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OFFICE OF NATIONAL DRUG CONTROL POLICY
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The Overdose Crisis: Interagency Proposal to Combat Illicit Fentanyl-Related Substances

Committee on Energy and Commerce
Subcommittee on Health
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Statement of
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Chairman Eshoo, Ranking Member Guthrie, and Members of the Subcommittee, thank you for inviting me to testify today on the dynamic illicit drug environment we face in the United States, particularly the sharp increase in the availability and use of fentanyl-related substances and their related harms to our communities.

Introduction

The Biden-Harris Administration is approaching America's overdose epidemic with the urgency it demands by developing evidence-based drug policy to effectively address the evolving and dynamic nature of the drug trafficking and substance use environment facing the United States and the world. While the United States regularly engages with our international partners on a range of policy matters, addiction and the overdose epidemic require astute domestic and global leadership, and the world should not expect anything less from the United States. It is critical that the United States apply the full weight of its energy, innovation, and resources to solving the challenge of drug availability and use on a global scale.

In its first-year drug policy priorities issued in April, the Biden-Harris Administration outlined a holistic and comprehensive strategy for addressing persistent and emerging challenges including expanding access to evidence-based prevention, treatment, harm reduction and recovery support services; reducing the

supply of illicit drugs; and tackling serious issues intertwined with this country’s drug-related challenges, such as advancing racial equity in drug policy.¹

One of the most complex and consequential drug challenges facing the United States and the world is illicitly manufactured fentanyl, fentanyl analogues, and fentanyl-related substances (FRS). These dangerous substances, and the dynamic threat they pose to our collective health and safety, continually challenge our efforts to reduce overdoses and related deaths. They have pervaded the nation’s illicit drug supply, are found throughout the country, and have been the main driver of the increase in drug poisoning deaths in the United States for at least the past six years. Since 2014, the number of drug overdose deaths involving synthetic opioids other than methadone, which includes illicit fentanyl, fentanyl analogues, and FRS has risen nearly seven-fold.² Provisional data from the Centers for Disease Control and Prevention (CDC) predict more than 100,000 people died of an overdose between April 2020 to April 2021. This is an alarming 28.5 percent increase over the previous year and the highest number ever recorded in a 12-month period.³ In 2020, overdose deaths involving synthetic opioids—primarily illicit fentanyl and its analogues—increased by 55 percent.⁴

¹ The White House. *The Biden-Harris Administration’s Statement of Drug Policy Priorities for Year One*. April 1, 2021. <https://www.whitehouse.gov/wp-content/uploads/2021/03/BidenHarris-Statement-of-Drug-Policy-Priorities-April-1.pdf>.

² Ahmad FB, Rossen LM, Sutton P. *Provisional Drug Overdose Death Counts*. National Center for Health Statistics. 2021. <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>

³ <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>

⁴ <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>

And there is no doubt the rapid rise in deaths attributed to these substances is directly related to their increased availability in America's communities.

According to the Department of Justice's (DOJ) National Forensic Laboratory Information System (NFLIS), in 2020 nearly 200,000 narcotic analgesics were seized and analyzed by forensic laboratories, representing 15 percent of the year's seized drug reports. Fentanyl accounted for approximately 60 percent of the total lab samples containing narcotic analgesics, and acetyl fentanyl, one of multiple common fentanyl analogues, accounted for 2 percent of the total samples containing narcotic analgesics.⁵ In fiscal year 2021, U.S. Customs and Border Protection's (CBP) Border Patrol and the Office of Field Operations seized more than twice the amount of illicit fentanyl (11,021 pounds) compared to fiscal year 2020 (4,791 pounds). The amount seized in fiscal year 2020 was also nearly double the amount seized in fiscal year 2019 (2,804 pounds).⁶

Based on the substances seized and identified by CBP's Laboratory and Scientific Services (LSS), U.S. partner forensic laboratories, and international laboratories, it may be possible to synthesize as many as 4,800 fentanyl analogues with relatively simple modifications to the base fentanyl molecule.⁷ At this time,

⁵ Drug Enforcement Administration. National Forensic Laboratory Information System (NFLIS). *NFLIS-Drug 2020 Annual Report*. Released November 2021. <https://www.nflis.deadiversion.usdoj.gov/publicationsRedesign.xhtml>

⁶ U.S. Customs and Border Protection. *Drug Seizure Statistics*. Retrieved November 9, 2021. <https://www.cbp.gov/newsroom/stats/drug-seizure-statistics>

⁷ U.S. Customs and Border Protection. Laboratories and Scientific Services. *Current Trends from the Bench*. September 2021. [Information from Official Use Only Report]

less than one percent of the analogues capable of being synthesized from existing molecules have been seized and identified by CBP LSS.⁸

Fentanyl and some fentanyl analogues are currently Schedule I and Schedule II drugs under the Controlled Substances Act (CSA). However, new and emerging FRS are being manufactured faster than the United States can schedule them individually, necessitating the permanent class-wide scheduling of FRS as a whole. Time is of the essence, deliberative action must be taken, and although scheduling is not a panacea, it is absolutely necessary to control substances yet to be made and yet to be available in our communities.

The recommendation the Administration submitted to Congress achieves these goals by permanently scheduling FRS as a class while creating a mechanism for expeditiously removing from schedule I of individual fentanyl-related substances that do not need such a restrictive scheduling, ensuring access for scientific research that is not unduly burdensome, and seeking to protect the civil rights of any American. This is a delicate balance, but we are confident we have reached a responsible and comprehensive solution.

⁸ Ibid.

Background on Development of Recommendations

On February 6, 2018, DOJ issued a rule temporarily placing the class of FRS not otherwise scheduled into Schedule I of the CSA.⁹ On May 4, 2021, President Biden signed into law the Extending Temporary Emergency Scheduling of Fentanyl Analogues Act, which extended the emergency scheduling actions until October 22, 2021.¹⁰ The emergency scheduling actions were extended to January 28, 2022 as part of the FY 2022 continuing resolution signed by President Biden on September 30, 2021.¹¹

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

⁹ Drug Enforcement Administration. *Schedule of Controlled Substances: Temporary Placement of Fentanyl-Related Substances in Schedule I*. February 6, 2018. [2018 - Temporary Scheduling Order: Temporary Placement of Fentanyl-Related Substances in Schedule I \(usdoj.gov\)](https://www.usdoj.gov/oea/press-releases/2018/02/06/2018-02-06-01)

¹⁰ The White House. *President Biden Signs H.R. 2630*. May 4, 2021. <https://www.whitehouse.gov/briefing-room/legislation/2021/05/04/bill-signing-h-r-2630/>

¹¹ The White House. *Bill Signed: H.R. 5305*. September 30, 2021. <https://www.whitehouse.gov/briefing-room/statements-releases/2021/09/30/bill-signed-h-r-5305/>

Administration Recommendations on Fentanyl-Related Substances

The Biden-Harris Administration's recommendations for a long-term, consensus approach that advances efforts to reduce the availability of illicitly manufactured, dangerous FRS, while balancing safety and security with the need to ensure racial equity in our drug policy, and providing access for scientific research for all Schedule I substances including FRS, are just one part of the Administration's larger effort to address addiction and the overdose epidemic.¹²

The Biden-Harris Administration's FRS proposal has five main components, and it is important to note that these scheduling recommendations do not apply to:

- Fentanyl, which is a Schedule II drug under the CSA;
- Fentanyl analogues that have already been individually scheduled under the CSA.

The Administration recommends the following:

- Permanently place all FRS (other than those specifically exempted or listed in another schedule) into Schedule I of the CSA. This provides law enforcement with the tools they need to respond to the trafficking and manufacture of these illicitly manufactured synthetic opioids. The NFLIS data show that following the temporary class-wide scheduling of FRS in

¹² The White House. *The Biden-Harris Administration's Statement of Drug Policy Priorities for Year One. April 1, 2021.* <https://www.whitehouse.gov/wp-content/uploads/2021/03/BidenHarris-Statement-of-Drug-Policy-Priorities-April-1.pdf>

2018, law enforcement encounters of fentanyl analogues that were not individually scheduled declined by almost 90 percent, when comparing total encounters from 2016 and 2017 to total encounters of uncontrolled fentanyl analogs from 2018 and 2019.¹³

- Exclude those FRS that are scheduled by class from all quantity-based mandatory minimum penalties normally associated with trafficking offenses of the most prevalent CSA Schedule I and II substances. It is crucial to note, this proposal does not exempt FRS offenses from existing mandatory minimums for cases where death or serious bodily injury can be directly linked to the FRS that was trafficked, as is the case for any other Schedule I or II controlled substance under 21 U.S.C. 841(b)(1)(C). DOJ reported only eight cases with FRS charges (some involving multiple defendants) from the time temporary class scheduling was adopted in 2018 through December 2020, of which only a handful included charges of quantity-driven mandatory minimums.¹⁴

¹³ U.S. Government Accountability Office. *Synthetic Opioids: Considerations for the Class-Wide Scheduling of Fentanyl-Related Substances*. GAO-21-499. April 2021, pp. 54-55.

¹⁴ U.S. Government Accountability Office. *Synthetic Opioids: Consideration for the Class-Wide Scheduling of Fentanyl Related Substances*. GAO-21-301SU. April 2021, pp. 57-58.

- Create a streamlined process, overseen by HHS, to identify and remove or reschedule any individual FRS that is found to not have a high potential for abuse as defined in the CSA.
- Ensure a federal court may vacate or reduce the sentence of an individual convicted of an offense involving an individual FRS that is subsequently removed or rescheduled from Schedule I.
- Establish a simplified process that would align research registration for all Schedule I substances, including FRS, more closely with the research registration process for Schedule II substances. The Biden-Harris Administration strongly supports expanding the research of Schedule I substances to help advance evidence-based public policy. For example, such research is critical in understanding the potential use of FRS to treat opioid addiction and overdose, chronic pain, and neurologic and psychiatric conditions, as well as its overall effects on human health.
- Finally, direct the Government Accountability Office to analyze the implementation and impact of permanent class scheduling of FRS, including its impact on research, civil rights, and the illicit manufacturing and trafficking of FRS.

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

Additional Administration Actions on Addiction and the Overdose Epidemic

The Biden-Harris Administration’s recommendations to Congress on FRS scheduling underscores its priority to advance evidence-based drug policy that reduces the supply of dangerous drugs in our communities and expands access to quality prevention, treatment, recovery support, and harm reduction services.

The Biden-Harris Administration has called on Congress to pass the “Eliminating a Quantifiably Unjust Application of the Law Act (EQUAL Act),” a bill that would eliminate the current disparity in sentencing between crack cocaine and powder cocaine. That disparity is not supported by the evidence and has caused significant harm for decades, particularly to communities of color.^{15,16,17}

¹⁵Walker, L. S., & Mezuk, B. (2018). *Mandatory minimum sentencing policies and cocaine use in the U.S., 1985-2013*. BMC international health and human rights, 18(1), 43. <https://doi.org/10.1186/s12914-018-0182-2>

¹⁶U.S. Sentencing Commission. “*Quick Facts: Crack Cocaine Trafficking Offenses*.” United States Sentencing Commission, FY 2016 through FY 2020 Datafiles, USSCFY16-USSCFY20

¹⁷Lewis, B., Hoffman, L., Garcia, C. C., & Nixon, S. J. (2018). *Race and socioeconomic status in substance use progression and treatment entry*. Journal of ethnicity in substance abuse, 17(2), 150–166. <https://doi.org/10.1080/15332640.2017.1336959>.

The President’s fiscal year 2022 Budget proposal to Congress would advance the Administration’s balanced approach to the overdose epidemic. It would provide a \$41.0 billion investment for national drug program agencies, including \$10.7 billion in HHS funding to expand access to substance use prevention, treatment, harm reduction, and recovery support services. Notably, the FY22 request for HHS’s Substance Abuse and Mental Health Services Administration (SAMHSA) request includes \$3.5 billion for the Substance Abuse Prevention and Treatment Block Grant, which for the first time, would include a 10 percent set-aside for recovery services. Additionally, the FY22 budget request includes an increase for interdiction and supply reduction programs, with a total request of \$17.5 billion.

Since the beginning of this Administration, ONDCP has worked with other agencies across the Federal Government to advance the Biden-Harris drug policy priorities. A few of the many actions taken thus far include:

- The American Rescue Plan, which invested nearly \$4 billion to allow SAMHSA and HHS’s Health Resources and Services Administration to expand access to vital mental health and substance use disorder services. The funding also included \$30 million in supports for harm reduction services—a historic amount that will enhance proven interventions like syringe services programs that are safe, effective, and cost-saving.

- HHS has released the Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder, which exempt eligible health care providers from Federal certification requirements related to training, counseling and other ancillary services that are part of the process for obtaining a waiver to treat up to 30 patients with buprenorphine. This action expands access to evidence-based treatment by removing a critical barrier to buprenorphine prescribing.
- The Drug Enforcement Administration revised existing regulations for narcotic treatment programs (NTPs) to allow the operation of a mobile component associated with a DEA-registered NTP. This rule change will help provide treatment to rural and other underserved communities, including incarcerated individuals.
- The CDC and SAMHSA have announced that Federal funding may now be used by any organization performing overdose prevention work to purchase fentanyl test strips in an effort to help curb the dramatic spike in drug overdose deaths.
- To address the supply of illicit substances in America's communities, ONDCP designated six new counties as part of its High Intensity Drug

Trafficking Areas (HIDTA) program. These counties in California, Illinois, Kentucky, and Pennsylvania will receive support for regional law enforcement efforts to disrupt and dismantle drug trafficking organizations.

- ONDCP provided funding for the nationwide expansion of the HIDTA Overdose Response Strategy to all 50 states, Puerto Rico, the U.S. Virgin Islands, and the District of Columbia. This Strategy brings together drug intelligence officers and public health analysts at the local and regional level to share information and develop evidence-based intervention and support services that reduce overdoses.
- ONDCP provided funding to support the establishment of model state-level legislation that advances efforts to expand access to harm reduction services such as access to the opioid overdose reversal drug naloxone, as well as guidance for states in using settlement funds from opioid litigation to address the overdose crisis.¹⁸
- In October, the United States and Mexico committed to the Mexico-U.S. Bicentennial Framework on Security, Public Health, and Safe Communities (Bicentennial Framework) which included a focus on reducing drug use

¹⁸Legislative Analysis and Public Policy Association (LAPPA). *Model Withdrawal Management Protocol in Correctional Settings Act*. July 7, 2021. <https://legislativeanalysis.org/model-withdrawal-management-protocol-in-correctional-settings-act/>

disorder and associated harms; providing quality, evidence-based treatment; strengthening early warning systems and the ability to track demand; and stemming the production and trafficking of methamphetamine and illicitly manufactured fentanyl, one of our most important cross-border issues.¹⁹

- In late October, ONDCP joined HHS Secretary Becerra to announce the HHS Overdose Prevention Strategy, which addresses the spectrum of drug use and addiction that can result in overdose and death: primary prevention, including safe prescribing; harm reduction, which will help keep people alive and reduce stigma; improving access to high-quality, evidence-based treatment; and expanding recovery services to more communities.
- From November 7 to 11, Director of National Drug Control Policy, Dr. Rahul Gupta was in Mexico in his role as a member of the Commission on Combating Synthetic Opioid Trafficking. During the visit, he met with U.S. Ambassador Salazar and several key Mexico officials to discuss ways to advance the Bicentennial Framework to bring a greater level of safety and security to both nations.

¹⁹[FACT SHEET: U.S.-Mexico High-Level Security Dialogue | The White House. Joint Statement: U.S.-Mexico High-Level Security Dialogue | The White House.](#) October 8, 2021.

Conclusion

To be certain, the illicit drug environment, particularly the issue of synthetic opioids, presents daunting challenges. However, as difficult as they may be, these challenges are not insurmountable. The Biden-Harris Administration's consensus recommendations submitted on permanent class-wide scheduling of FRS are a solid step forward in addressing the broader and overarching issues related to drug availability and use.

The Administration's leadership on this critical issue, the close collaboration among Federal departments and agencies, and the work the members of this Committee and your colleagues in Congress have done to keep this issue at the forefront of our national consciousness are changing the trajectory of this particularly complex national security, criminal justice, and public health challenge.

On behalf of Dr. Gupta and the men and women of the Office of National Drug Control policy, I would like to thank the subcommittee and your Congressional colleagues for your foresight and leadership, and on behalf of the Administration, ONDCP looks forward to continuing to work with you to reduce illicit drug availability, use, and their resulting harms.