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ONE HUNDRED FIFTEENTH CONGRESS

Congress of the United States
House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
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MEMORANDUM

February 26, 2018

To: Subcommittee on Health Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: Hearing on "Combatting the Opioid Crisis: Helping Communities Balance Enforcement and Patient Safety"

On **Wednesday, February 28th, at 1:00 p.m., in Room 2123 of the Rayburn House Office Building**, the Subcommittee will hold a legislative hearing entitled "Combatting the Opioid Crisis: Helping Communities Balance Enforcement and Patient Safety."

I. SCOPE OF THE OPIOID CRISIS

Opioid overdose death rates are now the leading cause of unintentional, non-traumatic deaths in the United States. According to the Centers for Disease Control and Prevention (CDC), overdose deaths from opioids have quadrupled in the last 20 years. Approximately 115 deaths per day occur from an opioid overdose resulting in over 42,000 deaths per year.[1] Of those deaths, 40 percent are due to a prescription opioid.[2] Every day, over 1,000 individuals are treated in emergency departments for complications due to the misuse of opioids, and

[1] Centers for Disease Control and Prevention (CDC), *Understanding the Epidemic* (Aug. 30, 2017) (https://www.cdc.gov/drugoverdose/epidemic/index.html); CDC, *Opioid Overdose* (Oct. 23, 2017) (https://www.cdc.gov/drugoverdose/index.html).

[2] *Id.*

hospitalizations have increased by over 60 percent since 2005.[3, 4] Estimated economic burdens related to prescription opioid use disorders range from $78.5 to over $500 billion per year.

The increased consumption of opioids has been driven by many factors, including increased use of prescription opioids for chronic, non-cancer pain and the increased production and importation of illegally manufactured opioids, such as heroin, fentanyl, and carfentanil.[5]

II. TREATMENT AND PREVENTION OF OPIOID USE DISORDERS

Current research indicates the most effective treatment for opioid use disorders (OUDs) and opioid addiction is medication assisted treatment (MAT), a combination of medications, including naltrexone, methadone or buprenorphine, and behavioral therapy (e.g., counseling and supportive services).[6] MAT has been proven effective in helping patients recover from addiction and reducing overdose risk. Despite the existence of evidence-based treatments, numerous barriers can impede or preclude substance abuse treatment for OUDs, including lack of health coverage, provider shortages, and health system failures. In 2016, approximately 19.9 million people aged 18 years or older needed substance abuse treatment, but only around 11 percent (2.1 million) received specialized substance abuse treatment.[7]

III. CONGRESSIONAL ACTION

The Affordable Care Act (ACA) expanded access to affordable care and treatment for individuals fighting substance abuse disorders through subsidies on the state and federal healthcare exchanges, allowing children to remain on their parents' health insurance until the age of 26, and expanded Medicaid.[8] The ACA also improved coverage for treatment of substance

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[3] Agency for Healthcare Research and Quality, Healthcare Cost and Utilization Project (HCUP), *Opioid-Related Inpatient Stays and Emergency Department Visits by State, 2009-2014* (Jan. 2017) (https://www.hcup-us.ahrq.gov/reports/statbriefs/sb219-Opioid-Hospital-Stays-ED-Visits-by-State.jsp).

[4] National Institutes of Health, National Institute on Drug Abuse, *Overdose Death Rates* (Sept. 2017) (https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates).

[5] National Academies of Sciences, Engineering, and Medicine, *Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use* (2017) (https://www.nap.edu/read/24781/chapter/1).

[6] National Institutes of Health, National Institute on Drug Abuse, *Effective Treatments for Opioid Addiction* (Nov. 2016) (https://www.drugabuse.gov/publications/effective-treatments-opioid-addiction/effective-treatments-opioid-addiction).

[7] Substance Abuse and Mental Health Services Administration, *Receipt of Services for Substance Use and Mental Health Issues among Adults: Results from the 2016 National Survey on Drug Use and Health* (Sept. 2017) (https://www.samhsa.gov/data/sites/default/files/NSDUH-DR-FFR2-2016/NSDUH-DR-FFR2-2016.htm).

[8] Department of Health and Human Services, Assistant Secretary for Planning and Evaluation, *Health Insurance Coverage and the Affordable Care Act* (Mar. 16, 2015).

use disorders by requiring all non-grandfathered plans in individual and small group markets to offer mental health and substance abuse disorder benefits through the Essential Health Benefits package.

Building upon health care coverage provided under the ACA, Congress stepped further towards addressing the national opioid crisis in 2016, by passing both the Comprehensive Addiction and Recovery Act (CARA) and the 21st Century Cures Act (Cures Act). CARA authorized several grant programs to help prevent overdose, expand access to treatment for OUDs, and help individuals recover. While some of these grant programs have received funding through the appropriations process, many of these important programs, unfortunately, have yet to receive funding. Those programs awaiting funding include *Grants for Reducing Overdose Deaths* intended to increase adoption of co-prescribing practices to individuals at high risk for overdose and their families. In addition, CARA extended the waiver authority allows providers to prescribe buprenorphine to individuals with opioid use disorders to nurse practitioners and physician assistants. CARA also took steps to reduce the amounts of opioids that permitting pharmacists dispense to partially fill Schedule II controlled substance prescriptions at the requests of patients or health care providers.

The Cures Act expanded Congressional efforts to combat the crisis by providing mandatory funding for grants to states. The *State Targeted Response to the Opioid Crisis Grants*, is administered by the Substance Abuse and Mental Health Services Administration (SAMHSA) and provided $1 billion over two years to states to develop prevention, treatment, and recovery activities for OUD. On February 9, 2018, Congress passed a bipartisan budget deal that included $6 billion of additional funding over two years for the opioid epidemic. That funding will be allocated through the appropriations process.

IV. DEA AUTHORITY AND ACTIONS OVER OPIOIDS

The DEA is responsible for enforcing and administering the Controlled Substances Act (CSA). The CSA requires individuals who handle controlled substances, such as drug manufacturers, wholesale distributors, doctors, hospitals, pharmacies, and scientific researchers to register with the DEA. Registrants are required to maintain records of their controlled substance inventories and transactions, as well as establish adequate security controls to minimize theft or diversion.

Substances are scheduled by DEA in consultation with the Food and Drug Administration (FDA), the National Institute on Drug Abuse, and Department of Health and Human Services (HHS). After conducting a medical and scientific evaluation, FDA makes recommendations to DEA as to whether substances should be controlled, and into what schedule the substance should be placed. Controlled substances are placed on one of five schedules under the CSA. They are scheduled based on whether they have an accepted medical use in the United States; their actual or relative potential for abuse; known scientific evidence of pharmacological effects; current scientific knowledge of the substances; psychological or physiological dependence liability; risk to public health; and whether the substance is an immediate precursor of an already-scheduled substance.

Schedule I substances have a high potential for abuse and may cause psychological or physical dependence. These substances are distinguished from the other schedules in that they have no currently accepted medical use in the U.S.; whereas, Schedules II through V substances all have a currently accepted medical use in treatment in the United States. Examples of Schedule I substances include heroin, Lysergic acid diethylamide (LSD), marijuana, ecstasy, methaqualone, and peyote. Schedule II substances have the same high potential for abuse as those in Schedule I and may also lead to severe psychological or physical dependence. Narcotics, including prescription opioids, generally fall within the Schedule II category. Schedules III through V include substances with a moderate to lower potential for abuse.

V. H.R. 2851, STOP THE IMPORTATION AND TRAFFICKING OF SYNTHETIC ANALOGUES (SITSA) ACT

Introduced by Rep. Katko (R-NY), the SITSA Act would provide DEA with additional authority over controlled substance analogues. Among other things, the legislation would add 13 chemical analogues to a newly established Schedule A. The new Schedule A, which is being established for broadly defined controlled substance analogues, would be added to the current five schedules of controlled substances. Schedule A substances would include drugs that have chemical structures similar to substances in one of the five other schedules, have a predicted stimulant, depressant, or hallucinogenic effect on the central nervous system, and are not otherwise included in any other schedule. The SITSA Act would also extend DEA's temporary scheduling authority up to five years and eliminate FDA's role in this process. The legislation would also strengthen penalties for individuals found in possession, manufacturing, importing, or distributing a Schedule A controlled substance.

VI. H.R. 5041, SAFE DISPOSAL OF UNUSED MEDICATION ACT

Introduced by Reps. Walberg (R-MI), Dingell (D-MI), and Hudson (R-NC), H.R. 5041 aims to reduce the number of unused controlled substances at risk of diversion or misuse by allowing hospice workers to safely dispose of these medications in patients' homes. This bill amends the CSA to authorize hospice program employees to manage and properly dispose of controlled substances of deceased hospice patients.

VII. DICUSSION DRAFT OF H.R. ___, THE ENSURING PATIENT ACCESS TO SUBSTANCE USE DISORDER TREATMENTS ACT OF 2018

The term "dispense" is defined in the CSA as the delivery of a controlled substance to an ultimate user or research subject by a practitioner, including its prescription, packaging, labelling or compounding necessary in preparing the substance for delivery.[9] The Drug Addiction Treatment Act of 2000 enables buprenorphine to be prescribed or dispensed in a physician's office. Since the enactment of CSA, long-acting formulations of buprenorphine designed to be injected or implanted by a health care practitioner have been developed. Currently, the CSA does not contemplate the ability of a pharmacy to directly dispense a controlled substance administered by injection, implantation, or intrathecal pump to a practitioner. Therefore, health

[9] 21 U.S.C. § 802 (10) (2016).

care practitioners must purchase the medications through a "buy and bill system" and cover the cost of the treatment in advance of any reimbursement.

The Ensuring Patient Access to Substance Use Disorder Treatments Act of 2018, authored by Reps. Costello (R-PA) and Nolan (D-MN) would allow controlled substances that are intended to be administered for purposes of maintenance or detoxification treatment by injection, implantation, or through the use of an intrathecal pump to be dispensed by a pharmacy to a health care practitioner.

VIII. DICUSSION DRAFT OF H.R. ___, THE SPECIAL REGISTRATION FOR TELEMEDICINE CLARIFICATION ACT OF 2018

The "practice of telemedicine" is defined under the Ryan Haight Online Pharmacy Consumer Protection Act as the practice of medicine by a practitioner who is at a location remote from the patient and is communicating with the patient or health professional treating the patient via a telecommunication system, provided that the patient "is being treated by, and [is] physically located in, a hospital or clinic" or "while the patient is being treated by, and in the physical presence of, a practitioner."[10] While DEA may establish a special registration process for practitioners to use telemedicine to prescribe controlled substances, DEA has not initiated a rule-making to date to do so.

The Special Registration for Telemedicine Clarification Act of 2018, authored by Reps. Carter (R-GA) and Bustos (D-IL) would direct the Attorney General to promulgate interim final regulations establishing a special registration process for engaging in the practice of telemedicine within 30 days after the bill's enactment.

IX. DISCUSSION DRAFT OF H.R. ___, THE IMPROVING ACCESS TO REMOTE BEHAVIORAL HEALTH TREATMENT ACT OF 2018

The CSA allows for the issuance of a prescription for a controlled substance without a prior, in-person patient medical evaluation in limited circumstances, known as telemedicine exceptions. The main way in which such telemedicine can be permitted or authorized is where the patient being treated is located in a DEA-registered hospital or clinic that a state has licensed. Many community mental health centers and addiction treatment facilities, however, are unable to practice telemedicine or to prescribe a controlled substance in connection with such treatment because unlike those licensed centers and facilities, they have not been authorized or recognized by a county, municipality, or state licensing authority.

The Improving Access to Remote Behavioral Health Treatment Act of 2018, authored by Reps. Harper (R-MS) and Matsui (D-CA), would enable community mental health centers and addiction treatment facilities to register under the CSA allowing them to use telemedicine. DEA is required to begin registering such facilities within 120 days of enactment.

[10] Controlled Substances Act, Sec. 102(54), Pub. L. 91-513 (1970).

X. DICUSSION DRAFT OF H.R. ___, THE TABLETING AND ENCAPSULATING MACHINE REGULATION ACT OF 2018

In recent testimony before the Committee, DEA noted that some traffickers of fentanyl and fentanyl analogues have had industrial pill presses shipped into the US directly from China and have been operating pill press mills domestically.[11] DEA has also acknowledged that industrial pill press machines are widely available on the open internet and that some vendors mislabel the equipment or ship it disassembled in order to evade regulatory oversight.[12] Under current law, importers and exporters are required to notify DEA of the shipment of tablet presses and encapsulating machines.

The Tableting and Encapsulating Machine Regulation Act of 2018, authored by Rep. Kustoff (R-TN), would define the terms 'tableting machine' and 'encapsulating machine' in statute. In addition, it would propose to schedule such machines in a schedule to be determined, which would require such machines to be subject to the same registration, record-keeping, reporting, and penalties associated with those controlled substances.

XI. H.R. 2063, OPIOID PREVENTING ABUSE THROUGH CONTINUING EDUCATION (PACE) ACT OF 2017

Introduced by Rep. Schneider (D-IL), this bill amends the CSA to require practitioners to complete a 12-hour training requirement, as a condition of obtaining or renewing a registration to prescribe or dispense opioids for the treatment of pain or pain management. The continuing medical education training should occur at least once during each three-year period. Training would focus on pain management treatment guidelines and best practices, early detection of opioid addiction, and the treatment and management of opioid-dependent patients. The training could be accomplished through classroom situations, seminars at professional society meetings, or electronic communications.

XII. H.R. 4275, EMPOWERING PHARMACISTS IN THE FIGHT AGAINST OPIOID ABUSE ACT

Introduced by Reps. DeSaulnier (D-CA) and Carter (R-GA), H.R. 4275 would help pharmacists detect fraudulent prescriptions by requiring the DEA to develop and disseminate training programs and materials to educate pharmacists, providers, and patients on signs of prescription-controlled substance misuse and abuse. H.R. 4275 would give pharmacists a greater

[11] House Committee on Energy and Commerce, *Hearing on Fentanyl: The Next Wave of the Opioid* Crisis, 115th Cong., Testimony of Louis J. Milione, Assistant Administrator, Drug Enforcement Administration (Mar. 21, 2017) (http://docs.house.gov/meetings/IF/IF02/20170321/105739/HHRG-115-IF02-Wstate-MilioneL-20170321.pdf).

[12] Letter from Stephen E. Boyd, Assistant Attorney General, U.S. Department of Justice to Congressman Tim Murphy (Oct. 24, 2017) (http://docs.house.gov/meetings/IF/IF02/20170321/105739/HHRG-115-IF02-Wstate-MilioneL-20170321-SD004.pdf).

understanding and ability to decline filling controlled substances when they suspect controlled substance prescriptions are fraudulent, forged, or appear to be subject to abuse or diversion.

XIII. WITNESSES

Panel I:

Susan A. Gibson
Deputy Assistant Attorney, Diversion Control Division
Drug Enforcement Administration

Panel II:

Frank L. Fowler
Chief of Police
Syracuse Police Department

Patrick M. Beardsley, Ph.D.
Professor, Department of Pharmacology and Toxicology
Virginia Commonwealth University

John Mulder, M.D., F.A.A.H.P.M., H.M.D.C.
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