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“Defeating Fentanyl: Addressing the Deadliest Drugs Fueling the Opioid Crisis”

Subcommittee on Crime and Terrorism
United States Senate

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Statement of:
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Chairman Graham, Ranking Member Whitehouse, and members of the Subcommittee, thank you for inviting me to discuss the public health and public safety issues resulting from the opioid epidemic – and in particular illicit fentanyl and fentanyl analogues.

Background

In 2016, more than 63,600 Americans, or approximately 174 people each day, died from a drug overdose. Opioids – a category of drugs that includes heroin, prescription pain medicines like oxycodone, and illicitly produced fentanyl and fentanyl analogues – are having a considerable impact on public health and public safety in communities across the United States. Of the overdose deaths in 2016, 66 percent (42,249) involved an opioid, nearly 54 percent (34,223) involved prescription pain medicines (including fentanyl), and 24 percent (15,472) involved heroin.¹

The threat posed by heroin and synthetic opioids has continued to grow dramatically over the past several years. Between 2007 and 2016, deaths involving heroin rose 544 percent, from 2,402 to 15,472, and since 2013 deaths involving both heroin and synthetic opioids other than methadone – a medical coding category driven by deaths involving fentanyl – have increased 267 percent. In 2016, 19,413 drug overdose deaths involved synthetic opioids other than methadone, up from 3,105 deaths in 2013, a 525 percent increase. Even with this substantial increase, it is likely that overdose deaths involving synthetic opioids other than methadone, like fentanyl, are undercounted. In 2016, among deaths where drug overdose was listed as an underlying cause of death, approximately 15 percent of death certificates did not indicate the specific drugs or drug types contributing to death.²

Fentanyl is a powerful Controlled Substances Act Schedule II synthetic opioid approved for administration as anesthesia and for use by prescription in a variety of transmucosal and transdermal formulations, most often used for the treatment of breakthrough cancer pain in opioid-tolerant patients.^{3,4} Licit pharmaceutical fentanyl is available in patches, lozenges, tablets, and liquid. Clandestinely-produced illicit fentanyl and its analogues are also available in a variety of powder, solid, liquid, tablet, and capsule forms. It may be cut into heroin to increase its effects, mixed with diluents and sold by itself as “synthetic heroin” or some other drug, or pressed into pill form and sold as commonly misused prescription opioids with or without buyers’ knowledge.⁵ On February 1, 2018, seven fentanyl related substances were temporarily placed under Schedule I.⁶

¹ An opioid-related death may involve more than one type of opioid.

² CDC National Center for Health Statistics. (2017). Multiple Cause of Death, 1999-2016 (WONDER Online Database). Available at: <http://wonder.cdc.gov/mcd-icd10.html>.

³ Schug, S.A., Ting, S. (2017). Fentanyl Formulations in the Management of Pain: An Update. *Drugs*. 77(7):747-763

⁴ Available at: <http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm>.

⁵ U.S. Department of Justice Drug Enforcement Administration. 2017 National Drug Threat Assessment. DEA-DCT-DIR-040-17. October 2017.

⁶ These seven substances are: N-(1-phenethylpiperidin-4-yl)-N-phenylpentanamide (valeryl fentanyl), N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)butyramide (para-fluorobutyryl fentanyl), N-(4-methoxyphenyl)-N-(1-

Public health and law enforcement officials nationwide believe that the emergence of illicit fentanyl and fentanyl analogues in the illegal drug market are compounding our country's current opioid crisis by driving recent steep increases in drug overdose deaths. It is important to note that law enforcement officials do not believe our Nation's fentanyl problem originates from diversion of licit fentanyl from pharmaceutical markets, but rather by clandestinely-produced illicit fentanyl and fentanyl analogues that are mixed with various illicit plant-based drugs, milled with adulterants and disguised as traditional illicit drugs, or pressed into tablets intended to mimic the appearance of prescription opioid medications such as oxycodone or hydrocodone. Mexico and China are the two largest sources of production and smuggling of illicit fentanyl and fentanyl analogues into the United States.⁷

Federal Response

The Trump Administration is fully committed to addressing the opioid crisis. Last month, President Trump released his Initiative to Stop Opioid Abuse, which aims to reduce drug demand through education, awareness, and preventing overprescribing; save lives by expanding opportunities for proven treatments for opioid and other drug addictions; and cut the flow of illicit drugs, such as illicit fentanyl and fentanyl analogues, across our borders and into our communities by getting tougher on drug traffickers and other bad actors. Among its actions to assist the Administration in implementing the President's Initiative, the Office of National Drug Control Policy (ONDCP) is addressing the illicit fentanyl problem set along several fronts.

Availability Reduction: The National Heroin Coordination Group. In November 2015, ONDCP, in coordination with the National Security Council (NSC), established the National Heroin Coordination Group (NHCG) to synchronize Federal efforts against illicit opioid trafficking and serve as the hub of a network of interagency partners that could leverage home agency authorities and resources to disrupt the global heroin and illicit opioid supply chains.

The NHCG, in close coordination with Federal departments and agencies, developed the Heroin Availability Reduction Plan (HARP) to bring together and synchronize strategies and partnerships at the Federal, state, local, and tribal levels to reduce the availability of heroin, illicit fentanyl, and fentanyl analogues. The HARP provides the structure for consistent and clear communication so we can examine the effectiveness of existing efforts and identify gaps and redundancies in government efforts to address this ever-evolving crisis. The close coordination of multi-agency, multi-jurisdictional actions, including investigations and prosecutions, against the organizations manufacturing and distributing heroin, illicit fentanyl, and fentanyl analogues directly contributes to our overall goal of reducing the number of Americans dying from these drugs.

phenethylpiperidin-4-yl)butyramide (para-methoxybutyryl fentanyl), N-(4-chlorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide (para-chloroisobutyryl fentanyl), N-(1-phenethylpiperidin-4-yl)-N-phenylisobutyramide (isobutyryl fentanyl), N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopentanecarboxamide (cyclopentyl fentanyl), and N-(2-fluorophenyl)-2-methoxy-N-(1-phenethylpiperidin-4-yl)acetamide (ocfentanil).

⁷ U.S. Department of Justice Drug Enforcement Administration. 2017 National Drug Threat Assessment. DEA-DCT-DIR-040-17. October 2017.

In 2015, the defining feature of the opioid crisis was the increased availability and use of heroin. However, as the crisis has developed over the past two years the NHCG helped interagency partners adapt to better address its changing nature:

- Agencies can now discover, identify, and disseminate information about the rapid changes to various fentanyl-family drugs. For example, when carfentanil, a powerful fentanyl-family drug used as a large animal tranquilizer, entered the illicit market and caused several multiple-death overdose outbreaks, the Federal Government was able to recognize and respond to its emergence.
- Agencies have collaborated to identify the source locations of the production of fentanyl and fentanyl analogues. Compared to heroin, which is derived from a plant that can be tested to determine geographical origin, fentanyl is synthesized from chemicals in a laboratory, making identification of its manufacturing origin extraordinarily difficult.
- Agencies are sharing important information to help law enforcement detect fentanyl in the field, including technology that is available or under development, as well as ensuring Customs and Border Protection counternarcotic canines are able to detect fentanyl.
- Agencies have increased the quantity and quality of data received about international packages bound for the United States, and they are using that data to successfully coordinate efforts to detect packages at international mail facilities, looking for illicit fentanyl shipments.
- Federal health agencies are more directly engaging in collaborative efforts with Federal law enforcement agencies to share information, collaborate on comprehensive responses, and discuss strategies to effectively address the evolving opioid epidemic.
- The NHCG worked with the NSC to produce science-based safe handling instructions for fentanyl and disseminated those instructions to Federal agents and local police to better protect law enforcement and first responders from potential fentanyl exposure.
- Federal law enforcement agencies are working together in an unprecedented fashion to identify, target, and neutralize both clear and dark web marketplaces that deal in illicit drugs.

Interagency Partnerships. The challenging and complex nature of the crisis not only demands increased collaboration and coordination among Federal agencies, but also enhanced partnerships at the state, local, and tribal levels. Moreover, state, local, and tribal partners have often demonstrated an enormous amount of energy and innovation, which are key to addressing the problem nationwide. Cooperation and communication among Federal, state, local, and tribal partners provides greater situational awareness and a more comprehensive understanding of changes in the domestic environment.

There are a number of efforts across the Federal Government that enhance collaboration and coordination. ONDCP's High Intensity Drug Trafficking Areas (HIDTA) program is a locally-based program that responds to drug trafficking issues facing specific areas of the country. Law enforcement agencies at all levels of government share information and implement coordinated enforcement activities; enhance intelligence sharing among Federal, state, local, and tribal law enforcement agencies; provide reliable intelligence to law enforcement agencies to develop effective enforcement strategies and operations; and support coordinated law enforcement strategies to maximize available resources and reduce the supply of illegal drugs.

The HIDTA Heroin Response Strategy (HRS) was launched in 2015 with an initial investment of \$2.5 million in HIDTA funds to address the heroin and opioid epidemic by coordinating the efforts of regional HIDTA programs across 17 states. In 2016, the initiative received an additional \$3.9 million in HIDTA funds and was expanded to three more states. In October 2017, ONDCP committed \$4.5 million to continue the initiative and expand into two additional states. At present, the HRS brings together ten regional HIDTAs – Appalachia, Atlanta/Carolinas, Chicago, Indiana, Michigan, New England, New York/New Jersey, Ohio, Philadelphia/Camden, and Washington/Baltimore – and encompasses 22 states and the District of Columbia. The HRS is fostering a collaborative network of public health-public safety partnerships, sharing best practices, innovative pilots, and identifying new opportunities to leverage resources.

In January 2017, the Washington/Baltimore HIDTA launched the Overdose Detection Mapping Application Program (ODMAP), which is a syndromic surveillance system that tracks local fatal and non-fatal drug overdoses in real-time. ODMAP links first responders at the scene of a drug overdose to a mapping tool that captures trends in overdoses throughout the region. This tool allows users to detect spikes in overdoses and to pinpoint outbreaks to specific locations, enabling public health and public safety agencies to mobilize immediate responses. Since its launch, more than 18,000 overdoses (fatal and non-fatal) have been logged.

International Engagement. International engagement with Mexico, Canada, and China, as well as multilateral bodies responsible for international control of these substances and their precursor chemicals, is essential to addressing this crisis at the very front end of the supply chain.

In June 2016, the leaders of the United States, Mexico, and Canada participated in the North American Leader's Summit, where U.S. concerns about heroin and illicit fentanyl were specifically raised. The annual trilateral meeting resulted in the first-ever North American Drug Dialogue (NADD), subsequently held in October 2016 and focused on the opioid crisis, with particular attention paid to heroin and illicit fentanyl. The parties shared information on best practices, data gathering methodologies, and avenues for further trilateral lines of cooperation, including public health efforts. As a follow up in March 2017, the United States hosted a NADD technical workshop here in Washington where representatives from the Federal Government met with the Mexican and Canadian delegations in discussions and conducted special trainings at the White House, the Department of Justice, the Treasury, and the Pentagon over four days, including discussions on heroin and illicit fentanyl, resulting in a list of tangible deliverables for all three countries.

The second annual meeting of the NADD took place in December 2017 in Mexico City to review the workshop deliverables and establish the next set of deliverables. The NADD continues to energize and harmonize interagency counter narcotics efforts across North America. Canada has agreed to host the next NADD in the summer or fall of 2018, institutionalizing the NADD framework.

The U.S. relationship with the People's Republic of China regarding illicit fentanyl and fentanyl analogues has been somewhat successful. The United States raised the need for better regulation of Chinese chemical and pharmaceutical industries and to update its list of scheduled substances, with an emphasis on those related to fentanyl, at a number of high and working-level engagements. China responded by scheduling 143 fentanyl analogues and other new psychoactive substances, including the critical fentanyl analogue carfentanil. Effective February 2018, China controls two critical precursor chemicals used in the illicit manufacture of fentanyl. The Drug Enforcement Administration (DEA) was a key player in this effort.

Federal law enforcement agencies are aggressively addressing the heroin and illicit fentanyl issue both here and abroad. Country and judicial attachés from the Federal Bureau of Investigation, Immigration and Customs Enforcement, and DEA work with international partners in Mexico and China to assist in criminal investigations targeting drug trafficking organizations and to help their international counterparts develop capacity to conduct the full range of narcotics interdiction activities within their countries to target both heroin and illicit fentanyl. Federal law enforcement agencies, in conjunction with the Department of State, are working with the countries who supply illicit fentanyl, and the precursor chemicals used in its manufacture, to stem the flow of these dangerous chemicals to the Western Hemisphere.

The United States has worked aggressively through the United Nations to strengthen international controls against illicit fentanyl-family drugs and the precursor chemicals used by criminals to produce them. In March 2017, in response to an official request from the United States, the United Nations Commission on Narcotic Drugs (CND) voted unanimously to schedule the two chemicals currently the most common means to produce illicit fentanyl and fentanyl analogues – N-phenethylpiperidone (NPP) and 4-anilino-N-phenethylpiperidine (ANPP) – for international control under the 1988 UN Drug Convention. In March 2018, CND voted unanimously to schedule carfentanil and five other fentanyl analogues. These decisions by the CND establish controls over the production and export of these substances and make it considerably more difficult for drug traffickers to acquire, produce, and traffic them.

Challenges Ahead

The interagency has worked to combat the exponential risk that illicit fentanyl and fentanyl analogues create and has laid a firm foundation for future efforts, but the continued rise of overdose deaths shows us that there is much more to be done. Through ONDCP's efforts to facilitate collaborations across the interagency, we have identified gaps in interagency knowledge, data, and abilities, and we are working to close them. Such challenges include:

- The Federal Government’s capability to detect illicit fentanyl at the U.S. border has increased, but it remains somewhat limited.
- The United States must continue to work with the Government of China to better regulate and control China’s chemical and pharmaceutical industries.
- Federal agencies need to better understand the true extent of the use of fentanyl and fentanyl analogues in the United States, and the role synthetic opioids play in the deaths of Americans.
- The law enforcement community must continue to improve its ability to monitor, and address online drug trafficking.

ONDCP looks forward to continuing its work with Federal, state, local, and tribal government partners, Congress, its international counterparts, and non-governmental organizations to address these challenges.

Conclusion

The opioid crisis is a complex national security, law enforcement, and public health issue that demands nothing less than all the effort, creativity, and interagency coordination we can bring to bear. The Trump Administration has been building a sustaining architecture where the Federal Government is applying its time and energy to address this multifaceted problem. President Trump’s announcement of his opioid initiative speaks to the seriousness of this crisis and the level of leadership and effort necessary to address it. It addresses the crisis by reducing drug demand through education, awareness, and preventing over-prescription; expanding opportunities for evidence-based treatment and recovery support services; and cutting off the flow of illicit drugs across our borders and within American communities.

The Office of National Drug Control Policy’s coordination thus far has afforded it a glimpse into how Federal, state, local and tribal law enforcement officials are increasingly becoming public health partners, helping those with an opioid addiction to obtain treatment for their disease. ONDCP will continue to work with its international partners, Federal departments and agencies, regional HIDTA programs, and its public and private stakeholders to reduce the availability of heroin, illicit fentanyl, and fentanyl analogues in order to lessen the profound effect these dangerous drugs are having in our communities.