CHAIRMAN FRANK PALLONE, JR.

MEMORANDUM

February 28, 2020

To: Subcommittee on Health Members and Staff

Fr: Committee on Energy and Commerce Staff

Re: Legislative Hearing on "Combatting an Epidemic: Legislation to Help Patients with

Substance Use Disorders"

On <u>Tuesday, March 3, 2020, at 10 a.m. in the John D. Dingell Room, 2123 of the Rayburn House Office Building,</u> the Subcommittee on Health will hold a legislative hearing entitled, "Combatting an Epidemic: Legislation to Help Patients with Substance Use Disorders."

I. STATE OF THE CURRENT DRUG EPIDEMIC

Substance use disorders (SUD) are complex but treatable diseases that impact brain function and behavior.¹ The most recent data available found that, in 2018, roughly 20.3 million people had a SUD, 3.7 million of whom received treatment.²

In 2018, drug overdose deaths decreased 4.1 percent to 67,367 total deaths. However, five states experienced higher overdose death rates in 2018 compared to 2017, and 31 states did not experience a statistically significant change.³ Additionally, the rate of drug overdose deaths caused by synthetic opioids like illicit fentanyl and fentanyl analogues continued to increase in 2018.⁴ The United States is also experiencing an increase in the rate of drug overdose deaths involving stimulants, including methamphetamine and cocaine.⁵

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 February 12, 2020).

² Substance Abuse and Mental Health Services Administration, *Key substance use and mental health indicators in the United States: Results from the 2018 National Survey on Drug Use and Health* (2019) (www.samhsa.gov/data/).

³ Centers for Disease Control. *NCHS Data Brief No. 356, Drug Overdose Deaths in the United States, 1999-2018* (January 2020) (www.cdc.gov/nchs/data/databriefs/db356-h.pdf).

⁴ *Id*.

⁵ *Id*.

The 2019 National Drug Threat Assessment highlights fentanyl and other synthetic opioids as the most lethal category of illicit substances taken in the United States. The report also warns about cocaine as a resurgent threat, including the combination of cocaine and fentanyl mixtures.

II. CONGRESSIONAL AND COMMITTEE ACTION

In 2016, Congress passed both the Comprehensive Addiction and Recovery Act and the 21st Century Cures Act.⁸ Each of these laws authorized funding to address SUD treatment, recovery, and prevention.⁹ In 2018, Congress also passed the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act).¹⁰

The SUPPORT Act authorized opioid-specific funding and expanded access to SUD treatment and resources. This legislation also increased opioid abuse and overdose prevention training; improved coordination and quality of care; and strengthened Food and Drug Administration (FDA) and law enforcement's respective abilities to combat illicit opioids.¹¹

The SUPPORT Act permanently allowed nurse practitioners and physician assistants to prescribe or dispense buprenorphine for treating opioid use disorder (OUD). ¹² Further, it expanded the type of providers who can treat OUD patients with buprenorphine to include clinical nurse specialists, certified nurse midwives, and certified registered nurse anesthetists. ¹³

The SUPPORT Act also mandated that every state Medicaid program be required to cover all forms of medication-assisted treatment (MAT) for five years and lifted the institutions for mental disease (IMD) exclusion for individuals with a SUD through September 30, 2023. The Centers for Medicare & Medicaid Services (CMS) is also required to carry out a demonstration project to provide an enhanced federal matching rate for state Medicaid expenditures related to the expansion of SUD treatment and recovery services, and a demonstration program to test quality-based incentives for the treatment of OUD in the Medicare

⁶ Drug Enforcement Administration, 2019 National Drug Threat Assessment, DEA-DCT-DIR-007-20 (December 2019).

⁷ *Id*.

⁸ Comprehensive Addiction and Recovery Act, Pub. L. No. 114-198; 21st Century Cures Act, Pub. L. No. 114-255.

⁹ *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).

¹⁰ Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act, Pub. L. No. 115-271 (2018).

¹¹ *Id*.

¹² *Id*.

¹³ *Id*.

program. The SUPPORT Act also expanded Medicare coverage of opioid treatment programs, which are authorized to prescribe methadone for the treatment of OUD.

Congress also provided additional resources to combat the current opioid epidemic through annual appropriations funding. The fiscal year (FY) 2018 Omnibus provided \$3.7 billion for this purpose, including \$1 billion to states and tribes for treatment and prevention. The FY 2019 Defense, Labor, Health and Human Services, and Education appropriations package made available additional SUD treatment funding, including \$1.5 billion through State Opioid Response grants administered by the Substance Abuse and Mental Health Services Administration (SAMHSA). The final FY 2020 funding package continued this investment at the same level while also allowing grantees to use this funding to address stimulant use. The same level while also allowing grantees to use this funding to address stimulant use.

Last December, the House passed \$10 billion of opioid funding as part of H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act. H.R. 3 includes direct funding to support opioid related activities at the Centers for Disease Control and Prevention (CDC), FDA, SAMHSA, National Institutes of Health (NIH), Health Resources and Services Administration (HRSA), and the Administration for Children and Families (ACF). 18

Further, the Committee has held multiple hearings on the opioid crisis.¹⁹ These hearings highlighted, among other things, some of the root causes of the crisis, the role of drug distributors and the Drug Enforcement Administration's (DEA) efforts to combat opioids, the

¹⁴ Consolidated Appropriations Act, 2018, Pub. L. No. 115-141.

¹⁵ Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019, Pub. L. No. 115-245.

¹⁶ Further Consolidated Appropriations Act, 2020, Pub. L. No. 116-94.

¹⁷ <u>H.R. 3</u>.

¹⁸ *Id*.

¹⁹ 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).

evolution of fentanyl abuse, and testimony from state and local addiction treatment experts and federal officials.

III. LEGISLATION

A. H.R. 1329, the "Medicaid Reentry Act"

H.R. 1329, the "Medicaid Reentry Act" was introduced by Reps. Tonko (D-NY) and Turner (R-OH). This bill would allow Medicaid payment for medical services furnished to an incarcerated individual during the 30-day period preceding the individual's release.

B. H.R. 2281, the "Easy Medication Access and Treatment for Opioid Addiction Act" or the "Easy MAT for Opioid Addiction Act"

H.R. 2281, the "Easy Medication Access and Treatment for Opioid Addiction Act" was introduced by Rep. Ruiz (D-CA). This bill would require the DEA to revise regulations within 180 days of enactment to allow a practitioner to administer up to a three-day supply of narcotic drugs to an individual for the purpose of maintenance or detoxification treatment at one time. This practice is intended to relieve potential acute withdrawal symptoms while the individual awaits arrangements for narcotic treatment. Currently, practitioners are only authorized to provide a one-day supply of such drugs.

C. H.R. 2466, the "State Opioid Response Grant Authorization Act"

H.R. 2466, the "State Opioid Response Grant Authorization Act" was introduced by Reps. Trone (D-MD), Armstrong (R-ND), Sherrill (D-NJ), and Riggleman (R-VA). This bill authorizes through FY 2024 the SAMHSA State Opioid Response Grants program.

D. H.R. 2482, the "Mainstreaming Addiction Treatment Act of 2019"

H.R. 2482, the "Mainstreaming Addiction Treatment Act of 2019" was introduced by Reps. Tonko, Lujan (D-NM), Delgado (D-NY), Budd (R-NC), Stefanik (R-NY), and Turner. 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.²⁰

E. H.R. 2922, the "Respond to the Needs in the Opioid War Act"

H.R. 2482, the "Respond to the Needs in the Opioid War Act" or the "Respond NOW Act", was introduced by Reps. Kuster (D-NH), Fitzpatrick (R-PA), Scanlon (D-PA), Pingree (D-ME), Stevens (D-MI), and Jackson Lee (D-TX). This bill would authorize \$5 billion annually for five years to support the federal public health response to the opioid epidemic through an Opioid Epidemic Response Fund that allocates money to: SAMHSA, CDC, FDA, NIH, HRSA,

²⁰ Children's Health Protection Act of 2000, Pub. L. No. 106-310.

and ACF. The bill would also increase funding for regional partnership grants and extends state and tribal support. Additionally, the bill would allow certain qualifying practitioners to continue to dispense and prescribe opioid addiction treatment beyond the October 1, 2023, time limitation in current law. Qualifying practitioners with authority expiring in 2023 include clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives.

F. H.R. 3414, the "Opioid Workforce Act of 2019"

H.R. 3414, the "Opioid Workforce Act of 2019" was introduced by Reps. Schneider (D-IL), Brooks (R-IN), Kuster, and Stefanik. This bill increases the number of residency positions eligible for graduate medical education payments under Medicare by 1,000 slots over a five-year period for hospitals that expand or establish approved residency programs in addiction medicine, addiction psychiatry, pain medicine, or a program that is a prerequisite of such programs.

G. H.R. 3878, the "Block, Report, And Suspend Suspicious Shipments Act of 2019"

H.R. 3878, the "Block, Report, And Suspend Suspicious Shipments Act of 2019" was introduced by Reps. McKinley (R-WV) and Dingell (D-MI). This bill would create additional requirements for drug manufacturers and distributors who discover a suspicious order for controlled substances. In addition to reporting the suspicious order to the DEA, a manufacturer or distributor must also exercise due diligence, decline to fill the order or series of orders, notify the DEA of each suspicious order or series or orders and the indicators that led to the belief that filling such orders would be a violation. These requirements would become effective six months following enactment.

H. H.R. 4141, the "Humane Correctional Health Care Act"

H.R. 4141, the "Humane Correctional Health Care Act" was introduced by Reps. Kuster and Norton (D-DC). This bill would repeal the Medicaid inmate exclusion, which prohibits Medicaid from paying for health care for Justice-involved individuals, and would require a report by the Government Accountability Office on issues related to inmate health care.

I. H.R. 4793, the "Budgeting for Opioid Addiction Treatment Act"

H.R. 4793, the "Budgeting for Opioid Addiction Treatment Act" was introduced by Reps. Norcross (D-NJ) and Larson (D-CT). This bill would impose a one cent per milligram fee on the sale of active opioids by the manufacturer, producer, or importer. Opioids used for purposes of treatment of opioid addiction would be excluded. The bill would also establish a rebate or discount program for hospice or cancer patients who pay any amount related to the stewardship fee. Federal revenues as a result of this fee would be distributed to states under the SAMHSA Substance Abuse Prevention and Treatment Block Grant program for certain purposes, including but not limited to new addiction treatment facilities, sober living facilities, recruiting certified mental health providers who provide substance abuse treatment in medically underserved communities, and expanding access to long-term, residential treatment programs for SUD patients. HHS is required to report to Congress no later than two years after enactment on the

impact of the program to the cost of active opioids, patient access, and improvements, if any, to substance abuse treatment efforts.

J. H.R. 4812, the "Ensuring Compliance Against Drug Diversion Act of 2019"

H.R. 4812, the "Ensuring Compliance Against Drug Diversion Act of 2019" was introduced by Rep. Griffith (R-VA). This bill terminates the controlled substance registration of any registrant if the registrant dies, ceases legal existence, discontinues business or professional practice, or surrenders registration. A registrant who ceases legal existence or discontinues business is required to notify DEA. Registrants must receive written consent from DEA in order to assign or transfer a registration. Registrants are also required to return certain documentation if a registrant's work is discontinued.

K. H.R. 4814, the "Suspicious Order Identification Act of 2019"

H.R. 4814, the "Suspicious Order Identification Act of 2019" was introduced by Reps. Matsui (D-CA) and Johnson (R-OH). This bill would require reporting on every sale, delivery, or other disposal of any controlled substance not later than 30 days after the sale, delivery, or other disposal of any controlled substance, until a real-time reporting system is established. The bill also establishes a Suspicious Order Task Force to implement a real-time suspicious order program not later than one year after enactment.

L. H.R. 4974, the "Medication Access and Training Expansion Act of 2019"

H.R. 4974, the "Medication Access and Training Expansion Act of 2019" was introduced by Reps. Trahan (D-MA), Bergman (R-MI), Carter (R-GA), Trone, Rogers (R-KY), and Kuster. 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. Practitioners can also fulfill training requirements through certain health professions schools and programs if curriculum meets standards in the bill.

M. H.R. 5572, the "Family Support Services for Addiction Act of 2020"

H.R. 5572, the "Family Support Services for Addiction Act of 2020" was introduced by Reps. Trone and Meuser (R-PA). This bill would authorize grants at SAMHSA to support family community organizations that develop, expand, and enhance evidence-informed family support services.

N. H.R. 5631, the "Solutions Not Stigmas Act of 2019"

H.R. 5631, the "Solutions Not Stigmas Act of 2019" was introduced by Reps. Kim (D-NJ) and Sherrill. This bill would direct HRSA to award grants to medical schools, nursing schools, and other health profession schools aimed at improving curricula on stigma and bias with respect to SUDs and chronic pain treatment.

IV. WITNESSES

Panel I:

ADM Brett P. Giroir, M.D.

Assistant Secretary for Health and Senior Adviser to the Secretary on Opioid Policy U. S. Department of Health and Human Services

Kimberly Brandt

Principal Deputy Administrator for Policy & Operations Centers for Medicare & Medicaid Services

Thomas W. Prevoznik

Deputy Assistant Administrator, Diversion Control Division Drug Enforcement Administration

Panel II:

Michael P. Botticelli

Executive Director, Grayken Center for Addiction Boston Medical Center

Smita Das, MD, PhD, MPH

Addiction Psychiatrist, Dual Diagnosis Clinic Clinical Assistant Professor, Psychiatry and Behavioral Sciences Stanford University School of Medicine

Patty McCarthy

Chief Executive Officer
Faces & Voices of Recovery

Robert I.L. Morrison

Executive Director/Director of Legislative Affairs
National Association of State Alcohol and Drug Abuse Directors

Margaret B. Rizzo

Executive Director JSAS HealthCare, Inc.

Shawn A. Ryan, MD, MBA

Chair, Legislative Advocacy Committee American Society of Addiction Medicine