

**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**

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**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.<sup>1</sup>

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.

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<sup>1</sup> 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.<sup>1</sup>

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.<sup>2</sup> 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.<sup>3</sup>

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.<sup>4</sup> 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.<sup>5</sup>

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<sup>1</sup> 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>.

<sup>2</sup> *Schedules of Controlled Substance: Temporary Placement of Fentanyl Related Substances in Schedule I*; February 6, 2018. 21 CFR §1308.

<sup>3</sup> Customs and Borders Protection--Analysis of FTIR data in April 2019.

<sup>4</sup> 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>.

<sup>5</sup> 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](https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf), reviewed on June 20, 2019.