United States Senate Committee on the Judiciary

Hearing on
"The Countdown: Fentanyl Analogues & the Expiring Emergency Scheduling Order"
June 4, 2019

Responses to Questions for the Record Submitted to
Kemp L. Chester
Assistant Director for the National Opioids and Synthetics Coordination Group
Office of National Drug Control Policy

Question from Chairman Lindsey O. Graham:

1. **During the hearing, Senator Lindsey Graham suggested criminalizing the act of creating a controlled substance analogue with the specific intent to distribute the analogue illicitly. Please describe the practical and legal limitations of criminalizing this act, including its potential advantages and disadvantages to prosecutors.**

ANSWER: The Office of National Drug Control Policy (ONDCP) and our agency partners stand ready to work with Senator Graham and his staff in developing legislation for a more effective approach to address the proliferation of unregulated fentanyl analogues and non-fentanyl opioids. Over the past two and a half years, a new fentanyl analogue, a non-fentanyl synthetic opioid, or fentanyl-related substance made through molecular deletion, has been seized at our borders nearly every single month. During that time period, as regulatory action was taken against a particular fentanyl analogue, traffickers simply expanded their production and trafficking efforts to a different analogue or non-fentanyl synthetic opioid to circumvent detection and law enforcement action. While permanent class scheduling will serve to codify the current temporary action the Drug Enforcement Administration has in place, it is also an opportunity to provide a comprehensive framework to better address the rapid changes in the dynamic illicit drug market, seize the initiative from illicit drug producers, and prevent these drugs from entering the country before they kill Americans.

Senator Graham's proposal has the potential to further this objective. While it is important to ensure that researchers maintain the ability to study fentanyl-related substances in order to develop new interventions aimed at addressing the opioid crisis, this proposal could clarify and enhance the tools available to law enforcement and federal prosecutors as they work to reduce the availability of fentanyl analogues and non-fentanyl opioids in the United States.

While China is the preponderant source of fentanyl, fentanyl analogues, and synthetic opioids, Mexico is a transit point and a source for finished fentanyl combined with heroin or another drug or pressed into pill form trafficked into the United States. This distribution model suggests that we need to address extraterritorial jurisdiction similar to what is included in the Controlled Substance Act at 21 U.S.C. 959.[1]

This provision makes it unlawful for any person to manufacture or distribute a Schedule I or II controlled substance or a listed chemical intending, knowing, or having reasonable cause to

believe that such a substance or chemical will be unlawfully shipped into the United States or into waters within a distance of 12 nautical miles of the coast of the United States.

[1] United States Code, 2017 Edition Title 21 - FOOD AND DRUGS CHAPTER 13 - DRUG ABUSE PREVENTION AND CONTROL SUBCHAPTER II - IMPORT AND EXPORT Sec. 959 - Possession, manufacture, or distribution of controlled substance.

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Questions from Senator Charles E. Grassley:

1. **China recently issued a class-wide control of fentanyl analogues. While it's a significant development, it's unclear if and when China will follow through and implement class-wide fentanyl controls.**
    a. **Assuming China implements its class-wide scheduling of fentanyl analogues, how will that impact the fentanyl crisis domestically?**

ANSWER: Illicit fentanyl produced in China is mainly sold directly to distributors and customers in the United States through purchases on the internet that are mailed in small quantities either through the U.S. Postal Service or express consignment carriers. Fentanyl and its analogues produced illicitly in China are also sold to Drug Trafficking Organizations (DTOs) outside the United States. Precursors and essential chemicals to the production of fentanyl and its analogues are produced in China and also sold to DTOs outside the United States.

We have early indicators that since May 1, 2019, the effective date of Beijing's scheduling action, that Chinese drug producers are responding to the new regulations. We are looking forward to seeing enforcement actions in China and a decrease in the flow of deadly fentanyl from China into the United States and other countries. We have asked China to control fentanyl analogues as a class, and they have indicated a commitment to do so. Controlling fentanyl analogues as a class here in the United States is now absolutely imperative to addressing the dynamic and ever-changing threat of synthetic opioids.

    b. **How can we ensure that any efforts in the U.S. work in tandem with China's actions?**

ANSWER: The Office of National Drug Control Policy (ONDCP) leads the Interagency effort to ensure that the Chinese government is implementing these new scheduling actions. The cornerstone of ONDCP's effort is regular information and intelligence sharing with counterparts at U.S. Embassy Beijing, who inform us of the Chinese government's progress in implementing and enforcing its anti-drug laws and the new class scheduling regime. Embassy colleagues also regularly raise concerns with the Chinese Government about its handling of illicit fentanyl precursor chemicals shipped to Mexico for use in producing fentanyl. Information is shared with U.S. law enforcement and intelligence experts. ONDCP's

responsibility is to ensure that Federal agencies seek pertinent intelligence, which is disseminated among the Interagency as broadly as permitted under the law and that appropriate actions are taken based upon reliable information.

2. **While opioids and fentanyl have caused thousands of overdose deaths, we're dealing with more than just two types of drugs. In Iowa, for example, methamphetamine is the most frequently abused drug and its use is continuing to rise.**

    a. **Is focusing on just fentanyl and its analogues short-sighted? How can we make sure we aren't repeating history and that dangerous drugs, like methamphetamine, don't reach levels of abuse like before?**

ANSWER: President Trump is focused on all illicit drugs, which he considers a complex national security, law enforcement, and public health problem. The Administration's *National Drug Control Strategy (NDCS)* is focused on achieving one overarching objective: Building a stronger, healthier, drug free society today and in the years to come by drastically reducing the number of Americans losing their lives to drug addiction in today's crisis, and preparing now to dominate the drug environment of the future. This will be done by preventing initiates to drug use, providing treatment services leading to long-term recovery for those suffering from addiction, and aggressively reducing the availability of illicit drugs in America's communities.[1]

In line with the *NDCS*, the ONDCP Director expanded the agency's National Opioids and Synthetics Coordination Group (NOSCG) area of responsibility to include both plant-derived and chemical-derived (synthetic) opioids and other synthetic drugs. Plant-derived and synthetic opioids include drugs such as heroin, fentanyl, fentanyl analogues, tramadol, and U-series drugs. Other synthetics include non-opioid drugs such as methamphetamine.

NOSCG's expansion, in conjunction with the Emerging Threats Committee created in ONDCP's 2018 reauthorization statute, is critical to help ensure Federal, state, local, and tribal agencies are prepared to combat the dynamic drug environment and to prevent use of, promote treatment and recovery for, and reduce the availability of all illicit drugs.

    b. **How are synthetic drugs different from fentanyl analogues, and how can we proactively combat them?**

ANSWER: Fentanyl and its analogues are a subset of synthetic drugs, as they are derived from chemicals rather than plants. Synthetic drugs also include methamphetamine and non-fentanyl synthetic opioids such as tramadol and U-series drugs.

The Drug Enforcement Administration's (DEA) temporary emergency scheduling of fentanyl-related substances in February 2018 has been crucial to stemming the flow of these illicit compounds from abroad and enhancing law enforcement efforts in the United States. However, the action is limited to fentanyl analogues (additions or substitutions to the core fentanyl skeleton) that have no accepted medical or veterinary use.[2] Additions or substitutions to the

fentanyl molecule are not technically difficult, and given the possible number of variations to the fentanyl molecule, there is the potential for over 3,000 analogues that may be created from the fentanyl molecule. These analogues have a wide variance in potency. Some analogues, like acetylfentanyl, are less potent than fentanyl; others, like carfentanil, are many times more potent; and still others, like benzylfentanyl, are believed to be essentially biologically inactive.[3]

In addition to the threat posed by additions or substitutions to the fentanyl molecule, ONDCP has observed the illicit drug industry produce non-fentanyl synthetic opioids, such as the U-series drugs, that have caused fatalities in the United States. These non-fentanyl synthetic opioids may have the same qualitative effect on the human body as fentanyl or a fentanyl analogue, but since they are not fentanyl analogues, they are not controlled under DEA's temporary scheduling action.

In addressing the problem of opioid analogues, Congress needs to enact class control of fentanyl analogues, while scheduling non-fentanyl synthetic opioids. In doing so, Congress will enable law enforcement to hold accountable those who are flooding the United States with these drugs and killing Americans – 28,466 in 2017.

c. As the agency tasked with creating and implementing a National Strategy on drug control, how can ONDCP ensure that we are identifying and anticipating future drug threats?

ANSWER: The *NDCS* is comprised of three fundamental elements: prevention, treatment and recovery, and reducing availability. These three elements inform and support each other. Almost all of the illicit drugs causing American deaths are produced outside of the United States and trafficked across our Nation's borders or mailed to purchasers using international mail and express consignment carriers by large established DTOs.[4] ONDCP assesses threats based on reporting from many sources: Customs and Border Protection seizures; United States Postal Service seizures; intelligence from Federal law enforcement agencies; and overdose statistics from the Centers for Disease Control and Prevention (CDC).

ONDCP has also developed a widespread network of state and local experts through its Heroin Availability Reduction Plan (HARP) Implementation Webinars. (The name reflects the origin of these group discussions.) As drug threats have evolved, ONDCP leadership has continued these webinars that are held on a regional basis during which participants provide a wide range of information regarding heroin, fentanyl, non-fentanyl synthetic opioids, prescription drugs, cocaine, methamphetamine, and more importantly any changes in usage of these drugs in that region. Data is collected, analyzed, and shared liberally with other communities of interest. Participants include emergency department personnel, treatment professionals, law enforcement, prosecutors, and leaders from Indian Country, many of whom express their appreciation for the opportunity to communicate directly at such a high level within the Executive Office of the President. One of the primary benefits of this program is the information provided on drugs of concern. This information is corroborated and enhanced by information provided by ONDCP's High Intensity Drug Trafficking Areas (HIDTA) Directors and Drug Free Communities grantees.

Additionally, the ONDCP Director convened the Emerging Threats Committee (ETC), which was part of the agency's 2018 reauthorization. The ETC consists of 14 representatives from National Drug Control Program Agencies, State, Local, and Tribal governments, and non-government agencies charged with identifying and responding to the evolving and emerging drug threats in the United States.

3. **You mention in your written testimony that thousands of tablets and capsules are seized within the United States, and that "34 percent were determined to contain fentanyl or a fentanyl analogue as its primary drug, with or without illicit drugs and non-narcotic substances," which is a significant increase from the seizures of these types of tablets in 2016.**

    a. **What has caused the increase of fentanyl and other analogues being pressed into pills?**

ANSWER: There are a number of interrelated factors contributing to the increase of fentanyl and other analogues being pressed into pills. There is likely a link between the decline in opioid prescriptions and the increase in counterfeit prescription pills. As fewer prescription drugs were available for misuse or diversion, a market opportunity arose for those trafficking in counterfeit pills containing fentanyl and its analogues. According to CDC data, from 2016 to 2017 there was an 11 percent decrease in the total number of opioid prescriptions dispensed in the United States, a reduction of over 23 million prescriptions. There is little significant evidence indicating that the demand for these pills similarly decreased during this time period. As the supply of pills decreased and the demand for pills for misuse remained relatively constant, those trafficking in counterfeit pills were able to exploit this gap in the market and seize a greater share. Another factor contributing to the increase of synthetic opioids being pressed into pills includes the low price of fentanyl. According to DEA, a kilogram of pure fentanyl can be purchased on the dark web for as low as $3,000. That kilogram can be divided and pressed into hundreds of thousands of counterfeit pills. These pills can then be sold at a tremendous profit margin. As the number of prescription pills available for diversion decreased, the high margins associated with fentanyl pressed into pills appealed to traffickers.

    b. **How can ONDCP structure its National Strategy and its implementation to address the growing concern of tableted synthetic and fentanyl drugs?**

ANSWER: As outlined in the *National Drug Control Strategy*, ONDCP will continue to implement several lines of effort aimed at reducing the availability and trafficking of illicit synthetic drugs. We are reevaluating regulatory measures regarding the importation, exportation, and domestic transfer of pill presses. Also, ONDCP continues to work with Congress to give DEA the authority to regulate the use of pill presses/tableting machines, with requirements for maintenance of records, inspections of verifying location, and stated use and security provisions.[5]

[1] Executive Office of the President, Office of National Drug Control Policy, *2019 National Drug Control Strategy*. Available at https://www.whitehouse.gov/wp-content/uploads/2019/01/NDCS-Final.pdf.
[2] *Schedules of Controlled Substance: Temporary Placement of Fentanyl Related Substances in Schedule I;* February 6, 2018. 21 CFR §1308.
[3] Customs and Borders Protection--Analysis of FTIR data in April 2019.
[4] Executive Office of the President, Office of National Drug Control Policy, *2019 National Drug Control Strategy*. Available at, https://www.whitehouse.gov/wp-content/uploads/2019/01/NDCS-Final.pdf.
[5] President's Commission on Combating Drug Addiction and the Opioid Crisis final report, pp. 62-63, 1 November 2017. https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf, reviewed on June 20, 2019.

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Questions from Senator Dianne Feinstein:

1. **Interagency Coordination**

   ONDCP is responsible for developing our nation's drug control policies. As part of that effort, ONDCP has played a leading role in attempting to coordinate a unified response to the fentanyl crisis, and to map out the federal government's next steps.

   I understand, that with respect to controlling fentanyl as a class, there are challenges from both an enforcement and research perspective.

   a) ***As it relates to scheduling fentanyl as a class, what challenges has ONDCP faced in terms of ensuring all of the agencies are on the same page? Have these challenges been resolved? If not, why not?***

ANSWER: The Office of National Drug Control Policy (ONDCP) has worked to coordinate the Interagency and align all parties' interests in light of varying missions.

The Administration is absolutely committed to supporting and promoting research into potential medical treatments and ensuring the research community has maximum and easy access to new substances. ONDCP is working with the Interagency to support any changes to current law that would help streamline researcher access to controlled substances and make the process less burdensome. We are steadfast in our resolve to work hand-in-hand with the research community.

Class scheduling could potentially relieve the burden of a researcher having to apply to add a new drug code to an existing registration each time the researcher wants to study a substance within that class. A researcher would submit a research protocol with his/her registration application, and would need to submit a revised research protocol when expanding the research to include a new substance. Such protocols would need to be reviewed by the Drug Enforcement Administration (DEA) and the Food and Drug Administration.

The long-standing reliance on having every single controlled drug identified up front by name has been addressed largely by the agencies themselves, as the Interagency responds and adapts to new public health and safety threats. From an enforcement perspective, entities that are interdicting and prosecuting prefer a definite list of drug names, to provide clarity regarding what

may be seized and charged. However, they have adapted in the recent past, since listing each individual new drug by name for its control may no longer be possible or practicable as some drug classes grow too quickly, such as fentanyl and its analogues. In addition, DEA has also published Federal Register notices listing specific names of drugs already controlled under its class-wide scheduling action. This combination of class control and subsequent naming of specific substances has the potential to close the distance between the activities of illicit drug manufacturers, the drug control process, and myriad interests of agencies in the scheduling process.

b) Are there any unintended consequences associated with scheduling the entire class of fentanyl-related substances that Congress should be aware of?

ANSWER: 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 the class-based scheduling. In crafting legislation, Congress should be careful to be inclusive of existing fentanyl analogues, potential fentanyl analogues, and non-fentanyl synthetic opioids. If the scope of the legislation were too narrow, its usefulness would be limited. In fact, we are already seeing the illicit drug industry begin to produce non-fentanyl synthetic opioids, such as the U-series drugs, which are now emerging as the cause of a new wave of fatalities in the United States. These non-fentanyl synthetic opioids may have the same qualitative effect on the human body as fentanyl and its analogues, but they are not structurally related to fentanyl and therefore are not controlled under DEA's temporary scheduling order. Accordingly, simply using DEA's temporary order would be expedient to address illicit fentanyl analogues, but these non-fentanyl synthetic opioids are already in the United States. ONDCP is working with the interagency to facilitate research on these and other compounds placed in schedule I. ONDCP is also working with the interagency to explore pathways for expeditiously decontrolling fentanyl-related substances that were controlled by legislative action but that lack high potential for abuse.

2. Temporary Scheduling and Preemptive Scheduling

The temporary class-wide scheduling of fentanyl-related substances marks the first time that DEA has used its authority to control an entire class of drugs pursuant to 21U.S.C. §811

If this temporary order is made permanent, it could set a precedent that allows the Justice Department and Drug Enforcement Administration to effectively circumvent the Department of Health and Human Services by regularly using the temporary, rather than permanent, scheduling process to control other classes of drugs moving forward.

a) How would you suggest that we strike the right balance between establishing necessary controls over dangerous substances as quickly as possible while also preserving the Department of Health and Human Service's role to conduct its portion of the statutorily required scientific and medical evaluation of these substances?

ANSWER: Emergency scheduling orders require the DEA Administrator to provide notice to the Assistant Secretary for Health of the Department of Health and Human Services (HHS) of its action under Schedule I , as described in section 201(h)(4) of the Controlled Substances Act, 21 U.S.C. §811(h)(4). While under administrative permanent scheduling authorized by section 201(a) of that Act (21 U.S.C. 811(a)), DEA is bound by HHS's scientific and medical evaluation and recommendation, legislative permanent placement of substances or classes of substances does not require input from the Executive Branch.

If fentanyl-related substances and non-fentanyl synthetic opioids were controlled by legislative action, HHS would need to conduct a scientific and medical evaluation as required by Section 201(b) of the Act (21 U.S.C. 811(b)) to recommend to the Attorney General to remove a substance from the CSA Schedule or to place an individual substance in a different CSA Schedule if, for example, it were found to have an accepted medical use. However, ONDCP is working with the interagency to explore pathways for access to fentanyl-related substances that were controlled by legislative action.

3. **Short- and Long-Term Solutions**

   Controlling an entire class of drugs can potentially produce positive short-term results.

   But, I am concerned that unless Congress also implements longer-term solutions, illicit drug manufacturers will create new, and potentially more deadly controlled substance analogues.

   a) What do you view as both short-and long-term solutions?

ANSWER: A short-term approach could be to accelerate the temporary and permanent scheduling via regulatory action of individual opioids, fentanyl-related opioids, or non-fentanyl synthetic opioids, or to legislatively enact a narrow chemical structure-based class scheduling. A longer-term solution could include class-based scheduling of broader chemical or pharmacological classes.

While the Federal Analogues Act has been invaluable in the Government's initial response to a fast paced flooding of the illicit market with new synthetic drugs, it is an imperfect tool and needs revisiting in light of the 21st century approach to manufacturing and trafficking of illicit drugs. The temporary scheduling time frame modifications enacted in 2012 have undoubtedly helped the Government's work, but further improvements are needed.

b) If Congress were to consider making changes to the current scheduling process, what would be the biggest priority for ONDCP?

ANSWER: The administrative control process currently requires analysis of information that is often well known for one or several related substances but unavailable for a specific new synthetic drug. The process of evaluating new synthetic drugs needs to be reviewed to encompass the rapidly expanding universe of synthetic compounds because new synthetic drugs that are closely related to controlled substances in their chemical structure, in their effect on the brain and body, and in their impact on public health and safety enter the illicit market at a fast pace.

c) Beyond scheduling, what other steps can either Congress or ONDCP take to prevent and treat addiction to synthetic and other illicit drugs?

ANSWER: The *National Drug Control Strategy* (*NDCS*) establishes the strategic framework that guides the Federal Government's efforts to reduce both the supply and the demand for illicit fentanyl and its analogues in the United States, and indeed all drugs of abuse that are harming individuals and negatively impacting the safety of America's communities. Every day, ONDCP works with the Interagency to implement these objectives.

The three fundamental elements that form the heart of the *NDCS* are prevention, treatment and recovery, and reducing availability. Reducing the size of the illicit drug using population involves preventing initiates to illicit drug use through education and evidence-based prevention programs. It also involves providing treatment services leading to long-term recovery for those suffering from substance use disorder, including using medication-assisted treatment for opioid use disorder combined with behavioral therapy, to move people out of the active user population and onto the path to recovery. By reducing the number of individuals who use illicit drugs through prevention and treatment, we can diminish the market forces pulling illicit drugs across our borders and into our communities. Drastically reducing the availability of these drugs in the United States through law enforcement and cooperation with international partners will reduce the opportunity for individuals to initiate drug use.

Finally, the *NDCS* is explicit in acknowledging that while confronting today's drug crisis to arrest its growth and reduce its effects is a vital task, we must also further develop the capability, knowledge, and infrastructure to respond to the evolving nature of the illicit drug threat as we move deeper into the 21st century. The *NDCS* states, "the exponential growth in the availability and use of synthetic drugs in the United States, especially synthetic opioids like fentanyl and its analogues, provides a window into the likely future of drug use and trafficking."

4. Fentanyl at the Southwest Border

According to the DEA, 85 percent of the fentanyl seized at the Southwest Border came through the San Diego ports of entry in 2017. Despite this, the Administration reassigned 51 agents from San Diego to staff border patrol holding cells on April 1, 2019. This caused a 20 percent decrease in operations at Otay Mesa, one of the busiest commercial ports of entry in the country. I understand that about half of the

reassigned agents have returned to Otay Mesa, but the port is still not operating at full capacity, which could result in intelligence gaps.

a) A primary goal outlined in ONDCP's National Drug Control Strategy is to significantly reduce the availability of illicit drugs in the United States by disrupting their flow across our borders. Given that ONDCP has the statutory responsibility to advise the President on drug control issues and the budgetary authority to ensure that agencies are appropriately resourced to implement this strategy, did ONDCP weigh in with the Administration about the potential negative consequences of reassigning agents from the San Diego ports of entry? If not, why not?

ANSWER: ONDCP articulates the President's drug control priorities and sets the strategic direction for the Administration to take measures to protect American citizens from the negative effects of drug trafficking and use. In addition, ONDCP provides National Drug Control Program agencies the strategic guidance they need to develop their own drug control plans and strategies, and it ensures programming and resource decisions about National Drug Control Program budget dollars are made in a manner consistent with the Administration's priorities. Events can trigger temporary needs that require reallocation of personnel. ONDCP does not make those operational decisions.

5. Class-wide Scheduling of Fentanyl in China

The Chinese government banned the illicit manufacture of all fentanyl-related substances, effective May 1st of this year.

a) What impact do you expect China's recent scheduling action to have on consumption rates in the United States?

ANSWER: While we hope consumption rates in the United States will decline as a result of China's actions, it is likely that fentanyl and fentanyl analogues will enter the United States from other countries, which may extend current consumption rates. We have put several measures in place to determine, and take appropriate action, when large-scale fentanyl production shifts to other countries. However, we expect that traffickers may shift their manufacturing and trafficking efforts to fentanyl analogues outside of the class scheduling action or to non-fentanyl synthetic opioids to circumvent law enforcement. So, while permanent class scheduling will serve to codify the current temporary action the DEA has in place, we must also see this as our opportunity to provide a comprehensive framework to better address the rapid changes in the dynamic illicit drug market.

b) Do you believe the Chinese scheduling action will encourage illicit drug manufacturers to create new, potentially more deadly substances? Is there anything that can be done to prevent this from happening?

ANSWER: If strictly enforced, the Chinese class scheduling action may lead illicit drug manufacturers and traffickers to shift their manufacturing and trafficking efforts to fentanyl analogues outside of the class scheduling or to non-fentanyl synthetic opioids to circumvent law enforcement. U.S. class scheduling of fentanyl, its analogues, and non-fentanyl synthetic opioids would serve as a strong deterrent because it would make smuggling these drugs into the United States much more difficult. We will continue to work with China and other countries to try and prevent such a scenario.

If Beijing strictly enforces its new regulations, it seems inevitable that other countries will take over its role as the primary supplier of illicit fentanyl-related substances.

Given China's new law, it seems inevitable that other countries will take over its role as the primary supplier of fentanyl-related substances.

a) Which countries do you expect to fill this gap?

ANSWER: We may indeed see drug traffickers in other countries begin to supply, or amplify their current trafficking of illicit fentanyl, fentanyl-related substances, non-fentanyl synthetic opioids, and their precursors. These are primarily produced overseas in countries with large chemical or pharmaceutical industries, particularly China. We may begin to see drug traffickers in Mexico become more independent in synthesizing precursors and illicit drugs for their United States-bound illicit fentanyl, fentanyl-related substances, and non-fentanyl synthetic opioids. Manufacturers in other countries, such as India, the Netherlands, Burma and Bangladesh, have the potential to become increasingly involved in supplying illicit synthetic opioids and their precursors the Chinese government. Finally, we may see domestic manufacturing within our own borders.

b) ***How is ONDCP proactively working with these countries to avoid another fentanyl, or other synthetic drug, epidemic?***

ANSWER: ONDCP participates in multilateral frameworks to address the global drug problem, particularly in terms of supporting the three international drug control conventions and providing leadership in the processes for internationally scheduling, controlling, and monitoring illicit drugs and their precursor chemicals. ONDCP is also actively engaged with the Government of Mexico, both bilaterally and through the multilateral North American Drug Dialogue. If there is a shift in manufacturing to Mexico, India, Burma, Bangladesh, or the Netherlands in the wake of China's class scheduling and presumptively in the United States, we are in position to push forward with bilateral discussions in collaboration with the State Department and Federal law enforcement agencies.

6. Impact of Expiration of Temporary Scheduling Order

The temporary class-wide scheduling of fentanyl-related substances has slowed the rate of increases in overdose deaths, but it expires in February 2020.

a) What, if any, impact the expiration of this order will have on ONDCP's work?

ANSWER: Expiration of the order would leave a gap in U.S. law regarding fentanyl analogues. We fully expect drug traffickers to exploit that void. We may see a surge in smuggling of fentanyl analogues into the United States by all means possible. Increasing the amount of illicit fentanyl and its analogues in the United States would be disastrous, given our ongoing efforts to save American lives. Prosecutions for substances previously emergency controlled under the Analogues Act would be affected, as a drug's lapse in control status could affect prosecution outcomes. This would be an enormous setback in our efforts to stem the opioid crisis in the United States.

b) *What impact, if any, will the expiration of this order have on the United States' ability to work with other nations to control fentanyl-related substances as a class, as China recently did?*

ANSWER: China has implemented class scheduling of fentanyl analogues. If the United States fails to legislatively make class scheduling of fentanyl analogues permanent, we will lose substantial credibility, not only with China but with other international partners. If we fail to permanently schedule illicit fentanyl analogues and non-fentanyl synthetic opioids, we risk serious damage to our domestic effort to save lives and our ability to lead on this and similar issues internationally.

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Questions from Senator Sheldon Whitehouse:

For all witnesses

1. **The emergency scheduling order has been in effect for over a year. In Rhode Island, the total number of overdose deaths fell for the second year in a row in 2018, but the number of fentanyl deaths is still going up. That problem is not unique to Rhode Island – fentanyl overdose death rates continue to increase across the country. What evidence do you have that the emergency scheduling order has supported the administration's efforts to reduce the number of fentanyl deaths?**

ANSWER: As stated in the Administration's *National Drug Control Strategy* released earlier this year, "while confronting today's drug crisis to arrest its growth and reduce its effects, we must also further develop the capability, knowledge, and infrastructure to respond to the evolving nature of the drug threat as we move deeper into the twenty-first century."[1] Over the last several years, when regulatory action has been taken against a particular fentanyl analogue, traffickers produced and trafficked different analogues or non-fentanyl synthetic opioids not currently regulated to circumvent detection and avoid law enforcement action. One of the most critical tools we can provide our law enforcement partners now is a regulatory and legal framework that provides certainty and does not prevent them from doing what is necessary to protect Americans from these ever-evolving and potent synthetic drugs. Controlling all fentanyl analogues as a class here in the United States, as we have asked China to do, is now absolutely imperative to addressing the dynamic and ever-changing threat of illicit synthetic opioids. But we must also ensure that we can more nimbly schedule the analogues that are not covered by this class scheduling action.

2. **When DEA issued its emergency scheduling order in 2018, it did so knowing the order would expire in 2020. What steps has DEA or DOJ taken since the order was issued to permanently schedule fentanyl analogues? If you have not taken any such steps, why not?**

ANSWER: The Office of National Drug Control Policy (ONDCP) and the Interagency have been evaluating the effect of this action and monitoring the adjustments illicit actors have taken to circumvent regulations in order to determine the best permanent solution. The

Department of Justice would be in the best position to address this, and ONDCP defers to them to provide the specifics and whether permanent control could be achieved in absence of legislation.

3. **You each stated that a pathway exists in order to conduct research on Schedule I drugs. However, that pathway involves a number of hurdles beyond the usual challenges of getting scientific research off the ground, and any changes to the research plan require starting that process over from the beginning.**

    a. How can necessary, timely scientific research be conducted on new fentanyl analogues under the existing restrictions on researching Schedule I drugs?
    b. Under existing restrictions, how would researchers be able to incorporate new fentanyl analogues into their existing study designs?

ANSWER: Research on synthetic opioids is needed to develop new effective responses to public health threats, chronic pain, and other neurologic and psychiatric conditions including prevention and treatment of overdose and addiction, as well as to advance basic research on brain function. If a generic class of substances is added to Schedule I, researchers can obtain registration to conduct research with any substance within that generic class. This spares the researchers from having to submit new applications for each synthetic substance. In the nine months between the emergency scheduling of fentanyl-related substances on February 6, 2018, and November 2018, 10 researchers applied and became registered to conduct research with fentanyl-related substances (for context, in December 2017 there were 590 researchers registered to study schedule I substances).

    c. If DEA is given sole authority to schedule fentanyl and fentanyl analogues, how would medical research on new analogues be reviewed and authorized?

ANSWER: If Congress places all fentanyl-related substances into Schedule I, researchers would need to obtain a schedule I research registration in order to conduct research with these substances. If the substances are placed into Schedule I as a class, a single Schedule I registration authorizing research on the class would enable the researcher to work with all of those substances without having to apply to add a new drug code to his/her registration. A researcher would submit a research protocol with his/her registration application, and would need to submit a revised research protocol when expanding the research to include a new substance. Such protocols would need to be reviewed by the Drug Enforcement Administration and the Food and Drug Administration.

    d. Would DEA and DOJ consider the creation of a separate research pathway to allow for the appropriate study of fentanyl analogues, particularly to help inform the development of new overdose reversal medications or medication-assisted treatments? What would such a pathway look like? If DEA is given sole legislative authority to schedule fentanyl and fentanyl analogues, would a separate research pathway also have to be created legislatively?

ANSWER: We intend to engage with the Interagency on options for facilitating the process for obtaining a registration to conduct research with schedule I substances.

4. **Unlike some Schedule I drugs, fentanyl does have legitimate medical uses, particularly for people with chronic illnesses who are near the end of their lives. I am concerned that efforts to schedule the entire class of fentanyl analogues could jeopardize access to this drug for people who desperately need it. What steps can DEA and DOJ take to ensure legitimate access to fentanyl is not improperly restricted?**

ANSWER: A generic class scheduling of fentanyl-related substances would not affect legitimate access to approved pharmaceutical preparations of fentanyl, sufentanil, or remifentanil or approved veterinary preparations of carfentanil or thiafentanil.

[1] Executive Office of the President, Office of National Drug Control Policy, *2019 National Drug Control Strategy*. Available at https://www.whitehouse.gov/wp-content/uploads/2019/01/NDCS-Final.pdf.

United States Senate Committee on the Judiciary

Hearing on
"The Countdown: Fentanyl Analogues & the Expiring Emergency Scheduling Order"
June 4, 2019

Responses to Questions for the Record Submitted to
Kemp L. Chester
Assistant Director for the National Opioids and Synthetics Coordination Group
Office of National Drug Control Policy

Questions from Senator Richard Blumenthal:

Drug Enforcement Administration (DEA) has claimed that the emergency order, which is scheduled to expire in February 2020, may expire before the agency can go through the process to permanently make fentanyl analogues illegal to possess or distribute. That is, any fentanyl analogues not already permanently placed in Schedule I or II would fall off the list and technically not be illegal substances. DEA emergency scheduled the fentanyl class of substances in February 2018, giving DEA and HHS two years to begin working on permanently scheduling this class of substances through rulemaking.

1. **What has been done since February 2018 to use this authority to initiate permanent scheduling?**

ANSWER: The Office of National Drug Control Policy (ONDCP), working through and with the Interagency, has been tracking the effect of the emergency scheduling order on the flow of illicit fentanyl and fentanyl analogues to the United States. In that regard, we have seen illicit drug producers increase their production of non-fentanyl synthetic opioids, such as the U-series drugs, some of which may have the same effect on the human body as fentanyl or an analogue, and can be fatal, but are not related in their chemical structure, and therefore are not controlled under the Drug Enforcement Administration's (DEA) temporary scheduling action. Initiating permanent scheduling of the substances covered by the emergency order would not impact these illicit non-fentanyl substances. ONDCP would like to work with the Committee to ensure that any legislative remedy is as comprehensive as possible, so we can account for the greatest number of potential variations, not only through manipulation of the fentanyl molecule, but other non-fentanyl synthetic opioids. The Interagency process to permanently schedule fentanyl as a class before the DEA's temporary action expires in February 2020, while calling for adequate access to the research community to study these substances for their appropriate placement in the schedule, is currently underway.

2. **Can the DEA work with HHS to permanently schedule the list of substances, and forgo the need for Congress to do so?**

ANSWER: We defer to the Departments of Justice and of Health and Human Services on their position regarding that process, and whether permanent control could be achieved in the absence of legislation.

3. **What is the average amount of time it takes to permanently schedule a substance through the non-emergency process?**

ANSWER: While some scheduling procedures have time limits, such as the emergency scheduling process or the scheduling of a new molecular entity that just received the Food and Drug Administration's approval, others do not**.** The administrative process initiated by DEA to permanently control a new substance does not have a time limit, and its timeframe varies significantly depending on the amount of information to be analyzed and other factors. ONDCP defers to DEA on other aspects of this timeline.

4. **How many fentanyl analogues and synthetic drugs have been permanently scheduled since the February 2018 emergency ban?**

ANSWER: Since the February 2018 emergency action, one fentanyl analogue and one synthetic cannabinoid previously temporarily scheduled were permanently controlled. In addition, six fentanyl analogues and one non-fentanyl-related synthetic opioid were permanently controlled in accordance with the United States obligations under the Single Convention on Narcotic Drugs (1961).

On April 1, 2019, China announced it was scheduling all types of fentanyl as a class effective May 1, 2019.

5. **Has importation of fentanyl from China declined? To what extent?**

ANSWER: It is too early to determine if China's announcement on April 1, 2019, to schedule all fentanyl-related substances, effective May 1, 2019, has led to a decline in the shipment of fentanyl from China to the United States. There are early indicators that Beijing has taken some action, but due to lagging public health indicators, it will take more time to determine the public health effect in the United States. ONDCP, working with U.S. Customs and Border Protection and DEA, will continue to monitor seizure data to establish trends related to fentanyl trafficking originating from China.

6. **Has China requested DEA to place a permanent ban on fentanyl analogues?**

ANSWER: ONDCP is not aware of any official request for DEA to permanently schedule all fentanyl-related substances. The U.S. Embassy in Beijing has been in constant communication with ONDCP and the Government of China regarding the class scheduling of all fentanyl-related substances. The Government of China has reached out to U.S. officials in Beijing regarding their fentanyl class scheduling implementation and sentencing guidelines associated with future law

enforcement actions. Controlling fentanyl as a class here in the United States, as we have asked China to do, is now absolutely imperative to addressing the dynamic and ever-changing threat of synthetic opioids. If the class scheduling of all fentanyl-related substances in the United States is not made permanent, the gap created has the potential to halt China's implementation and follow-on law enforcement action, and it will affect the U.S. Government's credibility in future drug control discussions.

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Responses to Questions for the Record Submitted to
Kemp L. Chester
Assistant Director for the National Opioids and Synthetics Coordination Group
Office of National Drug Control Policy

Questions from Senator Mazie K. Hirono:

1. **The Controlled Substances Act includes an administrative process for the Attorney General—in consultation with the Secretary of Health and Human Services—to control additional substances by placing them on the appropriate schedule.**

   Has the Department of Justice initiated this process to permanently add fentanyl analogues to Schedule I? If it has initiated this process, please provide the current status, including any feedback provided by the Secretary of Health and Human Services. If the Department of Justice has not initiated this process, please provide an explanation for why it has not done so.

ANSWER: We defer to the Department of Justice (DOJ) on progress made in that regard.

2. **There is fear among first responders, among others, about passive exposure to fentanyl and its analogues, such as through skin contact or inhalation. In June 2016, the Drug Enforcement Administration (DEA) put out a press release titled "DEA Warning to Police and Public: Fentanyl Exposure Kills." In the release, Acting Deputy Administrator Jack Riley was quoted as saying "[a] very small amount ingested, or absorbed through your skin, can kill you." The Department of Justice put out a video with similar warnings last summer.**

   Messages like these have had real-world impacts. There are multiple reports of first responders being given naloxone to treat suspected on-the-job exposures. There are additional reports that lifesaving treatment has been delayed or denied to individuals who are overdosing for fear of exposure. And, a number of states have charged—and sometimes convicted—individuals with reckless conduct, assault, and other crimes for exposing first responders to fentanyl and its analogues.

   We must ensure that any warnings about opioid exposure are grounded in science. *The New York Times* published an article in December of last year that quoted medical professionals as calling the alleged dangers of passive exposure "extraordinarily improbable." Around that same time, two doctors wrote a column in the online

publication *STAT* in which they called passive fentanyl exposure "more fact than reality."

a. Upon what scientific studies or analyses did the Drug Enforcement Administration and Justice Department base their warnings about passive exposure to fentanyl and fentanyl analogues?

ANSWER: In September 2017, the Office of National Drug Control Policy (ONDCP) and the National Security Council established a Federal Interagency working group to develop standardized, science-based guidance for first responders on the dangers of fentanyl exposure and safe-handling instructions. Civilian professional organizations, law enforcement, public health, occupational safety, medical, and emergency response experts from more than 22 Federal agencies worked together for approximately two months to develop the *Fentanyl Safety Recommendations for First Responders,*[1] a one-page, science-based document, which was reviewed and approved by a cadre of stakeholders. Developing and issuing this guidance was one of the 56 recommendations in the final report of the President's Commission on Combating Drug Addiction and Opioid Abuse.[2] The safe handling guide was published as an appendix to the Commission's final report on November 1, 2017. In addition, under ONDCP's leadership, the working group oversaw Customs and Border Protection's development and release of the companion training video, *Fentanyl: The Real Deal*.[3] The video was released at a public event hosted by DOJ on August 31, 2018.

At its initial launch, the *Fentanyl Safety Recommendations for First Responders* and *Fentanyl: The Real Deal* was released freely to all Federal working group agencies and the national stakeholder groups engaged with their development. The agencies and stakeholders in turn disseminated the recommendations to their personnel and constituents, respectively. The national stakeholder groups ran the gamut from law enforcement organizations to industrial hygiene professionals. A complete list of Federal agencies and stakeholders are included in the recommendations. Additionally, ONDCP distributed the recommendations and video to its external stakeholders, to ONDCP's High Intensity Drug Trafficking Areas covering over 19,000 Federal, state, local, and Tribal law enforcement personnel, and to over 700 of ONDCP's Drug- Free Communities coalitions, including 12 different constituencies ranging from schools to faith-based organizations and the treatment community. ONDCP's National Opioids and Synthetics Coordination Group (NOSCG) sent the recommendations and the video to over 700 Federal, state, local, and Tribal public safety and public health partners engaged in the implementation of ONDCP's Heroin Availability Reduction Plan, created by NOSCG's prior incarnation.

Moreover, ONDCP has been approached by key partner nations for subject matter expertise on the safe handling of fentanyl. At the recently concluded United Nations Commission on Narcotics Drugs held in Vienna, Austria, the recommendations were presented at an international side event for interested countries. Paper copies of the instructions and DVDs of the video were distributed to representatives from several countries who are considering translating the document into multiple languages.

b. **What is the current scientific consensus on the risks associated with passive exposure to opioids?**

ANSWER: ONDCP and its Interagency working group identify the *Fentanyl Safety Recommendations for First Responders*, a one-page, science- based document, as the current scientific consensus on the risks and the protection measures necessary for passive exposure to opioids. In order to provide further rigorous scientific knowledge to address these concerns, DOJ's National Institute of Justice, in conjunction with the Centers for Disease Control and Prevention's National Institute for Occupational Safety and Health, are conducting a series of experiments simulating real first responder activities, to quantify the risk of fentanyl exposure during these activities.

3. **What is the process for getting approval to perform scientific research on a Schedule I substance? On average, how long does this process take?**

ANSWER: DEA and the Food and Drug Administration (FDA) each have roles in overseeing research with Schedule I controlled substances. In addition, State-level authorities have licensing or registration requirements. For all nonclinical and clinical research protocols involving use of a schedule I drug, an investigator and his/her research protocol must be registered by DEA before the investigator may conduct the proposed research. DEA is responsible for ensuring applicants establish adequate safeguards against diversion of controlled substances from legitimate medical or scientific use. DEA will also refer research protocols to FDA for review. FDA is responsible for determining the qualifications and competency of applicants, as well as the merits of the research protocols. After receiving FDA recommendations on these matters, DEA will grant or deny registration applications. For research involving human subjects, proposed clinical protocols are also subject to oversight by FDA under regulations for investigational new drug (IND) applications. An IND submitted to FDA is reviewed within 30 days, and the sponsor of the IND is informed at that time whether the IND protocol has been authorized as safe to proceed, giving it "active" status. This active status should be documented by applicants as one of the considerations for DEA's protocol registration process.

In addition to the initial registration application, a researcher seeking to conduct research with a Schedule I substance may need to submit applications or documentation to DEA through a dedicated Internet portal at several additional points during the research, including registration renewal, addition of a new drug into the registration, amendment of a protocol (such as for an additional quantity of a drug), and a supplemental protocol for different research using a drug already included in the registration.[4]

Several steps of the initial registration process include permitted timeframes for submission to DEA and FDA. In practice, incompleteness or other issues with the application may extend those timeframes. Each of these interactions may be considered onerous by researchers, and ONDCP has and will continue to work with the Department of Health and Human Services and DOJ to explore streamlining and simplifying wherever possible.

4. **Since 2010, how many requests to perform research on a Schedule I substance have been received? Of those, how many have been approved?**

ANSWER: As of June 2015, DEA had not denied any research application that had met the Controlled Substances Act requirements. We defer to DEA for more current figures. As of January 2019, there were 737 separate researchers registered with DEA to conduct research with Schedule I substances, which is almost twice as many as there were five years ago, in 2014 (337).

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[1] The White House Office of National Drug Control Policy: *Fentanyl Safety Recommendations for First Responders*, https://www.whitehouse.gov/ondcp/key-issues/fentanyl/, reviewed 20 June 2019.
[2] The White House Office of National Drug Control Policy: *The President's Commission on Combating Drug Addiction and Opioid Abuse*, https://www.whitehouse.gov/ondcp/presidents-commission/, reviewed 20 June 2019.
[3] The White House Office of National Drug Control Policy: *Fentanyl Safety Recommendations for First Responders*, https://www.whitehouse.gov/ondcp/key-issues/fentanyl/, reviewed 20 June 2019.
[4] The Department of Justice, DEA: Division Control Division, Registration, https://www.deadiversion.usdoj.gov/drugreg/index.html, reviewed 20 June 2019.

United States Senate Committee on the Judiciary

Hearing on
"The Countdown: Fentanyl Analogues & the Expiring Emergency Scheduling Order"
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Responses to Questions for the Record Submitted to
Kemp L. Chester
Assistant Director for the National Opioids and Synthetics Coordination Group
Office of National Drug Control Policy

Questions from Senator Kamala D. Harris:

1. **In your testimony before the Senate Judiciary Committee, you said: "We must be equally determined about ensuring our research community has access to these [fentanyl] substances for their testing and that we rapidly move them into their appropriate place within the scheduling regime once their medical merit and potential for dependency or abuse is proven."**

    a. **Permanent scheduling would add fentanyl and the whole class of fentanyl analogues to Schedule I. It is well-known that conducting research on Schedule I substances is an onerous process. How exactly is the Office of National Drug Control Policy "ensuring our research community has access to these [fentanyl] substances"?**

ANSWER: The Administration is absolutely committed to supporting and promoting research into potential medical treatments and ensuring timely access to new substances by the research community. The Office of National Drug Control Policy (ONDCP) is working with the Interagency to support any changes to the process under current law that would help streamline and make less burdensome researcher access to controlled substances. We are steadfast in our resolve to work hand-in-hand with the research community. The National Institute on Drug Abuse (NIDA) provided input on ways to facilitate research with controlled substances. An overview of how to obtain some such substances through the NIDA Drug Supply Program is available on the NIDA website.

In 2018, DEA announced a new online application portal to speed up the application process for researchers.[1]

2. **If Congress codifies the February 6, 2018 emergency scheduling order, fentanyl and fentanyl analogues would be Schedule I substances. In your written testimony, you wrote: "More than 70,200 Americans died from a drug overdose in 2017, with 41 percent (28,466) of these deaths involving a synthetic opioid other than methadone (SOOTM). This is a statistical category that primarily includes illicitly produced synthetic opioids like fentanyl and its analogues."**

a. **Did the Office of National Drug Control Policy consider alternate ways to address deaths related to fentanyl and fentanyl analogues?**

i. **If yes, please provide details on those alternatives and explain why they were rejected. If no, why not?**

ANSWER: ONDCP leads the Interagency effort to implement the *National Drug Control Strategy* (*NDCS*), which clearly establishes the strategic framework that guides the Federal Government's efforts to reduce both the supply and the demand for all drugs that are harming individuals and negatively impacting the safety of America's communities, including illicit fentanyl and its analogues.

The three fundamental elements that form the heart of the *NDCS* -- prevention, treatment and recovery, and reducing availability -- are complementary and mutually supporting. Implementation incudes preventing initiates to illicit drug use through education and evidence-based prevention programs. It also involves providing treatment services leading to long-term recovery for those suffering from substance use disorder. By reducing the number of individuals who use illicit drugs, we diminish the market forces pulling illicit drugs across our borders and into our communities.

ONDCP and its government partners launched a media campaign to discourage opioid misuse and to encourage seeking treatment if needed. ONDCP has also encouraged research on evidence-based guidelines for the dosages and duration of prescription opioid treatment for injuries and post-operative pain and injuries, which led to the Centers for Disease Control and Prevention publishing guidelines for chronic pain. The agency is also working toward expanding Prescription Drug Monitoring Programs, expanding the capacity of State, local, rural, and Tribal communities to identify and prevent substance misuse, and developing evidence-based prevention programs all in furtherance of prevention. ONDCP has also strengthened its Drug Free Communities Support Program, which brings together myriad sectors of a community on youth substance use prevention.

To emphasize the role of treatment and recovery, ONDCP is enhancing evidence-based treatment of substance use disorder, working to eliminate barriers to treatment, and striving to increase employment opportunities for those in recovery. ONDCP has advocated for the large-scale expansion of the use of naloxone to reverse overdoses and save lives.

To reduce the availability of illicit drugs, we work with our international partners to combat illicit internet drug sales, educate mail and express consignment delivery services, and work with federal, State, local, and Tribal, law enforcement to facilitate their efforts to prevent illicit drugs from entering the United States at the borders and ports of entry. . We also partner with the Treasury Department to identify and seize illicit drug proceeds. The U.S. government sponsored a resolution at the March 2019 UN Commission on Narcotic Drugs (CND) calling on countries to implement effective and innovative national approaches to curb synthetic drugs, including successful legislative models such as class-wide scheduling of fentanyl-related substances. At the same CND, the U.S. Government also launched, in partnership with the UN Office on Drugs and Crime (UNODC) the UN Tool Kit on Synthetic Drugs. The Tool Kit provides a

comprehensive set of national interventions to help identify and address the synthetic drug threats, including legislative approaches, forensic capacity building, treatment and prevention, and enhanced controls on precursor chemicals. Finally, at the March 2019 CND session, the U.S. Government joined other members of the CND to place 12 substances, including four fentanyl analogues, under international scheduling control in order to reduce criminal access to these substances and enable law enforcement authorities around the world to target them as priority substances.

[1] Department of Justice: DEA Speeds Up Application Process For Research On Schedule I Drug, January 18, 2018, https://www.dea.gov/press-releases/2018/01/18/dea-speeds-application-process-research-schedule-i-drugs, reviewed on June 26, 2019.