature – they are simply counterproductive to the goals of public health.

Fentanyl is here to stay. They are the new norm. Instead of fear let us respond with a public health orientation of science, reason and compassion.

I have had the privilege to meet with criminal justice leaders, at various national meetings held by the National Institute of Justice, DEA, High Intensity Drug Trafficking Areas (HIDTAs) among others, and heard them state that “we are not going to arrest our way out of this.” They and leaders at the Office of National Drug Control Policy (ONDCP) have called for “public health / public safety partnerships. These shifts in political tone from leadership – and also the public – favor treatment over incarceration.

Chauncey Parker, Executive Assistant District Attorney in the Manhattan District Attorney's Office and Director of the New York/New Jersey HIDTA program often speaks of his “North Star” in tackling the fentanyl problem: to reduce deaths. So what strategies are most likely to reduce deaths?

- Offer treatment over punishment. Pre-arrest diversion and other strategies to move folks from prosecution to medical help for their substance use disorder have a growing evidence base of effectiveness.
- Expand treatment for opioid use disorder. Medically assisted treatment (MAT) includes three medications shown to be medically effective and cost-effective.²⁸ A recent meta-analysis showed impressive reductions in mortality attributable to receipt of MAT.²⁹ Buprenorphine is one of the efficacious medications. It is esp. effective from a public health standpoint as it can be prescribed by primary care providers, e.g. family docs and nurse practitioners. However, regulatory burden, e.g. mandatory prescriber training and DEA licensing, inscribed in the DATA 2000 law authorizing its use has led to lower levels of prescriber uptake.³⁰ **The Mainstreaming Addiction Treatment Act of 2019, with House (H.R.2482) and Senate (S.2074) versions, attempts to address the barriers inherent in the original legislation.**

²⁸ Volkow, N. D., Frieden, T. R., Hyde, P. S., & Cha, S. S. (2014). Medication-assisted therapies – Tackling the opioid-overdose epidemic. *The New England Journal of Medicine*, 370(22), 2063–2066. <https://doi.org/10.1056/NEJMp1402780>.

²⁹ Ma J. et al. Effects of medication assisted treatment on mortality among opioids users: a systematic review and meta-analysis. *Molecular Psychiatry* (2019) 24:1868-1883. <https://doi.org/10.1038/s41380-018-0094-5>

³⁰ Fiscella K, Wakeman SE, and Beletsky L. Buprenorphine Deregulation and Mainstreaming Treatment for Opioid Use Disorder: X the X Waiver. *JAMA Psychiatry*, 2019. 76(3): p. 229-230.

- Increase federal funding. Federal legislative efforts to address the opioid crisis, e.g. Comprehensive Addiction and Recovery Act (CARA) and the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT) are quite helpful, yet much more is needed. Overdose deaths from all opioids have only fallen 2% since their peak in 2017.
- Greater support for prevention. Harm reduction ideas and prevention technologies, once controversial, are gaining both evidence and acceptance. Ideas such as syringe exchange are now supported by such leaders as Assistant Secretary Giroir at Health and Human Services and naloxone distribution, once quite controversial, has broad support including endorsement by the US Surgeon General Jerome Adams. HR's goal is to reduce deaths and other harms from drug use; because it is person-centric it can reduce stigma and engage folks that use drugs; it can even serve as a bridge to treatment.
- Surveillance of the drug supply, a possible element of a public health / public safety partnership, can potentially act as an early warning system alerting front line responders to dangerous changes in supply.¹⁶ Another emerging novel approach includes drug checking. Heroin users who used fentanyl immunoassay test strips to check for fentanyl had greater odds of positive changes in behavior.³¹

At this moment we are, alas, still working on yesterday's problem. **The 4th wave of the opioid crisis sees a shift in use patterns to methamphetamine and a dramatically rising curve in methamphetamine-related deaths. To end the multi-decade multi-generational exponential increase in drug mortality we need bold answers and creative novel responses.** There is growing evidence that we need to address the social, economic determinants of health – the root causes of the drug crisis – if we are to ‘fill in the cracks’ of society that the waves of drug supply fall into.¹⁹

Assisting Josh Katz at the New York Times, we surveyed 30 experts to “think big, but realistically, about solutions. Imagine you had \$100 billion to spend over five years — a little less than current federal domestic H.I.V./AIDS spending — to address the opioid crisis. Where would you put that money?” The composite answer was a revelation: A comprehensive, but balanced plan including treatment, harm reduction, demand reduction and supply reduction.³² This schematic has been turned into policy platforms for a number of top political figures. Its implementation could signal the end of an unfortunate era.

³¹ Peiper NC, Clarke SD, Vincent L, Ciccarone D, Kral AH, Zibbell JE. Fentanyl Test Strips as an Opioid Overdose Prevention Strategy: Findings from a Syringe Services Program in the Southeastern United States. *Int J Drug Policy*. 2019 Jan;63:122-128. doi: 10.1016/j.drugpo.2018.08.007.

³² Katz, J. (2018). How a police chief, a governor and a sociologist would spend \$100 billion to solve the opioid crisis. Feb 14, Retrieved from The Upshot, New York Times <https://www.nytimes.com/interactive/2018/02/14/upshot/opioid-crisis-solutions.html>.

Ms. BASS. Thank you. We will now proceed under the 5-minute Rule with questions. I will begin by recognizing myself for 5 minutes.

In 1 minute, Mr. Butler, I am going to let you finish what you were trying to say because I did interrupt you, if there are other parts of your testimony that you wanted to give. Before I do that, I just wanted to know if you would comment. In the first panel, I asked the question about where this manufacturing of the analogues take place, and it was acknowledged it is in China and Mexico, and I don't understand why we can't get China and Mexico to stop. We slap tariffs on China, we threaten Mexico around the border, but we can't get that to happen, and I want to know your opinion about that. In other words, what can we do on the international side to stop the drugs from coming in? In addition, to trying to stop it from crossing the border, I am talking about stopping it from being manufactured. Turn your microphone on.

Mr. BUTLER. Chairwoman Bass, that is a wonderful question. I will be frank with you. It is above my level. By that, I mean I am the defender of a wonderful organization. We deal with, what I will say, the street-level impact of these drugs. As far as what needs to be done at a national level addressing and stopping the drugs from coming over the border, I can't answer that, but what I can say is this. What we are not seeing on a national level is the prosecution of the importers, the major traffickers. What we are seeing, like my office and others throughout the country, is the prosecution of a 4,000, 5,000 percent increase in prosecution of low-level and mid-level dealers.

I think DEA and Attorney General Barr in their statements regarding this crisis have indicated that they need this scheduling order to become permanent so that they can go after the higher-level people bringing it in from China, bringing it in from Mexico. Well, as to date, we are not seeing those prosecutions. What we are seeing is what saw back in the 80s and 90s, lower-level people getting mandatory sentences and being prosecuted under this offense.

Ms. BASS. Again, it is one thing to talk about the importation, but I am talking about the manufacturing.

Mr. BUTLER. Understood.

Ms. BASS. I don't understand why on a government level, and it just doesn't seem as though we are forcing the Chinese or the Mexican government to actually crack down on the manufacturing of it before it is even brought in. Mr. Holman, and then I will go back to you, Mr. Butler, did your son and did your family have access to drug treatment? Was it inpatient, outpatient?

Mr. HOLMAN. In our situation, it wasn't primarily the substance abuse issue. It was a variety of items that were going on. The synthetic opioid overdose or the use of that was in a 2-month period. It was so quick. He was not looking for something and found it. In essence, it was marketed to him. I brought his phone. This is what the drug dealer that sold it to him. He was told that he can go online and order this from a regular website, use bitcoins. This is a photograph of what was delivered to the house. It is an envelope that was addressed from China and the material that was in there. Once this was brought to his awareness, it was so fast. The strug-

gles we had before were seemingly manageable, but with this substance, it just totally derailed everything.

Ms. BASS. Thank you. Mr. Butler, would you like to finish the testimony you were giving?

Mr. BUTLER. Yes, thank you. The last part of my testimony was the Trump Administration estimates that the number of banned substances has ranged from hundreds to thousands to an infinite number. Even the Administration concedes that fentanyl-related substances can range from deadly to beneficial to benign. I have already spoken to this, but I will just repeat it. This will not work. We know that a punitive war on fentanyl will devastate communities and fuel mass incarceration. We are seeing that trend already. Let's keep evidence and health experts in the room, and together we will find a better way. Thank you. That was my last portion.

Ms. BASS. Thank you. Dr. Comer, you recommended that in any scheduling of synthetic fentanils, HHS, and, particularly, its science-based agencies, should be integrated into the process of reviewing the abuse liability of the suspect compounds. Can you talk about how that could be accomplished?

Ms. COMER. Yes. So, as we heard earlier today, the HHS is involved with, you know, scheduling decisions. What I referred to was a streamlined process for making it easier to evaluate the pharmacology of these compounds without going through the full 8-factor analysis, and, in fact, NIDA has a procedure in place for doing that. They have screened compounds rapidly for several decades actually.

Ms. BASS. Thank you. Mr. Gohmert?

Mr. GOHMERT. Thank you, Chairman. I appreciate you all being here. We had heard testimony from the prior witnesses about how many lethal doses could end up or are required to send somebody to prison for the minimum. Mr. Butler, do you have a recommendation on how many lethal doses of fentanyl should trigger a prison sentence?

Mr. BUTLER. Well, wonderful question. If your question is exactly how much fentanyl someone should have before they go to jail, that is not my place. That is, I believe, the legislators' place. What I can say that there were misrepresentations, I believe, by Ms. Liskamm, not regarding the actual doses, but how drugs are actually used in real world. By that I mean the circumstances Mr. Holman dealt with—that is, coming in through the mail and his son unfortunately and tragically using it—is not the circumstance that my office and other offices are seeing. What we are seeing an individual on the street who doesn't know that he has fentanyl, has a mixture of substance about the size of an aspirin pill, that he believes to be heroin. A small—

Mr. GOHMERT. My time is very limited, so let me move on. Mr. Holman, I understand how difficult it must be. We are told you can't truly sympathize with somebody unless you have been in their shoes. I do think there is something genetically in us that causes some people to have a much more addictive personality, and that is something I would love to see more research on. I can't help but wonder how you would feel about what Texas did back in the 90s when I was on the bench. Some people disagreed with it, but

they were locked down, felony punishment, the substance abuse felony punishment facilities.

Back then, I had some data indicating 70 percent of those who went to prison had a drug or alcohol addition, and it seemed to make sense to me that we ought to have facilities where if you are addicted to something, that is where you go, and everything is about furthering education and dealing with your addiction. Is that something that you contemplated might have been more help for your son?

Mr. HOLMAN. Yes. Those that are struggling are not maybe typical of what you would think. I mean, my son was bright, smart, intelligent. He could sit here and talk to you just as I am today. So sometimes they need to have that cloud lifted in some way so they can actually think clearer to get the treatment they need. So, in my case, that was not an option. You cannot force an adult into a treatment facility. I grew up in the 80s and 90s. I am very familiar. I have personal experience with how maybe things were not handled correctly then.

I talk about jail and prison reform, and Sheriff Cocchi I mentioned, I actually visited his facility and spent 5 hours. I would recommend anyone to look into what he is doing. Because of a law on the books, all his inmates are treated for substance abuse. They receive MAT. Even people who are not arrested go in, and it is not a bad thing.

Mr. GOHMERT. Is that a 12-step program, or what is it?

Mr. HOLMAN. It is a full program. You can sum it up in a few minutes. You have to go look at his facility and so forth. I honestly feel like this time where we are at, you have to pull people away. With the crack cocaine, just like with other substances, you may have a little bit more time. With the synthetic opioids, and especially fentanyl, it is not just pure fentanyl. It is put in a Xanax bar. It is mixed in with—

Mr. GOHMERT. It is put in all kinds of things.

Mr. HOLMAN. So, what used to be the low-level dealer then is actually a drug trafficker. You people are 95 percent there. You are getting close. You are talking about all the right things because it is a complex process. My only ask is that don't let this expire. Extend, but then let's keep working. I am local. I will come, whatever you need, to satisfy mandatory minimums, to satisfy research opportunities, that everybody wins.

Mr. GOHMERT. Well, my time is about to expire.

Mr. HOLMAN. Sorry.

Mr. GOHMERT. Let me just indicate that we have been hearing through the impeachment proceedings that it is totally inappropriate for a President to ask a foreign country to help us with some type of criminality that involves our country, but it sure sounds like that is something we ought to be doing to root this out.

Mr. HOLMAN. I am very close with those at ONDCP, and they are working. China is working with us. The indications are with their scheduling, if we do not extend, they will be ahead of us with their scheduling. Chairwoman Bass, that is something that I believe does help hold those countries accountable, not just China, but any other country that is poised to jump in and do the same thing, because these are smart people. We don't talk enough about the

criminals because it is not a good topic, but there are people out there that are high tech. They are chemists. They are technically capable to market this to our children and right under our noses.

Mr. GOHMERT. Thank you, Madam Chair.

Ms. BASS. Absolutely, and I would agree it is very important to hold foreign governments responsible when they are impacting the American people. Mrs. McBath?

Mrs. MCBATH. Thank you, Madam Chair, and thank you to each of you for being here today and just really shedding light on this really very deadly epidemic that we are dealing with. Mr. Holman, I want to thank you so much for your testimony. I offer you my deepest condolences because I understand what it is like to lose your child. I lost my child to an epidemic, but it was an epidemic of gun violence. So, thank you so very much for willing to lend your voice and give great credibility to the ills of what we have to be able to challenge and to save our families.

Dr. Comer, thank you for being here to speak with us today about the needs of our Nation's researchers that work to make our communities safer and healthier. Your testimony explains the success that we have had saving lives with naloxone, also known as Narcan. You mentioned that it doesn't always work well for fentanyl doses, and we may need to develop a related drug. How can we facilitate that life-saving research while also carefully controlling access?

Ms. COMER. I think that is the rub here. I understand the sentiment about wanting to put class-wide scheduling of fentanyl analogues into Schedule 1. The worry that is where the gap is, especially regarding antagonists. They have no agonist activity, so they would not likely rise to the occasion of being identified on the street.

The best way that they can be identified is by a chemist doing what is called structure activity relationships, so a chemist and pharmacologist kind of work together. The chemist takes the core structure, develops a whole series of compounds. As I said in my testimony, you can't tell just based on the chemical structure whether it would be an antidote or the toxic substance. So, the chemist develops a series of compounds, passes it on the pharmacologist, who runs these very rapid tests of whether it can be the antidote or whether it is really toxic. Those experiments together will help us determine whether something is beneficial medically.

These types of tests that I am talking about, I know that the concern of the DEA is this 8-factor analysis that takes a really long time to run. These pharmacology experiments that I am describing can be performed rapidly. I did them when I was graduate school. You can run a basic assay in a week to determine whether something is an agonist or antagonist. That is what I am suggesting.

Mrs. MCBATH. Thank you so much. I yield back the balance of my time.

Ms. BASS. Mr. Cline?

Mr. CLINE. Thank you, Madam Chair. I thank the witnesses for being here, for sharing their testimony. Mr. Holman, thank you for being here. I want to start with you. Is there anything you would like to add today given the testimony that was given?

Mr. HOLMAN. The only thing I would say, we touch on treatment. We touch on prevention. It is prevention, enforcement, treatment, and recovery. It is a Rubik's cube. We can't get one side correct and ignore the others. My only ask is don't let this expire so that we can continue to do what we are doing, but let's not give up, and let's not ignore the concerns, and let's address those for a permanent solution going forward. And let's not stand back. Again, let's look forward. Let's get in front of this and stop chasing it. Thank you.

Mr. CLINE. Thank you. Dr. Ciccarone, in your testimony, you say the class of the fentanils has a large number of unexplored compounds, some of which are theoretically beneficial for treatment or as overdose antagonists, and Schedule 1 classification would inhibit basic science and clinical research. So, I would ask, once a substance is placed in Schedule 1, does it mean researchers can't access it, or does it just mean the process for doing so takes more time?

Dr. CICCARONE. It simply takes more time. I was unaware of the interagency agreement. Admiral Giroir had mentioned today that there is a way to sort of de-schedule some of these things. I do share Dr. Comer's concern, though, and that is the discovery phase will have a wet blanket thrown on it.

Mr. CLINE. If a researcher has all the necessary permissions to access Schedule 1 drugs, what you are saying is they don't need to apply for different permissions to access the fentanyl analogues that are temporarily scheduled, right?

Dr. CICCARONE. That I don't know. Dr. Comer might know that.

Mr. CLINE. Okay. Dr. Comer, can you share any information on that?

Ms. COMER. I mean, the way the procedure works now, you apply for a Schedule 1 license, and it is compound by compound. So, I think, you know, some of the suggestions that have been made about, you know, providing research exemptions and streamlining the process are really good ones. The biggest worry, as I mentioned, that I have is that an antagonist, who has no pharmacological activity other blocking the receptor, and naloxone is an example of that. People don't get high off of it, but it is the antidote.

The worry is that naloxone in many cases of fentanyl- or carfentanil-related overdoses, it just doesn't work. I mean, I have heard from EMTs who say they have given 5, 6 doses of naloxone, and the person still dies. We need to find other kinds of antagonist solutions. So, it makes sense that the chemical structure of a compound that is an antagonist would be very similar to the agonist. The receptor has a certain confirmation, and then the agonist binds there, and it has a certain shape that fits into that confirmation, and then it activates the receptor. The antagonist is one that fits into that receptor, but it doesn't activate it because you add something to it. My big worry here is that with the synthetic putting everything into Schedule 1 will make it really difficult for us to find those kinds of antidotes.

Mr. CLINE. Thank you. I yield back.

Ms. BASS. Ms. Jackson Lee?

Ms. JACKSON LEE. Thank you very much, Madam Chair. Let me thank both of you for holding this hearing again in the Judiciary

Committee and full Committee Members. This is something that I have worked on for a long time. I remember when we were discussing fentanyl and nobody knew what it was, and it is now an epidemic.

Mr. Holman, may I offer my deepest sympathy? A child is so precious, and I have seen families bury children all over the Nation. So, I wanted to just make a point that we need to look globally because there are two points that you made that I want to pick up with legislation, and I want to ask Mr. Butler as well. One, how frustrating it is that you wanted to get your son help, and the only option was a jail, except you used the example of a sheriff who created instead treatment. A powerful country like us, so number one.

Number two, your son first was exposed to it online from China, if I think I was reading the notes, and so we have a layered issue that we must deal with. Could you just briefly talk about this whole thing of parents being frustrated by the fact that the only option you had was a jail, but then he couldn't stay in the jail or they wouldn't keep him?

Mr. HOLMAN. Yes, ma'am. Thank you. It doesn't start with that either and there are parents today. It is amazing. Talk to your Uber driver this afternoon. Talk to somebody, and mention naloxone, mention fentanyl, and they have no idea, and we are right here. We all start out with our kids. We want the best for them and you taper down. They start getting in trouble. Each person has a different path. When you do get to the point where you need help, you have to go through a process. First, jail, you are right, we don't want them to go to jail because there is so much. My opinion is on the mandatory minimum, how long they go to jail, yes. I didn't want my son to go to jail at all in the beginning. I didn't want him to be in there. My biggest concern though is what he was taking away from that. I have people that I have talked to since then, amazing, productive, great people that have had a situation and they have gone to jail for longer than they should, but it helped them. They are productive today, but they have felony charges, nonviolent felony charges.

Ms. JACKSON LEE. Right. Let me just interrupt you. Might it be better if it were a treatment facility that your son could go to that he would stay in and not be released to help him?

Mr. HOLMAN. Yes.

Ms. JACKSON LEE. That is what I was saying.

Mr. HOLMAN. Yes.

Ms. JACKSON LEE. Your option was a jail. Let me be on the record. I am against mandatory minimums because your son could get caught up with it as well as others can get caught up. First, we need to end this epidemic, but while it is here, we need a system that would have protected your child with treatment.

Mr. HOLMAN. Yes.

Ms. JACKSON LEE. Is that yes, or no?

Mr. HOLMAN. Yes, it is.

Ms. JACKSON LEE. Okay. Let me thank you and say to you that I am committed—

Mr. HOLMAN. Could I add one thing to that?

Ms. JACKSON LEE. Yes, you may.

Mr. HOLMAN. The example I gave was where someone is held in a correction facility and treated, but not charged. Now, that is unique, but if you are 18 or over, you can walk out any facility unless you are held in.

Ms. JACKSON LEE. Right. Treatment, I understand, might be a little different in terms of its framework, even though I understand what you are saying. You are saying that if you are an adult, they can't hold you against your will. We have dealt with that. That is a real serious issue, and that is something that we must look at on the State level and otherwise. My sympathy again and thank you for bringing your insight to this.

Mr. HOLMAN. Thank you.

Ms. JACKSON LEE. Let me try to get two more questions. Let me say that I am going to look. I am inspired by this Ryan White concept, Dr. Ciccarone, and we are going to immediately turn to that and see how we can fit it into this epidemic now. Let me ask the two of you, Mr. Butler, to clarify your earlier testimony of how many grams of a substance with a detectable amount of fentanyl trigger a mandatory minimum. I also want you to, when I asked the question of DOJ, and they said, oh no, we don't prosecute drug addicts, but you have enlightened it. It is these low-level people that also are victims of sorts, so I would like you to comment on that. I would like the professor/doctor to comment on framing this, and I only have a couple of seconds, so framing this response like the Ryan White treatment act. Mr. Butler, just quickly on that point?

Mr. BUTLER. Yes, I will try to answer all questions.

Ms. JACKSON LEE. Just answer the one about the triggering and the—

Mr. BUTLER. In front of Mr. Holman right now is a paper clip. That paper clip weighs approximately 10 grams. If an individual possesses that much in fentanyl combined with something else, an inert substance in order to be mixed with it, that person is looking at a mandatory 5 years in jail. If that person has something the size of 10 paper clips, he is looking at a mandatory 10 years in jail.

Ms. JACKSON LEE. Can I pause you for a moment? I know that some others will let you answer. Doctor, you have got about 2 seconds to say—

Dr. CICCARONE. I will just say that current Federal legislation has helped, but it is a drop in the bucket. Overdoses have gone down about 5 percent. We need a lot more if we want to tackle this crisis.

Ms. JACKSON LEE. Thank you. I am sorry, but I got your answer. Thank you so very much. I yield back.

Ms. BASS. Mr. Cicilline?

Mr. CICILLINE. Thank you, Madam Chair, for holding this really important hearing. First, thank you all for being here. Mr. Holman, we all extend to our deepest sympathies for the loss of your child, and sadly we have had in all our communities the same kind of loss. In my State, 233 Rhode Islanders last year lost their lives to opioid overdoses, so we want to get this right. We are living with the consequences of this addiction epidemic which is ravaging our country.

I want to understand how we have gotten to this place with respect to at least the legal framework. Professor Comer, the DEA's emergency authority expires on February 6th, 2020, and the DEA is ineligible for a 1-year extension to this timeline because it had not asked HHS or the FDA to determine if their scheduling action is medically and scientifically valid. Is that correct, and if so, why? Do you know why they have not made that request?

Ms. COMER. So, I think it has to do more with the blanket-wide scheduling issue. So normally, HHS does its 8-factor analysis on a single compound, which is reasonable and makes sense. You can't do that with a potentially infinite number of analogues, so there is nothing really that the FDA could evaluate as a single compound. That is where the problem comes.

Mr. CICILLINE. Okay. Now, we have heard the argument that if this classification or this extension is not granted, that the government will not be able to effectively prosecute fentanyl. Of course, there is the Analogue Act, which provides for up to 20 years in prison for a first offense, up to 30 years in prison for a second offense, and a mandatory minimum if death resulting. So, Mr. Butler, are there tools in place if this expires that would continue to allow the government to successfully prosecute fentanyl cases?

Mr. BUTLER. Yes, and fentanyl prosecutions under the Analogue Act are up approximately 5,000 percent.

Mr. CICILLINE. So, this notion of if we don't do this, the Attorney General has made the argument that somehow fentanyl will become legal is not true.

Mr. BUTLER. Yes.

Mr. CICILLINE. Okay. Yes, it is not true.

Mr. BUTLER. Yes, it is not true.

Mr. CICILLINE. Okay. I just want to understand because I think this is important, and we must actually get this record correct. In fact, if there is any danger that an extension on this will make the problem worse and make more victims of this public health crisis, then that is not a good idea. I want to be sure that the criminal prosecution framework is robust and remains in place regardless, and you say it is. Professor Comer, what I am also interested in is nearly \$6.8 million in new Federal grants will enable researchers to collaborate with State agencies to investigate innovative public health approaches to address the opioid crisis. For instance, researchers in my district at Brown University are working to find ways to reduce overdoses and provide evidence-based public health solutions to the opioid crisis. Is there any risk that class-wide scheduling may undermine evidence-based approaches to addressing this opioid crisis? If so, can you elaborate on how class-wide scheduling poses a risk to finding public health solutions to this deadly crisis, because that is the goal here. What we don't want to do is an effort to respond to this request actually make a very deadly problem more deadly.

Ms. COMER. So, I am familiar with the research that is coming out of your State, and it is excellent, and they have done a really great job of trying to move the field forward in terms of addressing this issue. The concern that I have, and thankfully things like Narcan, naloxone, are available for reversing overdose. The problem, as I stated is that it doesn't work in all cases, and we don't

know why. So the continued development of additional types of antagonists is really critical to getting a complete handle on this problem.

The impact on research is really more at the basic science level, the level of the chemists, the level of the pharmacologists who are searching for these kinds of antagonists that will be more effective than naloxone. That is where I think the greatest harm would occur.

Mr. CICILLINE. Thank you very much. Madam Chair, I would ask unanimous consent that this article, which appeared in the Providence Journal, which describes a comparison between the State of Rhode Island and Portugal on its public health response to the opioid crisis, be made a part of the record.

Ms. BASS. Without objection.

[The information follows:]

MR. CICILLINE FOR THE RECORD

PROVIDENCE Journal

Opinion

Our Turn: Mavis Nimoh, Annajane Yolken and Josiah "Jody" Rich: Portugal offers model for saving lives

By Mavis Nimoh, Annajane Yolken and Josiah "Jody" Rich

Posted Jan 23, 2020 at 5:45 PM

Updated Jan 23, 2020 at 5:45 PM

Rhode Island and Portugal have a strong connection, with almost 10% of Rhode Islanders having Portuguese lineage. We also share another tragic connection: a history of high rates of drug overdose.

However, through a public health model — rather than incarceration — Portugal has drastically reduced its overdose deaths. Last year, over 300 Rhode Islanders died as a result of a drug overdose. If we had Portugal's current rate, only three people would have died.

To help us reproduce the successes of the Portuguese approach, we brought to Rhode Island Dr. João Goulao, the often-heralded architect and implementer of the plan that drastically lowered Portugal's overdose death rate from the highest to the lowest in Europe. (<https://opioidcobre.org>)

During his weeklong visit, Dr. Goulao held conversations with over 1,000 people, including parents and family members who've lost a loved one to addiction; individuals in recovery and actively using; educators, clinicians and researchers; lawmakers and law enforcement; religious and community leaders; and advocates.

He emphasized that Portugal's success rested largely on treating addiction as a disease. Since 2001, people with an addiction in Portugal have been considered patients deserving treatment, not criminals.

The results from Portugal are staggeringly successful. Over the last twenty years, overdose and HIV rates plummeted by 80% and 95%, respectively. Drug use — most importantly, teen and problematic drug use — have decreased. Drug-related

crime decreased and law enforcement report higher rates of job satisfaction, as they're able to pursue drug distribution channels and drug dealers, as opposed to people using drugs. Finally, Portugal was also able to spend less money on incarceration, while saving lives.

It remains illegal to sell drugs in Portugal, and drug use is not encouraged. People are still arrested for possession of drugs. However, if they possess less than a 10-day supply of drugs, they are sent, instead of to jail, to a civil hearing complete with a social worker, a therapist and a judge. This body evaluates individuals in a comprehensive way and refers them to appropriate treatment and supports. Individuals do not go to jail for use of drugs nor do they receive a criminal record. They may be fined or issued other sanctions if they continue to use or possess drugs. The sanctions are similar to those issued here for driving without a seatbelt.

Fifty years into America's "war on drugs," we have more overdose deaths than ever, have incarcerated millions and bear witness to the drastic and damaging effects of the racial disparities of mass criminalization and mass incarceration.

For the first time in 100 years, the current overdose epidemic has led to a decrease in American life expectancy for three years in a row. People are left with lengthy criminal records that prevent them from full recovery. There is hardly a family in Rhode Island that has not been impacted. We need to do better.

Portugal's model presents lessons to save lives in Rhode Island. Dr. Goulao offered a message to Rhode Islanders that we, too, can succeed.

Not one of the over 300 Rhode Islanders who died last year died because we were not tough enough on crime, did not have enough laws, police, courts, prisons or jails. In fact, the opposite is glaringly obvious: the criminalization of drug use drives people away from treatment and reinforces negative stigma.

It is time to change drug policies in Rhode Island to treat addiction as the disease that it is and no longer continue to punish people with costly and counterproductive criminal sanctions.

1/28/2020

Our Turn: Mavis Nimoh, Annajane Yolken and Josiah "Jody" Rich: Portugal offers model for saving lives - Opinion - providencejournal.co...

Mavis Nimoh is the executive director of the Center for Prisoner Health and Human Rights at The Miriam Hospital. Annajane Yolken is executive director of Protect Families First. Josiah "Jody" Rich, M.D., is a professor of medicine and epidemiology and attending physician at The Miriam and Rhode Island hospitals.

Mr. CICILLINE. I yield back.

Ms. BASS. Ms. Mucarsel-Powell?

Ms. MUCARSEL-POWELL. Thank you, Ms. Bass. You come into these hearings and you have all the questions that you want to ask the witnesses. Then I hear testimony, and my head is spinning trying to ask specific questions to get answers on dealing with this issue. It is such a complicated issue because you want to make sure that you criminalize those that are distributing and trying to find the chemicals and changing the compound to the drug so that it stops, and at the same time, you know that this disproportionately affects communities of color.

I represent an area which is a majority minority community, and I know that they get into this prison cycle that they can't get out of, and people are punished because they have issues growing up. Mr. Holman, as a mom, I have an 11-year-old daughter. I have a 14-year-old son. It hits close to home. Believe me when I tell you that this should not be a political issue at all. I think we all want to deal with this issue the right way. We need to make sure that we provide support services to parents that are dealing with children that are experimenting.

I was just reading that the easiest way to now purchase fentanyl is online, that there was an investigative Committee in the Senate that found out there are six online sellers. People can purchase these drugs online. What are we doing in Congress to make sure that we provide the appropriate oversight to stop that? So, I don't think that allowing for fentanyl to extend in the Schedule 1 is going to be an issue. I think that many Members in the House agree that we have to do that right now. At the same time there has to be a way that even though we provide that extension, we can still do research. So, I wanted to ask first to Ms. Comer, do you think that there is a process in place for an institution that can conduct research into the health benefits of analogues under a Schedule 1 drug?

Ms. COMER. There is a process in place, and it can be done. As I wrote in my testimony and I think we have heard earlier today, the process is really complicated and burdensome. I know for a fact, so there are only a handful of chemists who are either willing or able to research these kinds of compounds, and they just don't want to go apply for a Schedule 1 license because it is so difficult. I think that the things that we have been discussing this morning about ways to streamline the process are definitely in the right, direction, and ways of removing some of the substances once they get placed into Schedule 1 is also helpful from a research perspective.

What is harder to get a handle on, is the impact of this chilling effect that it has on research. That is what is worrisome here. I know that, as you said, it is a very complicated issue. Our organization, me personally, understand the DEA's concerns about prosecuting these people. When I first found out that fentanyl was hitting the streets, I was shocked, and I was really dismayed because I worked with it when I was in graduate school, and I know that the dose that produces a euphoric effect and the dose that produces—

Ms. MUCARSEL-POWELL. Deadly.

Ms. COMER. —that is deadly is so small. Then when I heard that carfentanil hit the street, I was even more shocked. So, we need to do something, and I think having this kind of dialogue is critical.

Ms. MUCARSEL-POWELL. Thank you. Thank you, Ms. Comer. I wanted to ask Professor Ciccarone. That is the way to pronounce it, right?

Dr. CICCARONE. Yes.

Ms. MUCARSEL-POWELL. If you could explain the prominence of fentanyl in analogues that are used now among minority populations.

Dr. CICCARONE. So, the main thing to be aware of, on the street level, folks cannot tell the difference in what they are getting. There is no cultural lingo for fentanyl. There is not a lot of slang for it, which says that it is not a drug of choice. It is a contamination in the heroin stream. So, people are looking for heroin, but what they are getting is fentanyl and other analogues. The problem with the analogues is they come across in a great range of potencies from 3 times morphine to 10,000 times morphine. So those vicissitudes alone and the clandestine nature of the contamination is what is causing overdose, right? There is no way to level that out. There is no way that this ban will make the streets safer in terms of fentanyl vicissitudes. We see that fentanyl is still there, despite the 15 months of the emergency scheduling.

Let me just point out that all the fentanyl that comes into this country could fit into 10 industrial drum barrels right between dais and this table. All of it in the country right here. How do we stop that with the enormous Pacific Rim trade, you know, thousands of container ships that happen to come across the Pacific Ocean? How do we stop industrial barrels worth of product, right? Interdiction itself is a problem. Source control might have opportunity, working with China, working with Mexico to stop the production of substance. By the time we get to the street level, putting the genie back in the bottle ain't happening. It is just not.

Ms. MUCARSEL-POWELL. Thank you. Just one last word. Mr. Holman, if there is anything you would like to tell parents that are dealing with this issue, what would you recommend?

Mr. HOLMAN. The "not my child" thought process doesn't work. It doesn't matter what demographic you are, who are you are, where you are at, anyone can be affected. You know, I don't know. That is why I am here. We need a solution.

Ms. MUCARSEL-POWELL. We will work together on that.

Mr. HOLMAN. Thank you.

Ms. MUCARSEL-POWELL. Thank you.

Ms. BASS. Thank you so much. I would like to thank the witnesses for your time today. Just before we conclude, I agree with Ms. Mucarsel-Powell that I know that we will extend the ban. But at some point, in our country, I hope that we have the political will to force China and Mexico to stop manufacturing. We put tariffs, we stop Mexico or threaten Mexico around the border, but we can't figure out a way to get them to stop the manufacturing? I hope one day that we have the political will to stop the pharmaceutical industry from excessive manufacturing—we don't hold them accountable—and to stop online sales. I hope one day that we have the political will in this country to provide modalities of treatment in-

stead of doing what gives us a false sense of responding by locking folks up who are lower-level drug dealers, and missing the big kingpins that traffic, or the manufacturing.

With that we are adjourned.

[Whereupon, at 12:30 p.m., the Subcommittee was adjourned.]

APPENDIX

January 27, 2020

Speaker Nancy Pelosi House
1236 Longworth H.O.B.
Washington, DC 20515

Minority Leader Kevin McCarthy
2468 Rayburn H.O.B.
Washington, DC 20515

House Majority Leader Steny Hoyer
1236 Longworth H.O.B.
Washington, DC 20515

House Minority Whip Steve Scalise
2049 Rayburn H.O.B.
Washington, DC 20515

On behalf of the undersigned organizations, we write to express our concern with the Senate-passed Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act (S. 3201), a bill to temporarily extend the Drug Enforcement Administration's "class-wide" emergency scheduling of fentanyl-related substances. The bill will expose more people to prosecutions seeking harsh mandatory minimum sentences.

While this measure is an improvement over a permanent approach, like the Stopping Overdoses of Fentanyl Analogues Act, it does not address the civil rights implications of the Drug Enforcement Administration's unprecedented placement of a potentially limitless number of substances on Schedule I.¹ We urge leaders in the House of Representatives to ensure that before an extension measure is enacted, the legislation precludes mandatory minimums and protects people with limited knowledge, responsibility, and authority in the importation of fentanyl analogues.

We urge the House to address the following issues as it considers S.3201:

- Substantial increases in the length of sentences and DOJ's intention to seek mandatory minimums in cases prosecuted under the authority of the class-wide ban. **Any extension of the class-wide ban should bar the use of mandatory minimum sentences in cases prosecuted under this authority.** Legislation introduced in the Senate by Senator Rob Portman and three other Senate colleagues attempts to do exactly this. The House should adopt this approach. It has been only a year since Congress and President Trump enacted the First Step Act, which eased the length of some drug sentences and reflected broad bipartisan recognition that mandatory minimum sentences are costly and counterproductive. Congress should not undermine this progress on sentencing reform.
- The directive to the Government Accountability Office to evaluate the class-wide scheduling does not incorporate an examination of the effectiveness of the class-wide approach in reducing overdose deaths from fentanyl and its analogues, reducing demand for and supply of these and other substances, or how this control will interdict and stop extraterritorial manufacturers and exporters, or domestic high-level importers. We are still rebuilding after a failed war on drugs that did not improve public safety, ameliorate the high rates of substance misuse in the United States, or reduce the

¹ "Coalition Opposes S. 1622 Stopping Overdoses of Fentanyl Analogues Act (SOFA)," <https://www.hrw.org/news/2019/07/03/coalition-opposes-s1622-stopping-overdoses-fentanyl-analogues-act-sofa>

demand for or supply of harmful substances. In light of these failures, it is deeply troubling that Congress is considering measures that would expand the Department of Justice's authority to schedule and prosecute substances without analyzing if this measure—founded on the idea that incarceration is the answer to a drug epidemic—will somehow succeed where every similar prior measure has failed. **It is critical that any study evaluating the class-wide ban assess the impacts of this expanded authority on public safety, including overdose deaths and interdiction efforts.**

- Federal sentencing data shows that since 2014 the majority of those sentenced for fentanyl trafficking have been involved at the bottom of the distribution chain (such as street-level sellers and couriers/mules), and available data indicates that the vast majority of those prosecuted did not have clear knowledge that they were trafficking fentanyl.² Additionally, 2018 sentencing data reveals that 77% of individuals sentenced at the federal level for fentanyl trafficking are people of color,³ showing that fentanyl enforcement is exacerbating racial disparities in the criminal justice system.⁴ **Any extension of the class-wide ban should include an analysis of the impact of this expanded authority on the interdiction of high-level exporters, importers, and manufactures of fentanyl and its analogues.**

Congress must resist the appeal of simplistic solutions to complex problems and redouble its investment in public health approaches to reducing fentanyl overdose deaths and decreasing substance misuse rates. A punitive approach to addressing these public health concerns undermines evidence-based health approaches. We cannot allow enforcement-first rhetoric to divert our focus away from public health approaches that have been proven effective in reducing the harms associated with fentanyl and its analogues. Congress should prioritize removing barriers to medication-assisted forms of treatment, increasing access to overdose prevention tools like naloxone, and increasing investments in funding to help communities scale up access to treatment and harm reduction interventions that save lives and aid recovery.

Ultimately, we remain convinced that granting the Drug Enforcement Administration class-wide scheduling authority for fentanyl analogues will exacerbate already disturbing trends in federal drug prosecutions and incarceration levels and excise public health authorities from their critical role in promulgating drug policy. Congress made progress with its bipartisan passage of the First Step Act and we oppose efforts to undermine this reform.

We look forward to working with lawmakers on alternative approaches that would effectively address fentanyl overdoses and reduce the harms and unfairness of federal mandatory minimum sentences, and address our crises of overincarceration. If you have questions or

² "Public Data Briefing: Synthetic Drugs" – United States Sentencing Commission, https://www.ussc.gov/sites/default/files/pdf/research-and-publications/data-briefings/2018_synthetic-drugs.pdf; https://www.ussc.gov/sites/default/files/pdf/research-and-publications/quick-facts/Fentanyl_FY18.pdf

³ "Quick Facts: Fentanyl" – United States Sentencing Commission, https://www.ussc.gov/sites/default/files/pdf/research-and-publications/quick-facts/Fentanyl_FY18.pdf

⁴ "Criminal Justice Reform in the Fentanyl Era: One Step Forward, Two Steps Back," <http://www.drugpolicy.org/resource/criminal-justice-reform-fentanyl-era-one-step-forward-two-steps-back?spJobID=1682077373&spMailingID=41601505&spReportId=MTY4MjA3NzM3MwS2&spUserID=MTAwNiQyOTM2MDMzMAS2>

concerns, please contact Kara Gotsch at kgotsch@sentencingproject.org or Grant Smith at gsmith@drugpolicy.org.

Cc:

House Judiciary Chairman Jerrold Nadler
2141 Rayburn H.O.B.
Washington, DC 20515

Ranking Member Doug Collins
1504 Longworth H.O.B.
Washington, DC 20515

House Subcommittee on Crime, Terrorism, and Homeland Security Chair Karen Bass
2138 Rayburn H.O.B.
Washington, DC 20515

House Committee on Energy & Commerce Chairman Frank Pallone
2125 Rayburn H.O.B.
Washington, DC 20515

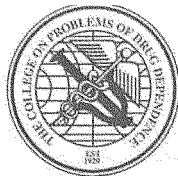
House Committee on Energy & Commerce Ranking Member Greg Walden
2322 Rayburn H.O.B.
Washington, DC 20515

Sincerely,

A New PATH (Parents for Addiction Treatment & Healing)
AIDS Alabama
Alliance for Positive Change, LES Harm Reduction Center
American Civil Liberties Union
Baltimore Harm Reduction Coalition
Broken No More
Charles Hamilton Houston Institute for Race and Justice at Harvard Law School
College and Community Fellowship
Colorado CURE
Congregation of Our Lady of the Good Shepherd, U.S. Provinces
CURE BOARD
Desiree Alliance
Dr. Bronner's

Drug Policy Alliance
Drug Policy Forum of California
Empire State NORML
FAMM
FedCURE
Free Minds Book Club & Writing Workshop
Friends Committee on National Legislation
Friends of Recovery New York Dutchess
Harm Reduction Coalition
Health in Justice Action Lab at Northeastern University School of Law
Human Rights Watch
International CURE
Iowa Justice Action Network/Catholic Charities
Justice Arts Coalition
Justice Roundtable
LatinoJustice PRLDEF
Law Enforcement Action Partnership
Legal Action Center
Life for Pot
Multidisciplinary Association for Psychedelic Studies
NAACP
National Advocacy Center of the Sisters of the Good Shepherd
National Association of Criminal Defense Lawyers
National Association of Social Workers
National Center for Lesbian Rights
National Center for Transgender Equality
National Juvenile Justice Network
National LGBTQ Task Force Action Fund
NETWORK Lobby for Catholic Social Justice
Operation Restoration

Prevention Point Pittsburgh
 Protect Families First
 R Street Institute
 Reframe Health and Justice
 Research For A Safer New York
 Safe Streets Arts Foundation
 Safer Foundation
 StoptheDrugWar.org
 Students for Sensible Drug Policy
 Substance Use Policy, Education, and Recovery PAC
 Texas CURE
 The Center for HIV Law and Policy
 The Leadership Conference on Civil and Human Rights
 The Sentencing Project
 The Taifa Group
 The United Methodist Church - General Board of Church and Society
 Treatment Action Group
 Treatment Communities of America
 Trinity United Church of Christ, Chicago
 Truth Pharm
 Virginia CAN (Change Addiction Now)
 VOCAL-NY
 Witness to Mass Incarceration
 Women With A Vision


THE COLLEGE ON PROBLEMS OF DRUG DEPENDENCE, INC.

5034A Thoroughbred Lane, Brentwood, TN 37027-4231

 Telephone: 615-432-0099 • Fax: 888-417-3311 • www.cpdd.org • info@cpdd.org
Executive Officer:

Loretta P. Finnegan, MD

Public Policy Officer:

Sandra D. Comer, PhD

Director, Executive Office:

Ellen B. Geller, MA

December 13, 2019

The Honorable Lindsey Graham
Chairman
U.S. Senate Committee on the Judiciary
224 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Dianne Feinstein
Ranking Member
U.S. Senate Committee on the Judiciary
152 Dirksen Senate Office Building
Washington, DC 20510

Re: Scheduling of Synthetic Opioids

Dear Chairman Graham and Ranking Member Feinstein:

On behalf of the College on Problems of Drug Dependence (CPDD) we are writing to express our concerns with any legislative proposals currently being considered by the Senate Judiciary Committee to add a large number of synthetic fentanyl compounds to Schedule I of the Controlled Substances Act either by extending the Temporary Emergency Scheduling of those compounds or to permanently add those compounds to Schedule I as proposed by the S. 1622, Stopping Overdoses of Fentanyl Analogues (SOFA) Act. The College has over 1,000 members, and serves as an interface among governmental, industry, and academic communities to maintain liaisons with regulatory and research agencies as well as educational, treatment, and prevention facilities in the drug abuse field.

We share the concerns of the Senate Judiciary Committee about the opioid epidemic and its devastating consequence to millions of Americans, their families, and their communities. According to the Centers for Disease Control, an estimated 28,466 Americans died in 2017 as a result of using synthetic opioids other than methadone. One of the main reasons for that dramatic and disturbing increase is the spread of fentanyl, a synthetic opioid that is inexpensive and potent, as well as its analogues. The College supports robust, science-based efforts to curb the sale and use of synthetic analogues.

CPDD supports efforts to give the Drug Enforcement Agency (DEA) authority to control the importation and distribution of synthetic fentanyls, but we also believe that any legislation to address this issue should

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William Stoops, PhD • Dace Svikis, PhD • Erin Winstanley, PhD

include language reducing some of the barriers to research currently imposed by Schedule I licensing requirements and must address the unintended consequences of including such a broad range of substances in the scheduling language.

The barriers to research imposed by Schedule I requirements could limit the ability of scientists to understand the pharmacology of these newer more powerful opioids and develop medications to treat use of and overdose on these substances. For example, the current language in the temporary emergency scheduling action of fentanyl analogues is broad and could result in an antidote, a fentanyl antagonist with no abuse liability, inadvertently being placed in Schedule I. Any further broadening of the language describing fentanyl analogues could have even greater negative implications for development of therapeutically useful medications that have no opioid activity.

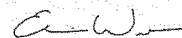
We strongly recommend that any legislation on scheduling synthetic opioids—either by extending the current temporary scheduling order or by making permanent scheduling of these compounds—should involve the Department of Health and Human Services' science-based agencies, specifically the National Institute on Drug Abuse and the Food and Drug Administration, in any decisions regarding scheduling of synthetic analogues.

We thank you for considering our position on how these decisions may have a potentially negative impact on our shared efforts to address this serious public health issue.

Respectfully,



Loretta P. Finnegan, M.D.
CPDD Executive Officer



Elise Weerts, Ph.D.
CPDD President

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1/28/2020

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COMMENTARY

New England U.S. Attorneys: We need a permanent ban on fentanyl analogues

By Commentary

Jan 22 2020 | 5 reader footnotes

Editor's note: This commentary is endorsed by the U.S. Attorneys in each New England district: Christina E. Nolan, Vermont; Aaron L. Weisman, Rhode Island; Scott W. Murray, New Hampshire; Andrew E. Lelling, Massachusetts; Halsey B. Frank, Maine; and John H. Durham, Connecticut.

In 2017, almost 50,000 Americans died from opioid overdoses. It's a sad reality that New England as a whole has been particularly hard hit by opioids. In fact, per capita, of the 12 states across the country with the most opioid overdose fatalities, all six of our states make the list. Much of that is due to illicitly produced fentanyl.

To maintain and build upon a recent decline in opioid overdose deaths nationwide, law enforcement must have all the necessary tools at their disposal. One such tool is the Drug Enforcement Administration's 2018 order making all fentanyl-related drugs illegal in the United States. Unfortunately, that order was temporary and will expire in just a few weeks. The Senate recently passed bipartisan legislation approving a 15-month extension of the temporary order. While this is a step in the right direction and the House should follow suit and pass the Senate's bill, a longer term solution is needed. A permanent ban on all fentanyl analogues would send a strong message to the cartels and sophisticated drug operations that pedal illicit fentanyl that the United States is serious about addressing this crisis and their actions will not be tolerated.

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Illicit fentanyl is manufactured in labs in China and Mexico. It is 50 times more powerful than heroin and 100 times more powerful than morphine. So powerful, in fact, that only a couple milligrams – the size of a few grains of salt – can kill the average person.

Fentanyl, however, is unique. Because it is made in labs using chemicals, its structure is easily manipulated. And the

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On Feb. 6, the DEA's temporary order expires, and all drugs seized by U.S. investigators over the past two years that have tested positive as fentanyl analogues will no longer be illegal. If Congress fails to pass the SOFA legislation it will have a dramatic impact not just on the prosecutors and law enforcement officers who spend their lives investigating and prosecuting drug dealers, but on communities already hard hit by the opioid epidemic, many of which are right here in New England.

Despite recent reductions in opioid deaths across New England for the first time in decades, prosecuting drug dealers – particularly those who peddle heroin and fentanyl – remains a top priority for each of our offices. But our federal resources are not infinite; we need all the help we can get. Passing this legislation would provide invaluable support to us as prosecutors and the entire law enforcement community as we continue to combat the opioid crisis in New England and all throughout America.

A number of organizations have voiced opposition to the proposed legislation, arguing that the bill does not "embrace public health approaches to the overdose crisis." We agree that a comprehensive approach to the crisis is needed, and a permanent fentanyl analogue ban should be viewed as part of a holistic effort. But time is running out: there is no doubt that drug traffickers are eagerly awaiting the temporary order's expiration to start flooding our communities with these dangerous drugs. The passage of this legislation is quite literally a matter of life and death.

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There should be nothing partisan about declaring fentanyl analogues illegal, any more than there is partisanship about the dangers of ricin or cyanide. And there is certainly nothing partisan about saving lives and bringing justice to those who profit from addiction and even death. For the safety of our New England communities, we urge Congress to pass legislation making permanent the DEA's temporary scheduling of all fentanyl-related drugs.

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