Attachment—Additional Questions for the Record

Subcommittee on Health
Hearing on
"The Overdose Crisis: Interagency Proposal to Combat Illicit Fentanyl-Related Substances"
December 2, 2021

Mr. Kemp L. Chester, Assistant Director, Executive Office of the President, Office of National Drug Control Policy

The Honorable Frank Pallone, Jr., (D-NJ)

Q. As you know, the most recent data released by the Centers for Disease Control and Prevention (CDC) reported that more than 100,000 American lives were lost from April 2020 to April 2021 due to an overdose, many of which were synthetic opioid, namely fentanyl, related. The Biden-Harris Administration has shared with Congress a legislative proposal for addressing this crisis, which includes several provisions related to fentanyl-related substances (FRS) such as through class-wide regulation, research, and judicial considerations.

- **Under this proposal, what would the criminal penalties be for offenses involving FRS? Specifically, how does this proposal change mandatory minimum penalties for offenses involving fentanyl-related substances?**

  A: The proposal would subject defendants who import or traffic FRS domestically to the advisory penalties set forth under the U.S. Sentencing Guidelines (sentencing guidelines) without subjecting them to quantity-based mandatory minimum penalties. The 20-year mandatory minimum for death or serious bodily injury resulting from such trafficking would remain. Moreover, the recommended penalties under the sentencing guidelines – for offenses involving fentanyl and all fentanyl analogues (including FRS) – would be unchanged. What would change under the proposal is that FRS would now be defined as a special Schedule I class, and would be exempt from the quantity-based mandatory minimum penalties that otherwise apply to fentanyl analogues, except when death or serious bodily injury is connected to such trafficking.

- **How do the modified penalties for trafficking FRS differ from offenses involving fentanyl?**

  A: Under the Administration FRS Proposal, the penalty scheme for fentanyl itself will be unchanged. This means: five- and ten-year mandatory minimum penalties for trafficking offenses involving fentanyl would still be triggered by 40 and 400 grams, respectively, and for trafficking offenses involving non-FRS fentanyl analogues, would be triggered by 10 and 100 grams, respectively.

- **What evidence is there that these mandatory minimum changes would lead to reduced disparities in the criminal legal system and reduced overdose deaths?**

  A: Besides being advisory, unlike mandatory minimums, the sentencing guidelines provide guidance to the courts on accounting for the full range of factors characterizing the offender's conduct in the offense. As Attorney General Garland has testified, mandatory minimum sentences constrain the ability of trial judges to make determinations based on all of the sentencing factors, such as those outlined in the sentencing guidelines, that judges normally apply.

  The proposal retains the potential imposition of a mandatory minimum penalty where death or serious bodily injury results from the trafficking of an FRS, as is the case for any other Schedule I and II controlled substance under 21 U.S.C. § 841(b)(1)(C). Although rarely applied across drug cases taken as a whole, it was applied in a much higher proportion of cases involving fentanyl and, even more, fentanyl analogues.

- **Why does the Administration believe that is important to change mandatory minimum standards for FRS?**

  A: Exemption from mandatory minimum penalties recognizes the fact that FRS are being added to Schedule I in a manner that abbreviates the ordinary, multi-factor scheduling process. Although scheduling an entire class of a substance is a relatively rare action, the Administration's proposal here appropriately seeks to avoid unintended criminal justice consequences by excluding FRS from quantity-based mandatory minimum penalties. We believe that it is important to balance all of the equities and that is why our proposal contains the mandatory minimum exemption for substances that have not been subject the scheduling process. If not exempted, the FRS class of substances would be subject to quantity-based mandatory minimum penalties as a result of being "any analogue of [fentanyl]," see 21 U.S.C. §§ 841(b)(1)(A)(vi) and (B)(vi) and parallel import/export provisions in 21 U.S.C. § 960.

Q. The Department of Justice (DOJ) plays a major role in efforts to curb the overdose epidemic and to take action against the illicit manufacture and distribution of controlled substances. DOJ has reported eight federal prosecutions involving FRS since the temporary scheduling order was put in place in 2018. Data from the U.S. Sentencing Commission indicates that federal cases involving fentanyl analogues are higher, citing 233 federal cases in 2019 alone. What is cause for the discrepancy between these numbers? Given these trends, do you believe that the DOJ has sufficient authority to prosecute offenses involving FRS? If not, does the proposal provide sufficient authority?

A: The Department has found only eight cases with FRS charges against 33 defendants from the time temporary class scheduling was adopted in 2018 through December 2020. FRS falls into the broader category of fentanyl analogues, which are substances that do not meet the statutory definition of FRS but are structurally related to fentanyl, and which are individually scheduled

by DEA or found through the Controlled Substance Analogue Enforcement Act of 1986 (Analogue Act).

Recent experience has demonstrated the success of class-wide scheduling in reducing the availability of FRS, to the benefit of law enforcement, and in turn the American public. As the Government Accountability Office (GAO) recently found, after the United States class-scheduled FRS on February 6, 2018, through DEA administrative action, and after China imposed class controls on May 1, 2019, law enforcement encounters of fentanyl analogues not individually scheduled by name plummeted, falling nearly 90%, from 7,058 encounters in 2016 through 2017, to 787 encounters in 2018 through 2019. The number of new FRS encountered by law enforcement also declined significantly, though less dramatically, from 32 in 2016 through 2018 to just 12 from February 2018 to July 2020.

While scheduling is not the only factor in reducing the proliferation of FRS, permanent class-wide scheduling of FRS is a critical step to enable our laws to keep pace with the evolving and dynamic synthetic drug market.

Q. The opioid crisis continues to claim lives every day and a larger driver of this crisis is illicit fentanyl. In 2020, overdose deaths involving synthetic opioids increased by 55 percent. It is clear that more must be done to prevent the use and availability of illicit fentanyl, however, I have also heard very real concerns about taking a law enforcement only approach to this problem.

- **Concerns have been raised that the Administration's FRS proposal could lead to wrongful prosecutions or penalties for schedule I substances that do not pose a high risk of abuse or threat to public health. How would the Administration's proposal address this concern?**

  A: While there is no indication that in the near-four years since class-wide scheduling of FRS has been in effect that the over-scheduling of any medically useful and psychoactively benign substances has occurred, the Interagency FRS Proposal includes an off-ramp process, overseen by HHS, to identify and remove or reschedule from Schedule I any individual FRS, if it is found not to have a high potential for abuse (and so it can be swiftly rescheduled to Schedule III) or found to have a potential for abuse lower than Schedule V substances (and so can be removed entirely).

- **One provision within the Administration's FRS proposal would ensure that a federal court may vacate or reduce the sentence of an individual that was convicted of an offense involving an FRS that is later removed from the schedules or rescheduled. How will the Administration ensure that a court would take such action?**

A. Section 6 of the proposal addresses convictions based on offenses involving an FRS that has since been removed from the schedules or rescheduled from Schedule I and provides that a federal court, upon motion of the defendant, the government, or on its own, may

vacate the sentence or impose a reduced sentence for such a defendant. The Department would expect that the vacatur or reduction of sentences, in the event of the removal or transfer of an FRS from Schedule I, would be handled as a matter of course by the federal courts.

The Office of National Drug Control Policy (ONDCP), the Department of Justice, and the Department of Health and Human Services met regularly to develop a comprehensive approach that addresses the complex issues surrounding the scheduling of FRS. For all these questions above, ONDCP defers to Department of Justice.

Q. **Enhancing evidence-based harm reduction efforts is one of the key priorities in the Biden Administration's first year drug policy priorities as well as the HHS' Overdose Prevention Strategy. What evidence-based harm reduction approaches will the Biden Administration seek to implement and what is the benefit of using such approaches?**

A. As established in the Administration's first-year drug priorities to address the overdose epidemic, ONDCP is currently focused on the scaling of three evidence-based harm reduction practices:

- Naloxone distribution: Because naloxone is a medicine that rapidly reverses an opioid overdose, it has been a contributing factor in saving lives. ONDCP supports widespread distribution of naloxone in locations and communities where it is most needed and in the hands of people who use drugs (PWUD), community and family members, harm reduction workers, law enforcement, emergency medical technicians, fire fighters, and medical staff at clinics and hospitals. While naloxone formulations and prices vary, they are an extremely affordable life-saving intervention, especially in comparison to the cost of an emergency room visit or an intervention by emergency medical services or law enforcement, that produces a significant return on investment.[i] Harm reduction organizations working on the frontline of the epidemic need a steady supply of naloxone to ensure continuity of service. One study suggests the need for 20 times as many naloxone kits to be publicly distributed as numbers of annual opioid-related deaths per year.[ii] ONDCP recently released a model law for states to help expand access to naloxone. The model law is crafted to permit widespread prescribing of naloxone upon request and widespread administration of naloxone by anyone who believes in good faith that an individual is experiencing an opioid overdose.

- Fentanyl test strips (FTS): There has been a direct connection between the presence of fentanyl and fentanyl analogues in the supply of illicit drugs and rising overdose death rates. The distribution of FTSs among PWUD helps to determine if their drugs are contaminated with fentanyl. FTS are an inexpensive, portable, and easy-to-access way to help prevent overdoses. Last year Centers for Disease Control and Prevention announced that federal funds may now be used to purchase fentanyl test strips in an effort to help curb the dramatic spike in drug overdose deaths.

- Syringe Service Programs (SSPs): SSPs offer evidence-based, yet underutilized, tools to save lives, increase access to testing for HIV and Hepatitis C Virus (HCV), and increase access to care. SSPs engage with PWUD to provide sterile syringes, fentanyl test strips,

and naloxone and often connect them with a broad range of healthcare services, including substance use disorder treatment. SSPs frequently partner with community health clinics to provide low-threshold buprenorphine induction as a life-saving measure. SSPs protect the public and first responders by facilitating the safe disposal of used needles and syringes.

These harm reduction practices can have life-saving benefits. Further, these harm reduction practices provide opportunities to engage PWUD by treating them with compassion and respect, building relationships, and offering access to healthcare, social services, case management, substance use disorder (SUD) treatment, and recovery support services. Harm reduction efforts also are intended to meet patients at their present level of motivation for pursuing recovery by providing life-saving measures that permit an ongoing dialogue with the patient about further engagement in care and adoption of healthier behaviors including abstinence from substances. Harm reduction approaches to care are not unique to the treatment of substance use disorder; harm reduction is endemic to appropriate treatment efforts of chronic diseases in general, e.g., medications for HTN and DM do not cure those diseases, they protect life even when the patient hasn't made other related healthier behavior changes such as diet and exercise.

Q. **According to your testimony and the National Forensic Laboratory Information System, nearly 200,000 reported drug seizures in 2020 involved narcotic analgesics. Nearly 60 percent of those seizures were fentanyl. It is important that we understand the role of fentanyl-related substances, not just fentanyl, in the epidemic.**

- **Compared to fentanyl and other opioids, what role have fentanyl-related substances played in the overdose crisis and what impact has temporary scheduling made?**

- **Your testimony notes that illicit fentanyl seizures doubled in both 2020 and in 2021. What is causing the increases of illicit fentanyl in the drug supply? How has the temporary scheduling order reduced FRS in the drug supply?**

- **The Government Accountability Office (GAO) noted that fentanyl analogues and other related compounds, including individually scheduled analogues, have increased since implementation of class-wide scheduling. Why does the Administration believe permanent class-wide scheduling can address this issue?**

A. Since 2014, the number of drug overdose deaths involving synthetic opioids other than methadone, which includes illicit fentanyl, fentanyl analogues, and FRS has increased more than nine-fold. Provisional data from the Centers for Disease Control and Prevention (CDC) predict more than 69,000 people died of an overdose involving these substances between November 2020 and October 2021. This is an alarming 25.4 percent increase over the previous year and the highest number ever recorded in a 12-month period.

In the six-year period from 2014 to 2020 the number of overdose deaths involving synthetic opioids other than methadone has increased over 1,000% [iii]. These dangerous substances, and the dynamic threat they pose to our collective health and safety, continually challenge our efforts to reduce overdoses and related deaths. Fentanyl is inexpensive to manufacture, requiring

inexpensive chemical precursor ingredients and small manufacturing footprints, and is highly potent, which means it is not only lethal in small doses, but can be smuggled in much smaller quantities to obtain even greater profits.

On February 6, 2018, DOJ issued a rule temporarily placing the class of FRS not otherwise scheduled into Schedule I of the Controlled Substances Act (CSA).[iv] On May 4, 2021, President Biden signed into law the Extending Temporary Emergency Scheduling of Fentanyl Analogues Act, which extended the emergency scheduling actions until October 22, 2021.[v] The emergency scheduling actions were extended to February 18, 2022 as part of the FY 2022 continuing resolution signed by President Biden on September 30, 2021.[vi] Class scheduling is not a panacea, but it is necessary to control substances yet to be made and yet to be available in our communities. Following the temporary class-wide scheduling of FRS in 2018, DEA National Forensic Laboratory Information System (NFLIS) data show that law enforcement encounters of fentanyl analogs that were not individually scheduled declined by almost 90%, when comparing total encounters from 2016 and 2017 to total encounters of uncontrolled fentanyl analogs from 2018 and 2019. However, the emergency scheduling actions currently in effect are only one aspect of the comprehensive recommendation the Administration submitted to Congress.

The recommendation permanently schedules FRS as a class while creating a mechanism for expeditiously removing from schedule I of individual fentanyl-related substances that do not need such a restrictive scheduling, ensures access for scientific research that is not unduly burdensome, and seeks to protect civil rights. This is a challenging issue and we have sought to offer a responsible and comprehensive approach.

Q. According to the National Safety Council, there are several groups that are disproportionately impacted by the overdose epidemic. Black Americans and individuals aged between 25 to 54 are overrepresented in overdose deaths. Additionally, the increase in female overdose deaths far exceeds that of males. How would the proposal put forth by the Administration address the needs of the groups most disproportionately impacted by the overdose epidemic?

A. Permanent class-wide scheduling is an important tool for law enforcement to respond to the trafficking and manufacture of illicitly manufactured synthetic opioids. However, given the unusual nature of class-wide scheduling, we must ensure that this process protects civil rights and supports scientific research.

Overall, the impact of the Interagency FRS Proposal on the enforcement and prosecution of FRS importation and exportation offenses is anticipated to be similar to the effect that class-wide scheduling has had since February 2018. The observed impact has been a decrease in the number of cases involving importation of FRS because class-wide scheduling eliminates the incentive for drug trafficking organizations and their skilled chemists to make trivial modifications to fentanyl to avoid detection and prosecution. However, mindful of the need to balance all equities, the Interagency FRS Proposal exempts FRS from quantity-based mandatory minimum penalties, creates an expedited off-ramp process, expands opportunities for research of all Schedule I substances. The proposal also asks the GAO to review the impact of our proposal.

The overdose rate has continued to increase and as is noted in the question certain groups are overrepresented. The disparate impact on certain groups in overdose death rates mirrors how these groups generally face systemic barriers to accessing health care and treatment, including substance use treatment, demonstrating the need for a public health response that improves access to services for groups that are disproportionately impacted. Since day one, the Biden-Harris Administration has been working to lower those barriers. That is why ONDCP supports expanding access to evidence-based prevention, harm reduction, treatment and recovery support services, , in turn advancing equity in addressing substance use in America, as detailed in our policy priorities and budget requests.

Q. This year the country has witnessed a high of 100,000 overdose deaths. I recognize that this is a complex and multifaceted problem that requires a multifaceted solution. What additional policies should be considered to reduce overdose deaths?

A. The overdose crisis is complex requiring attention to the full continuum of prevention, harm reduction, treatment and recovery support services. Two area of significance in the short-term are increased access to naloxone and reduced-barrier treatment.

Provision of naloxone, the overdose reversal medication, is a critical tool in the overdose crisis. This opioid antagonist medication can be used to reverse opioid overdoses and effective in preventing opioid overdose fatalities. ONDCP has worked with the Legislative Analysis and Public Policy Association (LAPPA) to produce a model law for states to increase access to this life-saving medication but more needs to be done.

The supply and distribution of naloxone does not meet the demand for most communities. Over-the-counter naloxone, reimbursable by insurance and no or low-cost naloxone distributed through harm reduction programs, emergency departments, and to individuals re-entering from correctional settings would help to meet the needs of individuals most in need.

In combination with a number of other tools, increasing access to evidence-based treatment, available when and with individuals who are ambivalent about being engaged, is a critical tool to stem the overdose crisis. Buprenorphine, one of the three medications for opioid use disorder (MOUD), has been proven highly effective for treating opioid use disorder and has the advantage of being able to be prescribed in an office-based setting, making it one of the most accessible treatments. Additional efforts are needed to offer buprenorphine as a reduced-barrier treatment option. Reduced-barrier, also referred to as low-threshold, can improve on this by setting a lower bar for admission and retention in the program, offering care the same day and or in settings where people who use drugs spend time and accommodating the daily work life and demands on the patient's time.

Additional efforts are needed to increase access to methadone, another medication for opioid use disorder. Last year, DEA revised existing regulations for narcotic treatment programs (NTPs) to allow the operation of a mobile component and SAMHSA announced the extension of the methadone take-home flexibilities. These efforts will help provide treatment to rural and other underserved communities, including incarcerated individuals. We need to continue our work

modernize methadone as both a tool for treating opioid use disorder and for reducing overdose deaths.

Concerns about health-related stigmatization and discrimination often dissuade people with opioid use disorder from seeking medical care. Thus, programs integrated with syringe service programs or other community-based settings that operate in judgement free environments may be more likely to be utilized.

Q. With respect to buprenorphine, an effective treatment for opioid use disorder, the Biden-Harris Administration took an important step in expanding access to this treatment by increasing the number of providers who are eligible to prescribe buprenorphine. However, a recent NPR article found that some pharmacies remain hesitant to distribute this medication due to fears of having their registrations to dispense controlled substances revoked. What further steps is the Administration considering to expand access to buprenorphine?

A. While enforcement of regulations on the dispensing of controlled substances falls under the Drug Enforcement Administration (DEA), the Biden-Harris Administration eased buprenorphine prescribing regulations with release of its Practice Guidelines issued on April 27, 2021 by HHS Secretary Becerra. This Guideline exempted eligible physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and certified nurse midwives from federal certification requirements related to training, counseling and other ancillary services that are part of the process for obtaining a waiver to treat up to 30 patients with buprenorphine.
Further, HHS is currently evaluating the impact of the Practice Guidelines on buprenorphine prescribing patterns. We anticipate results will be available and ready to be shared this spring.

The Honorable Anna G. Eshoo (D-CA)

Q. Please describe how social media is used to facilitate the trafficking of fentanyl, fentanyl-related substances, and other opioids.

- **Has the ONDCP observed an issue with private, peer-to-peer sales often facilitated in private groups?**
- **Has the ONDCP observed formal, monetized advertisements on social media services for illicit drugs? Is this problem wide-spread?**
- **To what degree and how often does the ONDCP coordinate with social media companies to combat the sale of opioids on social media?**
- **Which social media companies has the ONDCP worked with?**
- **How does the ONDCP collaborate with social media companies?**
- **Have social media companies been receptive to the ONDCP outreach?**
- **Which social media companies have been the most productive partners on responding to issues involving illicit drug sales?**
- **Are there legal, technical, personnel, or other barriers to effectively coordinating to combating the sale of opioids on social media?**

A. While traditional drug trafficking methods continue, law enforcement reporting indicates drug trafficking organizations (DTO) use of social media to market and sell drugs is widespread and will likely continue as long as DTOs see it as an effective and low-risk tool for connecting with the buyers of illicit drugs. Illicit drug activity has been observed across numerous internet sites and social media and communications applications. Moreover, DTOs in other countries use social media to publicize their acts of violence to intimidate rivals and the public in order to decrease opposition and increase their influence. As use of social media by DTOs has expanded, so have tactics such as the use of emoji codes by drug traffickers to communicate with prospective buyers on open platforms.

U.S. law enforcement agencies are engaged at various levels with industry to increase awareness of criminal use of commercial infrastructure, such as the internet, social media and eCommerce applications to market and sell a wide variety of contraband, which includes illicit drugs such as fentanyl, fentanyl related substances and opioids. In 2019, ONDCP coordinated with the interagency to release a series of advisories for private industry known as the "4Ms" which highlighted characteristics of the movement, marketing, manufacturing, and money associated with drug traffickers and their illicit activities.

Also, other effective initiatives are ongoing, such as the FBI-led DOJ initiative Joint Criminal Opioids Darknet Enforcement (JCODE) program, which pursues traffickers who exploit the dark web to market and sell opioids. We also know that transnational criminal organizations (TCOs) are poly-crime, and that their illicit revenues come from a variety of criminal activities in addition to illicit drugs. Organizations like Homeland Security Investigations' (HSI) Cyber Crimes Center (C3) is dedicated to the criminal transborder investigation of internet-related crimes, including the sale and distribution of illicit drugs, as well as other criminal activities such as money laundering, illegal arms trafficking, child exploitation, and human trafficking. The United States will pursue TCOs through all appropriate means, whether those are investigations into illicit drug trafficking, or any of their numerous other criminal activities.

Additionally, ONDCP recognizes that the internet and social media have streamlined connections between drug traffickers and the buyers of illicit substances worldwide. Addressing the globalization of the illicit drug trade requires collaboration with like-minded international partners. A complicating factor is that some social media and peer-to-peer communication applications operate beyond United States jurisdiction. The global nature of these issues is why a key component of ONDCP's strategic approach is working with the international community through U.S. law enforcement engagement in multi-lateral forums such as the United Nations International Narcotics Control Board (INCB) to help elevate key issues for action by the international community.

U.S. law enforcement collaboration with industry is a sensitive topic and we do not make a lot of that information public so drug traffickers do not know the extent of our activities. There are a number of robust and ongoing interagency efforts investigating drug sales on the internet. For more information, we defer to Departments of Justice, Department of Homeland Security, and the U.S. Postal Inspection Service (USPIS).

The Honorable Ann M. Kuster (D-NH)

Q. Last year, I led a letter to the Drug Enforcement Agency on the importance of at-home disposal as part of a harm reduction strategy during the COVID-19 pandemic. The Administration's Overdose Prevention Strategy includes a prevention pillar as well as a focus on harm reduction. How can the agencies involved in implementing this plan ensure that strategies such as at-home fentanyl deactivation and disposal options are accessible to help families and other stakeholders eliminate the risk of leftover medications and illicit opioids in the home? Can ONDCP facilitate and coordinate this effort across the federal government?

A. Of the more than 104,000 people who died from drug overdose between October 2020 and September 2021, it is believed that nearly 14,000 involved common prescription opioid painkillers, like oxycodone and hydrocodone.[vii] Though the majority of the increase is driven by overdose deaths related to illicitly manufactured fentanyl and other synthetic opioids, prescription drug misuse remains a significant contributor to fatal overdoses. The increase in drug overdose deaths appeared to begin prior to the COVID-19 health emergency, but accelerated significantly during the first months of the pandemic.

National Prescription Drug Take-Back Day events allow individuals to properly dispose of prescription drugs that could be diverted or misused. Americans participating in the Drug Enforcement Administration's (DEA) Take-Back Days dropped off more than 15.2 million pounds (approximately 7,600 tons) of unwanted or expired medications for safe and proper disposal at sites in all 50 states, the District of Columbia and U.S. territories. The initiative provides safe, convenient and environmentally-responsible means of disposing of prescription medications, while also educating the general public about the dangers of misusing prescription drugs.[viii]

In related legislation, the DUMP Opioids Act (that amends section 3009 of the Johnny Isakson and David P. Roe, M.D. Veterans Health Care and Benefits Improvement Act), and requires a physical location where any individual may dispose of controlled substances medications at any VA medical facility with an onsite pharmacy or a physical location dedicated for law enforcement purposes. However, disposal of illicit substances remains a challenge. It is not advisable to dispose of illicit substances into public sewage or trash systems as they can contaminate ground and water supplies.

The DEA can provide additional details on this effort across the Federal government.

The Honorable Robin Kelly (D-IL)

Q. What is the evidence that class-wide scheduling for fentanyl related substances will reduce drug-related mortality and morbidity, particularly among Black and Latinx communities?

A. Permanent class-wide scheduling is an important tool for law enforcement to respond to the trafficking and manufacture of illicitly manufactured synthetic opioids. However, given the unusual nature of class-wide scheduling, we must ensure that this process protects civil rights and supports scientific research. We believe that the Administration bill does so.

The beneficial impact of the Administration FRS Proposal for all Americans should be recognized. Since class-wide scheduling was introduced in February 2018, there has been a decrease in cases involving importation of FRS because class-wide scheduling eliminates the incentive for drug trafficking organizations and their skilled chemists to make trivial modifications to fentanyl to avoid detection and prosecution. Class-wide scheduling of FRS ensures that our nation's laws keep pace with the evolving and dynamic synthetic drug market. For this reason, we believe the Administration FRS Proposal will improve the safety and health of our communities.

Overall, the impact of the Interagency FRS Proposal on the enforcement and prosecution of FRS importation and exportation offenses is anticipated to be similar to the effect that class-wide scheduling has had since February 2018. The observed impact has been a decrease in the number of cases involving importation of FRS because class-wide scheduling eliminates the incentive for drug trafficking organizations and their skilled chemists to make trivial modifications to fentanyl to avoid detection and prosecution.

Despite our efforts, the overdose rate has continued to increase. This demonstrates the need for a public health response that improves services for groups that are disproportionately impacted. That is why ONDCP supports expanding access to evidence-based prevention, harm reduction, treatment and recovery support services, as detailed in our policy priorities and budget requests.

Q. Class-wide scheduling of fentanyl related substances may increase the development of new synthetic opioids, such as nitazenes which was recently identified in DC. How does ONDCP plan to address this to avoid a "whack a mole" approach to regulating novel harmful synthetic opioids?

A. Class-wide scheduling of fentanyl related substances is a substantial step in controlling the development of synthetic opioids. However, class-wide scheduling is not a panacea as Transnational Criminal Organizations (TCOs) are extremely adaptable and quickly evolve their products and tactics to work around our efforts to disrupt the global flow of illicit substances, including those trafficked into the United States.

As such, ONDCP engages regularly with our interagency partners, including at the state, local, and tribal levels, through a wide variety of fora to understand what communities across the United States and internationally are encountering in order to detect emerging threats. Specific regulatory actions, however, are better addressed by the Drug Enforcement Administration and the Food and Drug Administration.

The Honorable Lisa Blunt Rochester (D-DE)

Q. During the hearing, you testified that if the emergency scheduling order for fentanyl-related substances were to expire, such substances would be "uncontrolled…and essentially legal for sale and for purchase." Congress passed the Analogue Act to criminalize the harmful and unscheduled chemical variants of controlled substances "that otherwise would escape the reach of the drug laws."[ix] The U.S. Department of Justice (DOJ) has explained in past testimony[x] (submitted during the Trump Administration) to the Senate Judiciary Committee that DOJ is equipped to prosecute harmful fentanyl-related substances that have not been individually scheduled by utilizing authorities found in the Federal Analogue Act. In fact, DOJ went further to say that the "government has a very good track record in Analogue Act prosecutions."[xi]

Considering the already existing authorities and noted success of the Analogue Act to prosecute harmful unscheduled substances, please clarify your testimony that the expiration of the FRS class-wide ban would make FRS legal for sale and purchase. Please include an explanation for why you believe the current authorities are insufficient.

A. While Department prosecutors have in many instances successfully pursued Analogue Act cases, proof of these elements to a jury or judge by a criminal standard of proof is a cumbersome and resource-intensive process; it is also inefficient in that the findings in one case have no precedential value in another.

Absent class scheduling, dangerous fentanyl analogues, that have been encountered within the United States and have caused American deaths, will become unregulated as a practical matter, and only subject to prosecution on a case-by-case basis under the Controlled Substance Analogue Enforcement Act of 1986 (Analogue Act). Several times the People's Republic of China has mentioned that it is looking to the United States to exert the same control over these substances as we have asked them to. We have seen the positive effects of this temporary scheduling action in the United States, combined with the People's Republic of China's recent actions, in trafficker behavior and inbound seizures.

While the Analogue Act is an important prosecution tool to combat synthetic drugs in many contexts, it should not be regarded as an adequate substitute for class-wide scheduling. If FRS class-wide scheduling is allowed to lapse, it would still be possible to investigate and prosecute trafficking offenses (*e.g.*, importation, manufacturing, and distribution) under the Analogue Act. However, because the substances in question would not be scheduled, the Act would require in each case that the government prove (1) that the substance involved was intended for human consumption, (2) that the substance is substantially similar in chemical structure to a Schedule I or II substance (in this instance, most likely fentanyl, which is in Schedule II), and (3) that it has a substantially similar effect on the central nervous system as such a substance (fentanyl) – or was intended or represented as having such an effect in a specific case. While Department prosecutors have in many instances successfully pursued Analogue Act cases, proof of these elements to a jury or a judge by a criminal standard of proof (beyond a reasonable doubt) is a cumbersome and resource-intensive process; it is also inefficient in that the findings in one case have no precedential value in another.

By proposing to permanently control fentanyl-related substances as a class, the Administration consensus language adopts a proactive, legislative solution instead of relying on a prosecution tool to be applied to individual cases on an ad hoc basis. This was done because the rapidity with which these substances are being created and introduced into America's communities far outpaces our ability to test each of them fully prior to making a determination about their potential harm. FRS scheduling has succeeded in doing what it was designed to do; we should not lightly test fate by undoing a proven approach.

Q. Representatives from the criminal justice and civil rights communities are concerned that class-wide scheduling would remove the prosecutorial burden to prove that a substance produces similar, harmful biological effects to fentanyl. Can you comment on that concern?

A. The Office of National Drug Control Policy (ONDCP), the Department of Justice and the Department of Health and Human Services (HHS) met regularly to develop these recommendations for a comprehensive, consensus approach that addresses the complex issues surrounding the scheduling of Fentanyl Related Substances (FRS). This process involved input from the Congress, public health officials, law enforcement partners at all levels, and stakeholder groups.

This recommendation creates a streamlined process, overseen by HHS, to identify and remove or reschedule any individual FRS that is found to not have a high potential for abuse as defined in the Controlled Substances Act (CSA). Additionally, this recommendation ensures a federal court may vacate or reduce the sentence of an individual convicted of an offense involving an individual FRS that is subsequently removed or rescheduled from Schedule I.

The foundation of these recommendations as is the case with all drug policies, is to ensure these actions will make our communities healthier and safer, without causing unintended harm, particularly related to racial equity and the fundamental civil rights of all Americans.

<u>The Honorable Lori Trahan (D-MA)</u>

Q. Mr. Chester, during your testimony you referenced HHS' Buprenorphine Practice Guidelines when asked about steps the Administration has taken to help close disparities in access to medication assisted treatments to treat opioid use disorder. I was pleased to hear in your answer that since these practice guidelines have been in place there has been an expansion in buprenorphine prescriptions and increased access to treatment. What can you share about the increase in buprenorphine prescriptions since these practice guidelines have been in effect? When will data on the number of buprenorphine prescriptions and prescribing practitioners since the practice guidelines be available?

A. The release of the Practice Guidelines on April 27, 2021 by HHS Secretary Becerra exempted eligible physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and certified nurse midwives from federal certification requirements

related to training, counseling and other ancillary services that are part of the process for obtaining a waiver to treat up to 30 patients with buprenorphine.

Further, HHS is currently evaluating the impact of the Practice Guidelines on buprenorphine prescribing patterns. We anticipate results will be available and ready to be shared this spring. ONDCP defers to HHS for data on the total number of new buprenorphine prescriptions under the new program.

The Honorable Brett Guthrie (R-KY)

Q. As you know, methadone is still only given at treatment centers that must be visited once a day – which can be a burdensome and disruptive model to individuals' lives. However, there are products in development that would allow methadone to be given orally once per week – improving ability to receive and comply with treatment, reducing the risk of relapse, and providing a better quality of life. What actions can your agency take to speed development and uptake of these kinds of products, and how can the federal government at-large play a bigger role in supporting innovative dosage forms?

A. ONDCP has historically relied on the scientists in the private sector, academics and particularly leadership from government agencies like those at the National Institutes of Health to provide oversight for and drive pharmacotherapy development process. There is a tremendous difference in utility between a medication in the development pipeline and one that is Food and Drug Administration (FDA) approved and available as a generic at low-cost.

That is why ONDCP is committed with its first-year priorities to improving access to evidence-based treatments.[xii] The FDA has already approved a number of relatively inexpensive medications that could be much more widely adopted for treating opioid use disorder if policy barriers were eliminated. Thus, we are focused on ensuring that the highly effective treatment medicines we have available now are made as widely available as possible while maintaining protections against diversion, as the evidence warrants. Several examples of ONDCP's first-year efforts are below:

- Entered a contract with the National Academy of Sciences Engineering and Medicine to provide a Modernizing Methadone workshop on March 3rd and 4th of 2022.[xiii] The workshop proceedings will inform the interagency concerning needed regulatory changes based on the experience of expert clinicians, researchers and people with lived experience.
- Convened interagency regulators to finalize practice guidelines that allow practitioners treating 30 or fewer patients to legally work without a Data 2000 registration after notifying SAMHSA of intent to provide care with this medicine.
- Additionally, worked with HHS, VA, DOD, and DOJ to promote continuation of methadone take-home flexibilities established during the COVID-19 Emergency so patients may continue to obtain multiple days of methadone dosing and reduce the need for them to come to the clinic so frequently. HHS through its 2021 Fall Unified Agenda has proposed its intent to conduct rulemaking to extend availability of methadone take-home doses[xiv].

The Honorable Michael C. Burgess, M.D. (R-TX)

Q. **I've been hearing stories about how dealers are using social media and apps like Snapchat to infiltrate chats with teens or young kids and sell them illicit drugs. We have no idea what they are selling and whether or not the drug is laced with fentanyl.**

- **What should we think about as regulators and what is our role in protecting our kids from dangerous social media threats?**

- **What tools can we provide to parents to monitor their children's social media, where they are actively being targeted? What can social media companies do to increase awareness to parents?**

A. ONDCP shares your concern about drug traffickers using social media and peer-to-peer communication applications to target youth as prospective users. ONDCP defers to federal regulatory and law enforcement agencies for a more detailed discussion about potential approaches to regulation.

Q. The SUPPORT Act was signed into law on October 24, 2018. Under this law, advanced electronic data (AED) must be submitted for all international mail shipments to assist Customs and Border Protection in identifying illicit fentanyl drugs.

- **Are there efforts to identify illicit substances in fraudulent international mail shipments that would not be included in advanced electronic data?**

- **What trends have been identified in illicit drug shipments and is there any international coordination to prevent fentanyl analogues and counterfeit drugs from crossing borders?**

A. Drug seizure data from U.S. Customs and Border Protection (CBP) indicates that implementation of the STOP Act's advance electronic data requirements has led many traffickers to limit their previously widespread the international mail system, so that the majority of illicit drugs seized at U.S. borders is seized at southwest border ports of entry. CBP leverages advance data as part of a multi-layered approach to cargo security. Additional measures include Non-Intrusive Inspection technology and narcotics detection K9's. Law enforcement intelligence is also leveraged to identify high-risk shipments for inspection. Maintaining vigilance in the international mail system remains crucial, however: The United States Postal Inspection Service (USPIS) and the Department of State work with the United Nations Office on Drugs and Crime (UNODC), the International Narcotics Control Board (INCB), and the Universal Postal Union (UPU) to conduct training and capacity building to police, customs, and foreign posts. These engagements allow the United States to provide expertise and insight into mail processing and analytical systems which help interdiction and investigative functions.

Our multilateral engagement in international bodies such as the UN Office on Drugs and Crime (UNODC) and the International Narcotics Control Board (INCB) promotes international cooperation to implement the three UN drug-control treaties. In February, 2022, at the request of the United States, the INCB recommended international control of three precursor chemicals, 4-AP, boc 4-AP, and norfentanyl, used to manufacture, illicit fentanyl and its analogues. On March 16, 2022, Member states of the UN Commission on Narcotic Drugs (CND) voted unanimously to take international action and control the acquisition, production, and export of these precursor chemicals. International control of these chemicals is a critical aspect in reducing availability of synthetic opioids.

The Office of National Drug Control Policy (ONDCP), alongside our State Department partners, leads interagency efforts in engagement with international partners like Mexico and Colombia to address cross-border flows. The Biden-Harris Administration recently announced a new U.S.-Mexico Bicentennial Framework for Security, Public Health, and Safe Communities as well as a new, holistic U.S.-Colombia counternarcotics strategy. Both of these efforts address multiple factors fueling the opioid epidemic and aim to protect the American people by investing in public health, preventing transborder crime, and pursuing criminal networks.

For a more detailed discussion about specific trends observed by U.S law enforcement agencies, and specific actions taken as a result, ONDCP defers to DOJ, Department of Homeland Security, and USPIS.

The Honorable H. Morgan Griffith (R-VA)

Q. What benefits, if any, do you believe long-acting forms of buprenorphine offer to reduce the risk of misuse and diversion that are associated with oral buprenorphine? Do you believe Congress and federal agencies should enact laws/policies making it easier for prescribers to treat their patients with long-acting forms of buprenorphine?

A. The scientific literature testing long-acting forms of buprenorphine compared to sublingual buprenorphine shows a range of improved efficacy for these medications depending on the population under treatment and the formulation used.[xv,xvi] Additionally, by virtue of being injectable, they may be less divertible by patients once they are injected. However, policy makers must also consider the dramatically increased cost to purchase these benefits.

For example, Sublocade by Indivior is one form of FDA approved injectable product containing buprenorphine on the market as of January 2022. According to the Sublocade website, this medication costs $1829.05 per month.[xvii] In contrast, a thirty-day supply (60 films) of 16mgs of buprenorphine/naloxone is listed on Good RX site at pharmacies as of early February 2021, near a local northern Virginia zip code at prices as low as $112.14 and for the same amount of generic sublingual tablets prices are as low as $71.09.[xviii,xix]

Q. Do you believe that increasing access to long-acting injectable buprenorphine is vital to treating opioid use disorder and reducing drug overdose deaths? Why or why not?

ONDCP believes these formulations may have some utility for slightly better treatment outcomes relative to the sublingual product. However, based on available information concerning cost, ONDCP does not think these products are a practical solution for many states who are trying to accommodate a range of populations. For more information on this, see the response to the question above.

The Honorable Richard Hudson (R-NC)

Q. **The COVID-19 pandemic has tragically led to an increase in the number of overdose deaths in the United States. While a growing percentage of these deaths are caused by fentanyl and synthetic opioids, far too many overdoses and substance use disorders are also attributable to leftover prescriptions in medicine cabinets.**

During the 115th Congress, a provision I championed was included in H.R. 6, the SUPPORT for Patients and Communities Act, which was signed into law in 2018. Section 3032, Safety-enhancing packaging and disposal features, provided FDA with the authority to require certain opioids be dispensed with at-home disposal solutions. While members of Food and Drug Administration's (FDA) leadership have spoken favorably in regard to this provision, the agency has unfortunately not taken any concrete steps towards implementation.

- **Considering the number of deaths we are witnessing related to overdoses from leftover prescriptions, does the Office of National Drug Control Policy's (ONDCP) have plans to update its drug disposal guidelines? My understanding is that they were last updated over a decade ago. If so, can you provide a comprehensive status update on ONDCP's plans to update, including a description of next steps, an estimated timeline, as well as a detailed overview of the updated guidelines.**

A. Substance use disorder, including prescription drug misuse, has taken a heartbreaking toll on too many Americans and their families. Provisional data from the Centers for Disease Control and Prevention (CDC) reports that the United States has seen an increase in overdose deaths during the COVID-19 pandemic, with more than 105,000 people predicted as having died from drug overdoses between November 2020 and October 2021. Of these, it's predicted that nearly 14,000 involved common prescription opioid painkillers, like oxycodone and hydrocodone.[xx] Though the majority of the increase is driven by overdose deaths related to illicitly manufactured fentanyl, prescription drug misuse still contributes to overdose numbers. The increase in drug overdose deaths appeared to begin prior to the COVID-19 health emergency, but accelerated significantly during the first months of the pandemic.

The Biden-Harris Administration is working to bend the curve on overdose deaths. National Prescription Drug Take-Back Day events allow individuals to properly dispose of prescription drugs that could be diverted or misused. Americans participating in the Drug Enforcement Administration's (DEA) Take-Back Days have dropped off more than 15.2 million pounds (approximately 7,600 tons) of unwanted or expired medications for safe and proper disposal at sites in all 50 states, the District of Columbia and U.S. territories. The initiative provides safe,

convenient and environmentally-responsible means of disposing of prescription medications, while also educating the general public about the dangers of misusing prescription drugs.[xxi]

We would refer you to the DEA for additional details on this effort across the Federal government.

In addition, the recently enacted DUMP Opioids Act (P.L. 117-29) will allow the Department of Veterans Affairs to use its healthcare facilities for disposal of controlled substances medications during designated times.

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[iv] Drug Enforcement Administration. Schedule of Controlled Substances: Temporary Placement of Fentanyl-Related Substances in Schedule 1. February 6, 2018. 2018 - Temporary Scheduling Order: Temporary Placement of Fentanyl-Related Substances in Schedule I (usdoj.gov)

[v] The White House. President Biden Signs H.R. 2630. May 4, 2021. https://www.whitehouse.gov/briefing-room/legislation/2021/05/04/bill-signing-h-r-2630/

[vi] The White House. Bill Signed: H.R. 5305. September 30, 2021. https://www.whitehouse.gov/briefing-room/statements-releases/2021/09/30/bill-signed-h-r-5305/

[vii] National Center for Health Statistics/Centers for Disease Control and Prevention. Vital Statistics Rapid Release Provisional Drug Overdose Death Counts, available at https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm (February 2022).

[viii] Drug Enforcement Administration. Headquarters. DEA's National Prescription Drug Take Back Day Brings in nearly 745,000 Pounds of Unneeded Medications. November, 1, 2021. https://www.dea.gov/press-releases/2021/11/01/deas-national-prescription-drug-take-back-day-brings-nearly-745000-pounds

[ix] 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.").

[x] See, e.g., Amanda Liskamm, June 2019:
"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."

[xi] 21 U.S.C.§ 813.

[xii] Executive Office of the President, Office of National Drug Control Policy. The Biden-Harris Administration's Statement of Drug Policy Priorities for Year One https://www.whitehouse.gov/wp-content/uploads/2021/03/BidenHarris-Statement-of-Drug-Policy-Priorities-April-1.pdf

[xiii] Methadone Treatment for Opioid Use Disorder: Examining Federal Regulations and Laws - A Workshop https://www.nationalacademies.org/event/03-03-2022/methadone-treatment-for-opioid-use-disorder-examining-federal-regulations-and-laws-a-workshop

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https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6145749/?report=printable

[xvii] https://www.sublocade.com/cost-savings

[xviii] https://www.goodrx.com/buprenorphine-naloxone?dosage=8mg-2mg&form=film&label_override=buprenorphine%20%2F%20naloxone&quantity=60&sort_type=popularity

[xix] https://www.goodrx.com/buprenorphine-naloxone?dosage=8mg-2mg&form=sublingual&label_override=buprenorphine%20%2F%20naloxone&quantity=60&sort_type=popularity

[xx] National Center for Health Statistics/Centers for Disease Control and Prevention. Vital Statistics Rapid Release Provisional Drug Overdose Death Counts, available at https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm (January 2022).

[xxi] Drug Enforcement Administration. Headquarters. DEA's National Prescription Drug Take Back Day Brings in nearly 745,000 Pounds of Unneeded Medications. November, 1, 2021. https://www.dea.gov/press-releases/2021/11/01/deas-national-prescription-drug-take-back-day-brings-nearly-745000-pounds