COMMITTEE ON
ENERGY & COMMERCE
CHAIRMAN FRANK PALLONE, JR.

MEMORANDUM

November 30, 2021

To: Subcommittee on Health Members and Staff

Fr: Committee on Energy and Commerce Staff

Re: Hearing on "The Overdose Crisis: Interagency Proposal to Combat Illicit Fentanyl-Related Substances"

On **Thursday, December 2, 2021, at 10:30 a.m. (EST), in the John D. Dingell Room, 2123 of the Rayburn House Office Building, and via Cisco WebEx online video conferencing**, the Subcommittee on Health will hold a hearing entitled, "The Overdose Crisis: Interagency Proposal to Combat Illicit Fentanyl-Related Substances."

I. FENTANYL EPIDEMIC AND REGULATORY RESPONSE

A. Background

The drug overdose epidemic is one of the biggest public health challenges that America faces, and there has been an acceleration of overdose deaths during the coronavirus disease of 2019 (COVID-19) pandemic. Drug overdose deaths reached a record high of more than 100,000 in the 12-month period between April 2020 and April 2021.[1] The latest data show that synthetic opioids have contributed greatly to this increase. In 2015, synthetic opioids were involved in 18 percent of all overdose deaths; in 2020, it is estimated to be more than 60 percent.[2] Recent data from the Centers for Disease Control and Prevention (CDC) show that deaths at least partially attributable to synthetic opioids likely increased by around 20,000, or 54 percent, in 2020 alone.[3]

B. Fentanyl and Fenatnyl-Related Subtances

[1] Centers for Disease Control and Prevention, National Center for Health Statistics, Provisional Drug Overdose Death Counts (accessed Nov. 3, 2021) (www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm).

[2] The Commonwealth Fund, *The Drug Overdose Toll in 2020 and Near-Term Actions for Addressing It* (Aug. 16, 2021) (www.commonwealthfund.org/blog/2021/drug-overdose-toll-2020-and-near-term-actions-addressing-it).

[3] *Id.*

Research suggests that the increase in synthetic opioid-related overdoses is largely due to illicitly manufactured fentanyl, including fentanyl analogues.[4] Fentanyl is a powerful synthetic opioid that is 80-100 times stronger than morphine.[5] While fentanyl is a prescription drug primarily used to treat patients with severe pain, such as after or post-surgery, it is also made and used illegally.

Fentanyl abuse has become both more prevalent and more dangerous in recent years because of the increasing presence of substances chemically or pharmacologically similar to fentanyl, such as "fentanyl analogues" and "fentanyl-related substances" (FRS), many of which are even more powerful than fentanyl.[6] Recently, many FRS that have no prior evidence of medical use have been appearing on the illicit market.[7] The 2020 National Drug Threat Assessment released by the Drug Enforcement Administration (DEA) identifies illicit fentanyl and FRS, produced in foreign underground laboratories, and trafficked into the United States, as a significant threat to public health and safety.[8] Illicitly manufactured fentanyl and FRS are often mixed with other drugs, such as heroin, cocaine, and methamphetamine, to increase their potency.[9] These fentanyl-mixed or "cut" drugs significantly increase the risk of misuse and overdose death.[10] Further, there has been an increase in counterfeit prescription pills containing fentanyl. The DEA reported that more than 9.5 million counterfeit pills were seized so far this year, which is more than the last two years combined.[11]

C. Temporary Scheduling

In response to the increase in fentanyl-related overdoses, the DEA issued nationwide public health and safety alerts regarding the lethality of the drug in March 2015 and June 2016, and it also issued an alert regarding the increase in fake prescription pills containing fentanyl in

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[4] Center for Disease Control and Prevention, Opioids, Data Analysis and Resources (accessed Nov. 4, 2021) (www.cdc.gov/opioids/data/analysis-resources.html).

[5] Drug Enforcement Administration, Fentanyl Factsheet (accessed Nov. 4, 2021) (www.dea.gov/factsheets/fentanyl).

[6] United States Sentencing Commission, *Fentanyl and Fentanyl Analogues* (Jan. 2021) (www.ussc.gov/sites/default/files/pdf/research-and-publications/research-publications/2021/20210125_Fentanyl-Report.pdf).

[7] Drug Enforcement Administration, *Fentanyl-Related Substances* (Oct. 2021) (www.deadiversion.usdoj.gov/drug_chem_info/frs.pdf).

[8] Drug Enforcement Administration, *2020 Drug Enforcement Agency National Drug Threat Assessment* (Nov. 2021) (www.dea.gov/sites/default/files/2021-02/DIR-008-21%202020%20National%20Drug%20Threat%20Assessment_WEB.pdf).

[9] *See* note 5.

[10] *See* note 8.

[11] Drug Enforcement Administration, *DEA Issues Public Safety Alert on Sharp Increase in Fake Prescription Pills Containing Fentanyl and Meth* (accessed Nov. 10, 2021) (www.dea.gov/press-releases/2021/09/27/dea-issues-public-safety-alert) (press release).

2021.[12, 13] On February 6, 2018, the DEA used emergency authority under the Controlled Substances Act (CSA) to temporarily place FRS in Schedule I.[14] As the most restrictive class, Schedule I is reserved for drugs that are deemed as having no accepted medical use, a high potential for abuse, and a lack of accepted safety, and the CSA prohibits the manufacture, distribution, dispensation, and possession of Schedule I substances except for federal government-approved research studies.[15] This emergency action allowed fentanyl-related substances to be temporarily scheduled for up to two years. Prior to the order's expiration, Congress passed the Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act, which extended the emergency scheduling through May 6, 2021.[16] Congress has since acted to extend the emergency scheduling twice more; the current emergency scheduling order was extended through January 28, 2022.[17]

II. PRIOR CONGRESSIONAL AND COMMITTEE ACTION

In response to the opioid epidemic, Congress has passed a number of laws to provide additional authorities and resources to federal and state agencies leading response efforts. The Comprehensive Addiction and Recovery Act, which was signed into law on July 22, 2016, created an awareness campaign that required inclusion of information on the dangers of fentanyl, and created a grant program through ONDCP to support drug-free coalitions in responding to local drug crises and emerging drug abuse issues in their communities.[18] The 21st Century Cures Act, which was signed into law on December 13, 2016, provided $1 billion in Opioid State Targeted Response grants to help States increase access to treatment and support prevention and recovery activities.[19] In 2018, Congress passed the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act).[20]

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[12] U.S.-China Economic and Security Review Commission, *Fentanyl: China's Deadly Export to the United States* (Feb. 2017) (www.uscc.gov/sites/default/files/Research/USCC%20Staff%20Report_Fentanyl-China%E2%80%99s%20Deadly%20Export%20to%20the%20United%20States020117.pdf).

[13] *See* note 11.

[14] Drug Enforcement Agency, U.S. Department of Justice, Schedules of Controlled Substances: Temporary Placement of Fentanyl Related Substances in Schedule I, 83 Fed. Reg. 5188 (Feb. 6, 2018) (temporary amendment; temporary scheduling order).

[15] Controlled Substances Act, Pub. L. No. 91-513 (1970).

[16] Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act, Pub. L. No. 116-114 (2020).

[17] Extending Government Funding and Delivering Emergency Assistance Act, Pub. L. No. 117-43 (2021).

[18] Comprehensive Addiction and Recovery Act of 2016, Pub. L. No. 114-198 (2016).

[19] Comprehensive Addiction and Recovery Act of 2016, Pub. L. No. 114-198; 21st Century Cures Act, Pub. L. No. 114-255 (2016).

[20] Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act, Pub. L. No. 115-271 (2018).

This law authorized significant levels of opioid-specific funding and expanded access to substance use disorder (SUD) treatment and resources.[21] The law also increased opioid abuse and overdose prevention training; improved coordination and quality of care; and strengthened the Food and Drug Administration (FDA) and law enforcement's respective abilities to combat the trafficking of illicit opioids.[22]

Congress also included resources to combat the opioid epidemic in annual appropriations and legislative packages responding to COVID-19. The fiscal year (FY) 2021 Consolidated Appropriations Act provided $3.8 billion for opioid and stimulant misuse, including over $1 billion to states and tribes for treatment and prevention.[23] The FY 2021 package also included $1.5 billion for State Opioid Response grants administered by the Substance Abuse and Mental Health Services Administration (SAMHSA).[24] Recognizing the need for increased mental health and substance use services during the pandemic and in its aftermath, Congress deployed additional resources in passing the American Rescue Plan (ARP) Act. The ARP Act provided $4 billion to enhance mental health care and SUD treatments, the largest aggregate amount of funding to date for mental health and substance use grant programs at SAMHSA, including $1.75 billion for community mental health services and $1.75 billion for substance abuse prevention and treatment.[25, 26]

Further, the Committee has held numerous hearings on the opioid crisis. These hearings highlighted, among other things, some of the root causes of the crisis, the evolution of fentanyl abuse, and DEA's efforts, its resources, and the role it must play in continuing to combat opioids.[27]

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[21] *Id.*

[22] *Id.*

[23] Consolidated Appropriations Act, 2021, Pub. L. No. 116-260 (2020).

[24] *Id.*

[25] American Rescue Plan Act of 2021, Pub. L. No. 117-2 (2021).

[26] Substance Abuse and Mental Health Services Administration, *HHS Announces $3 Billion in American Rescue Plan Funding for SAMHSA Block Grants to Address Addiction, Mental Health Crisis* (May 18, 2021) (www.samhsa.gov/newsroom/press-announcements/202105181200) (press release).

[27] House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, *Fentanyl: The Next Wave of the Opioid Crisis*, 115th Cong. (Mar. 21, 2017); House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, *Combating the Opioid Crisis: Battles in the States*, 115th Cong. (July 10, 2017); House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, *The Drug Enforcement Agency's Role in Combating the Opioid Epidemic,* 115th Cong. (Mar. 20, 2018); House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, *Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion*, 115th Cong. (May 8, 2018); House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, *Oversight of Federal Efforts to Combat the Spread of Illicit Fentanyl*, 116th Cong. (July 16, 2019); House Committee on Energy and Commerce, Subcommittee on Oversight

III. BIDEN ADMINSTRATION'S LEGISLATIVE PROPOSAL

On September 2, 2021, the Biden Administration announced an interagency proposal to address illicit FRS in the United States.[28] The interagency proposal includes recommendations to Congress from the Office of National Drug Control Policy (ONDCP), the Department of Health and Human Services (HHS), and the Department of Justice (DOJ), which includes the DEA.[29]

The Biden Administration's proposal includes several provisions related to class-wide regulation, research, and judicial considerations of FRS. First, it would permanently place FRS into Schedule I of the CSA, and it would amend Schedule I of the CSA to include all FRS except those specifically exempted or listed in another schedule. In addition, the proposal would create an expedited process for removing individual FRS from the schedules or moving them to a lower schedule if it is found that they do not have a high potential for abuse.

The proposal would also exclude those FRS that are not specifically listed in Schedule I or II from certain mandatory minimum penalties associated with domestic trafficking and import and export offenses. Specifically, FRS would be excluded from the five-year and ten-year mandatory minimum terms applicable to offenses under the CSA involving ten grams or more, and 100 grams or more of a mixture or substance containing a detectable amount of fentanyl analogue, respectively, as well as FRS that are transferred from Schedule I to Schedule III because of a relatively lower potential for abuse. It would further ensure that a federal court can vacate or reduce the sentence of an individual convicted of an offense involving a FRS that is later removed or rescheduled from Schedule I.

The proposal would establish a simplified process that would align research registration for all Schedule I substances more closely with the research registration process for Schedule II substances. An applicant seeking to conduct Schedule I research funded by HHS or the Department of Veteran Affairs (VA), or under an Investigative New Drug (IND) exemption from FDA, would be required to notify DOJ of the substance they intend to use, quantity of such substance, demonstration that funding criterion is met, and demonstration of legal authority to do the research in the state where the research will be conducted. If the researcher already holds a Schedule I or II research registration, they can begin their research 30 days after notifying the

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and Investigations, *A Public Health Emergency: State Efforts to Curb the Opioid Crisis*, 116th Cong. (Jan. 14, 2020); House Committee on Energy and Commerce, Subcommittee on Health, *Combatting an Epidemic: Legislation to Help Patients with Substance Use Disorders*, 116th Cong. (Mar. 3, 2020); House Committee on Energy and Commerce, Subcommittee on Health, *An Epidemic within a Pandemic: Understanding Substance Use and Misuse in America*, 117th Cong. (Apr. 14, 2021).

[28] The White House, *Biden-Harris Administration Provides Recommendations to Congress on Reducing Illicit Fentanyl-Related Substances* (Sept. 2, 2021) (www.whitehouse.gov/ondcp/briefing-room/2021/09/02/biden-harris-administration-provides-recommendations-to-congress-on-reducing-illicit-fentanyl-related-substances/).

[29] *Id.*

DOJ. If they do not hold either registration, the DOJ has 45 days to grant registration or issue a show-cause order. The proposal also reforms separate registration requirements related to employees of registrants, research site registrations, requirements for new inspections, continuation of research for newly scheduled substances, manufacturing coincident to research, and transparency regarding special procedures.

Lastly, the proposal would require the Government Accountability Office (GAO) to analyze the implementation and impact of permanent class scheduling of FRS. The analysis would include impacts on research, removal and rescheduling actions, illicit manufacturing and trafficking, FRS proliferation within the drug supply, and sentencing outcomes.

IV. WITNESSES

The following witnesses have been invited to testify:

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

Louis J. Milione
Principal Deputy Administrator
U.S. Drug Enforcement Administration

Lisa O. Monaco
Deputy Attorney General
U.S. Department of Justice

Douglas Throckmorton, M.D.
Deputy Director for Regulatory Programs, Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Nora D. Volkow, M.D.
Director, National Institute on Drug Abuse
National Institutes of Health