

CHAIRMAN FRANK PALLONE, JR.

MEMORANDUM

April 12, 2021

To: Subcommittee on Health Members and Staff

Fr: Committee on Energy and Commerce Staff

Re: Legislative Hearing on "An Epidemic within a Pandemic: Understanding Substance Use and Misuse in America"

On <u>Wednesday, April 14, 2021, at 10:30am (EDT) via Cisco Webex online video</u> <u>conferencing</u>, the Subcommittee on Health will hold a legislative hearing entitled, "An Epidemic within a Pandemic: Understanding Substance Use and Misuse in America."

I. STATE OF THE CURRENT DRUG EPIDEMIC

Addiction and substance use disorders (SUD) are complex, treatable diseases that impact physical and mental health.¹ In 2019, roughly 20.3 million Americans – including over one million children ages 12 to17 – had a SUD.² Of the 20.3 million with a SUD, over ten million experienced opioid misuse.³ If untreated, SUDs can lead to severe health outcomes and in the most tragic cases, death.

² Substance Abuse and Mental Health Services Association, 2018-2019 National Surveys on Drug Use and Health Estimated Totals by State, (www.samhsa.gov/data/report/2018-2019-nsduh-estimated-totals-state) (Jan. 28, 2021).

³ Substance Abuse and Mental Health Services Administration, *Dr. Elinore F. McCance-Katz Webcast Slides, National Survey on Drug Use and Health: 2019,* (www.samhsa.gov/data/sites/default/files/reports/rpt29392/Assistant-Secretary-nsduh2019_presentation/Assistant-Secretary-nsduh2019_presentation.pdf) (Sept. 11, 2020).

¹ National Institute on Drug Abuse, *The Science of Drug Use and Addiction: The Basics*, (www.drugabuse.gov/publications/media-guide/science-drug-use-addiction-basics) (accessed Feb. 12, 2020).

⁽www.samhsa.gov/data/sites/default/files/reports/rpt32879/NSDUHsaeTotal2019/2019NSDUHs aeTotal.pdf).

Prior to the coronavirus disease of 2019 (COVID-19) pandemic, opioid overdose deaths were increasing in the United States.⁴ Recent data from the Centers for Disease Control and Prevention (CDC) indicates an acceleration of overdose deaths during the pandemic. In the 12 months leading up to August 2020, 88,000 drug overdose deaths were reported; the highest total ever recorded in a 12-month period.⁵

Fentanyl and fentanyl analogues are synthetically produced opioids up to 100 times more potent than morphine.⁶ Fentanyl is a controlled substance with a strictly regulated approved use if prescribed by a physician. However, illicit fentanyl production, distribution, and use is a primary driver of the current opioid crisis and the recent increased overdose deaths.⁷ The 2020 National Drug Threat Assessment released by the Drug Enforcement Administration (DEA) identifies illicit fentanyl, produced in foreign underground laboratories, and trafficked into the United States, as a significant threat to public health and safety.⁸ DEA also reports widespread availability of fentanyl-mixed or "cut" drugs, like methamphetamine and cocaine.⁹ The increased availability of cut substances significantly increases the risk of misuse and overdose death.¹⁰

CDC estimates that three in five overdose deaths presented opportunities for care and prevention.¹¹ They observed that a significant number of overdose deaths involved individuals recently released from institutions, who previously experienced overdose, with metal health diagnoses, or treated for a SUD.¹² President Biden's Office of National Drug Control Policy (ONDCP) has recognized these indicators as an opportunity to provide care. As such, ONDCP is

⁴ Centers for Disease Control and Prevention, *Trends and Geographic Patterns in Drug and Synthetic Opioid Overdose Deaths – United States, 2013-2019*, (www.cdc.gov/mmwr/volumes/70/wr/mm7006a4.htm?s cid=mm7006a4 w) (Feb. 21, 2021).

⁵ Centers for Disease Control and Prevention, National Center for Health Statistics, *Provisional drug overdose death counts*, (www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm) (accessed Apr. 2, 2021).

⁶ U.S. – China Economic and Security Review Commission, *Fentanyl: China's Deadly Export to the United States* (Feb. 1, 2017).

⁷ Centers for Disease Control and Prevention, *Drug Overdose Deaths*, (www.cdc.gov/drugoverdose/data/statedeaths.html) (accessed Apr. 2, 2021).

⁸ Drug Enforcement Administration, 2020 National Drug Threat Assessment, (www.dea.gov/sites/default/files/2021-02/DIR-008-21%202020%20National%20Drug%20Threat%20Assessment WEB.pdf) (Mar.2021).

⁹ Id.

¹⁰ *Id*.

¹¹ Center for Disease Control and Prevention, Overdose Deaths and the Involvement of Illicit Drugs: Urgent Need for Overdose Prevention Interventions,

(www.cdc.gov/drugoverdose/pubs/featured-topics/VS-overdose-deaths-illicit-drugs.html) (Sept. 4, 2020).

¹² *Id*.

working to expand evidenced-based treatments, advance racial equity in drug policy, support evidence-based prevention and harm-reduction efforts, and enhance the addiction workforce and recovery support services.¹³

II. CONGRESSIONAL AND COMMITTEE ACTION

In 2016, Congress passed both the Comprehensive Addiction and Recovery Act and the 21st Century Cures Act.¹⁴ Each of these laws authorized funding to address SUD treatment, recovery, and prevention.¹⁵ In 2018, Congress also passed the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act).¹⁶

The SUPPORT Act authorized opioid-specific funding and expanded access to SUD treatment and resources. 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.¹⁷

On February 6, 2018, DEA used emergency authority under the Controlled Substances Act (CSA) to temporarily place "fentanyl-related substances" in schedule I.¹⁸ This authority was provided by Congress in 1984 to provide DEA with the ability to "avoid an imminent hazard to the public safety",¹⁹ and enables the temporary emergency scheduling of substances for up to two years. In anticipation of this expiring order, Congress passed the Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act, which was signed into law on February 6, 2020.²⁰ The provisions are set to expire on May 6, 2021.

¹⁴ Comprehensive Addiction and Recovery Act, Pub. L. No. 114-198; 21st Century Cures Act, Pub. L. No. 114-255.

¹⁵ *Id. See* also Department of Health and Human Services, *HHS Provides States Second Installment of Grant Awards to Combat Opioid Crisis* (Apr. 18, 2018) (press release).

¹⁶ Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act, Pub. L. No. 115-271 (2018).

¹⁷ *Id*.

¹⁸ 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).

¹⁹ Pub. L. No 98-473 (1984).

²⁰ Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act, Pub. L. No. 116-114 (2020).

¹³ Executive Office of the President Office of National Drug Control Policy, *The Biden-Harris Administration's Statement of Drug Policy Priorities for Year One*, (www.whitehouse.gov/wp-content/uploads/2021/03/BidenHarris-Statement-of-Drug-Policy-Priorities-April-1.pdf) (Apr. 1, 2021).

Congress also provided resources to combat the current opioid epidemic through annual appropriations and recent emergency packages responding to COVID-19. The fiscal year (FY) 2021 Consolidated Appropriations Act, 2021 provided \$3.8 billion for opioid and stimulant misuse, including over \$1 billion to states and tribes for treatment and prevention.²¹ 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).²² Recognizing the need for increased mental health and substance use services during the pandemic and in its aftermath, Congress further provided additional resources in the American Rescue Plan (ARP) Act. ARP provided \$4 billion to enhance mental health care and SUD treatments, including \$1.75 billion for community mental health services and \$1.75 billion for substance abuse prevention and treatment.²³

Further, the Committee has held multiple hearings on the opioid crisis. These hearings highlighted, among other things, some of the root causes of the crisis, the role of drug distributors and DEA's efforts to combat opioids, the evolution of fentanyl abuse, and included testimony from state and local addiction treatment experts and federal officials.²⁴

III. LEGISLATION

A. H.R. 654, the "Drug Free Communities Pandemic Relief Act"

H.R. 654, the "Drug Free Communities Pandemic Relief Act" was introduced by Reps. Joyce (R-OH) and Kilmer (D-WA). This bill would allow ONDCP to waive a "Drug-Free Communities" program's local matching requirement during the COVID-19 pandemic if they are unable to meet the match.

²¹ Consolidated Appropriations Act, 2021, Pub. L. No. 116-260 (2020).

²² *Id*.

²³ American Rescue Plan Act of 2021, Pub. L. No. 117-2.

²⁴ 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. (Jul. 16, 2019); House Committee on Energy and Commerce, Subcommittee on Oversight 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).

B. H.R. 955, the "Medicaid Reentry Act of 2021"

H.R. 955, the "Medicaid Reentry Act" was introduced by Reps. Tonko (D-NY), Turner (R-OH), Trone (D-MD), McKinley (R-WV), Underwood (D-IL), Fitzpatrick (R-PA), and Hastings (D-FL). This bill would extend Medicaid eligibility to incarcerated individuals 30 days before their release. Earlier eligibility would help to minimize disruptions in access to care, including access to medication-assisted treatment (MAT), when individuals transition back into the community.

C. H.R. 1384, the "Mainstreaming Addiction Treatment Act of 2021"

H.R. 1384, the "Mainstreaming Addiction Treatment Act of 2021" was introduced by Reps. Tonko and Turner, along with 45 original cosponsors. This bill would eliminate the separate DEA registration requirement for practitioners who seek to prescribe buprenorphine for SUD treatment. Under current law, a practitioner must meet certain criteria in order to treat opioid addiction with buprenorphine outside of an opioid treatment program.²⁵

D. <u>H.R. 1910, the "Federal Initiative to Guarantee Health by Targeting</u> <u>Fentanyl Act"</u>

H.R. 1910, the "Federal Initiative to Guarantee Health by Targeting Fentanyl Act" or the "FIGHT Fentanyl Act" was introduced by Reps. Chabot (R-OH) and Latta (R-OH). This bill would authorize DEA to permanently classify all fentanyl analogues as schedule I substances.

E. H.R. 2051, the "Methamphetamine Response Act of 2021"

H.R. 2051, the "Methamphetamine Response Act of 2021" was introduced by Reps. Peters (D-CA) and Curtis (R-UT). This bill would designate methamphetamine as an emerging threat and requires ONDCP to develop a national plan to prevent methamphetamine addiction from becoming a crisis.

F. H.R. 2067, the "Medication Access and Training Expansion Act of 2021"

H.R. 2067, the "Medication Access and Training Expansion Act of 2021" or the "MATE Act of 2021" was introduced by Reps. Trahan (D-MA), Carter (R-GA), McKinley, Kuster (D-NH), Trone, and Tonko. This bill would require all DEA registrants who prescribe controlled substances to fulfill a one-time training requirement on treating and managing patients with opioid and substance use disorders. It would also create a standard training model in professional health education programs like medical, nursing, and pharmacy schools. Practitioners would be allowed to fulfill the training requirement if their health professional programs' curriculum met the standards set in the bill.

G. H.R. 2355, the "Opioid Prescription Verification Act of 2021"

²⁵ Children's Health Protection Act of 2000, Pub. L. No. 106-310.

H.R. 2355, the "Opioid Prescription Verification Act of 2021" was introduced by Reps. Davis (R-IL), Bilirakis (R-FL), and Wagner (R-MO). This bill directs federal agencies to develop, disseminate, and periodically update training materials for pharmacists on verifying the identity of individuals picking up a prescription for a controlled substance. It also creates a preference for grants awarded to States by CDC for evidence-based overdose prevention activities to states that utilize prescription drug monitoring programs (PDMPs), require pharmacists to confirm the identity of individuals retrieving prescriptions for schedule II, III, or IV controlled substances via state-approved photo identification, and require entry of information about the purchase of such prescriptions into the State's PDMPs including the quantity dispensed, the name of the patient, the name of the ultimate user, the name of the individual picking up the prescription if different, and the date filled.

H. <u>H.R. 2364, the "Synthetic Opioid Awareness Act"</u>

H.R. 2364, the "Synthetic Opioid Awareness Act" was introduced by Reps. Kim (D-NJ) and Pappas (D-NH). This legislation requires several federal agencies to provide education and training related to synthetic opioids, including fentanyl and its analogues.

I. <u>H.R. 2366, the "Support, Treatment, and Overdose Prevention of Fentanyl</u> <u>Act of 2021"</u>

H.R. 2366, the "Support, Treatment, and Overdose Prevention of Fentanyl Act of 2021" or the "STOP Fentanyl Act of 2021" was introduced by Reps. Kuster and Blunt Rochester (D-DE). This legislation expands CDC drug surveillance, promotes fentanyl detection, calls for a NAM report on overdose prevention centers, establishes naloxone pricing transparency, provides good Samaritan immunity for individuals who administer opioid overdose reversal drugs, eliminates certain requirements for MAT, and provides for telehealth for substance use disorder treatment.

J. H.R. 2379, the "State Opioid Response Grant Authorization Act of 2021"

H.R. 2379, the "State Opioid Response Grant Authorization Act of 2021" was introduced by Reps. Trone and Sherrill (D-NJ). This bill would authorize the State Opioid Response Grant program and would harmonize the uses of these grants with the opioid funding provided under the 21st Century Cures Act.

K. <u>H.R. 2405, the "Streamlining Research on Controlled Substances Act of 2021"</u>

H.R. 2405, the "Streamlining Research on Controlled Substances Act of 2021" was introduced by Reps. Griffith (R-VA) and Crenshaw (R-TX). This bill amends registration requirements for researchers under the CSA. Specifically, the bill would allow for a single registration for a contiguous campus, and change criteria for when an inspection is required. The bill also adds pathway for research on substances that are newly added to schedule I of the CSA

and requires a review of the research registration process by the Departments of Justice and Health and Human Services.

IV. WITNESSES

Panel I:

Regina M. LaBelle Acting Director White House Office of National Drug Control Policy

Panel II:

Geoffrey M. Laredo Principal Santa Cruz Strategies, LLC.

Patricia L. Richman

National Sentencing Resource Counsel Federal Public and Community Defenders

Mark Vargo

Pennington County State's Attorney Legislative Committee Chairman, National District Attorneys Association

Timothy Westlake, MD, FFSMB, FACEP

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