

ONE HUNDRED FOURTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
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MEMORANDUM

October 6, 2015

To: Subcommittee on Health Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: Hearing on “Examining Legislative Proposals to Combat our Nation’s Drug Abuse Crisis”

The Subcommittee on Health will hold a legislative hearing titled, “Examining Legislative Proposals to Combat our Nation’s Drug Abuse Crisis,” on Thursday, October 8, 2015, at 10:15 a.m. in 2322 Rayburn House Office Building. The hearing will address seven specific pieces of public health legislation: *Recovery Enhancement for Addiction Treatment Act* (H.R. 2536); *Heroin and Prescription Drug Abuse Prevention, Education, and Enforcement Act of 2015* (H.R. 2805); *Opioid Addiction Treatment Modernization Act* (H.R. 2872); *Medical Controlled Substances Transportation Act of 2015* (H.R. 3014); *Synthetic Drug Control Act of 2015* (H.R. 3537); *Improving Treatment for Pregnant and Postpartum Women Act of 2015* (H.R. ____); and *Co-Prescribing to Reduce Overdoses Act of 2015* (H.R. 3680). In addition to the witnesses listed here, other witnesses may be invited to testify at a later date.

I. BACKGROUND

A. Substance Abuse Crisis

The Centers for Disease Control and Prevention (CDC) has called prescription drug abuse in the United States an epidemic and found drug overdose to be the leading cause of injury death in the United States in 2013.¹ Between 1999 and 2010, the death rate from prescription opioids more than quadrupled, and in 2013 alone, prescription opioids were involved in 16,235

¹ Office of National Drug Control Policy, *Prescription Drug Abuse* (online at www.whitehouse.gov/ondcp/prescription-drug-abuse).

overdose deaths.² Nearly two million Americans, aged 12 or older, either abused or were dependent on opioids in 2013.³ The rate of heroin overdoses has also increased dramatically in recent years. In 2010, approximately 3,000 drug-poisoning deaths were connected to heroin. In 2013, that number jumped to a total of 8,000 overdose deaths.⁴

Increased opioid consumption over the past few decades has been driven largely by greater patient use for chronic non-cancer pain. The Substance Abuse and Mental Health Services Administration (SAMHSA) found that between 2000 and 2010, there was a four-fold increase in the prescribing of opioids for treating pain.⁵ The number of prescriptions for opioids (like hydrocodone and oxycodone) escalated from about 76 million in 1991, to about 207 million in 2013.⁶ The United States has become the biggest consumer globally, accounting for almost 100 percent of the world total for hydrocodone and about 81 percent for oxycodone.⁷ Notwithstanding these increases, there is limited scientific evidence supporting the safety and efficacy of opioids for chronic non-cancer pain.⁸

Greater availability of opioid drugs and their misuse has had adverse consequences and effects. For example, the estimated number of emergency department visits involving the nonmedical use of prescription opioids increased from 144,600 in 2004, to 305,900 in 2008.⁹ Additionally, treatment admissions for primary abuse of opiates (other than heroin) jumped from one percent of all admissions in 1997 to five percent in 2007.¹⁰ Further, according to

² Centers for Disease Control and Prevention (CDC), *Prescription Drug Overdose Data*, (online at <http://www.cdc.gov/drugoverdose/data/index.html>).

³ CDC, *Prescription Drug Overdose Data* (online at www.cdc.gov/drugoverdose/data/index.html).

⁴ National Institute on Drug Abuse, *Overdose Death Rates* (online at www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates).

⁵ Substance Abuse and Mental Health Services Administration (SAMHSA), *SAMHSA Opioid Overdose Prevention Toolkit* (2014).

⁶ Senate Caucus on International Narcotics Control, Testimony of Nora D. Volkow, *America's Addiction to Opioids: Heroin and Prescription Drug Abuse*, 113th Cong. (May 14, 2014).

⁷ *Id.*

⁸ Andrew Kolodny et. al., *The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction*, Annual Review of Public Health (Jan. 12, 2015); Gary M. Franklin, *Opioids for Chronic Noncancer Pain: A Position Paper of the American Academy of Neurology*, Neurology (Sept. 30, 2014).

⁹ Senate Caucus on International Narcotics Control, Testimony of Nora D. Volkow, *America's Addiction to Opioids: Heroin and Prescription Drug Abuse*, 113th Cong. (May 14, 2014).

¹⁰ Senate Caucus on International Narcotics Control, Testimony of Nora D. Volkow, *America's Addiction to Opioids: Heroin and Prescription Drug Abuse*, 113th Cong. (May 14, 2014).

the CDC, there was a 150 percent increase in reports of hepatitis C between 2010 and 2013, which is believed to be attributable to injectable drug use.

The opioid epidemic has also been linked to a recent outbreak of HIV in Indiana. The CDC has issued an advisory to health departments to alert them of the possibility of HIV outbreaks and to provide guidance to assist in the identification and prevention of such outbreaks.¹¹

B. Treatment for Opioid Addiction

Current research suggests that the most effective treatment to combat opioid addiction is a combination of medication-assisted treatment (MAT) and behavioral treatment (e.g. counseling and other supportive services).¹²

MATs have proven effective in helping patients recover from addiction and reduce their risk of overdose. For instance, a study of heroin overdose deaths in Baltimore between 1995 and 2009 found an association between the availability of methadone and buprenorphine and an approximate 50 percent decrease in the number of fatal overdoses. In addition, MATs have been found to increase patients' retention in treatment, improve social functioning, and reduce the risks of infectious-disease transmission and of engagement in criminal activities.¹³ Nevertheless, MATs were available in only nine percent of all substance abuse treatment facilities nationwide in 2013.¹⁴

There are three Food and Drug Administration (FDA)-approved medications for the treatment of opioid addiction. These include "opioid agonist" medications, which suppress withdrawal symptoms and relieve cravings by acting on the same targets in the brain as heroin and morphine, and "opioid antagonist" medications, which block the effects of heroin or other opioids on the receptor sites.¹⁵

¹¹ CDC, *Outbreak of Recent HIV and HCV Infections Among Persons Who Inject Drugs* (Apr. 24, 2015) (online at emergency.cdc.gov/han/han00377.asp).

¹² National Institute on Drug Abuse, National Institutes of Health (NIH), *Treating Prescription Drug Addiction* (Nov. 2014) (online at <http://www.drugabuse.gov/publications/research-reports/prescription-drugs/treating-prescription-drug-addiction>).

¹³ Nora D. Volkow et. al., *Medication-Assisted Therapies – Tackling the Opioid Overdose Epidemic*, *New England Journal of Medicine* (May 29, 2014).

¹⁴ Substance Abuse and Mental Health Services Administration, *National Survey of Substance Abuse Treatment Services: 2013* (Sept. 2014).

¹⁵ National Institute on Drug Abuse, National Institutes of Health, *Treatment Approaches for Drug Addiction* (Sept. 2009) (online at <http://www.drugabuse.gov/publications/drugfacts/treatment-approaches-drug-addiction>).

Methadone, approved nearly 50 years ago, is a synthetic opioid agonist medication. It is a DEA Schedule II drug (see section C below for a discussion of scheduling). Methadone is administered orally on a daily basis and is available in all but three states through federally approved opioid treatment programs (OTPs). OTPs must be accredited and certified by SAMHSA and must provide treatment in accordance with federal opioid treatment standards.¹⁶

Studies show that there was a marked decrease in illicit opioid use in the first several decades after the introduction of methadone maintenance treatment. Effective treatment of opioid dependence was also found to substantially reduce the rates of criminal activity and reduce transmission of infectious diseases.¹⁷

Extensive research on the effectiveness of methadone maintenance, covering more recent time periods, shows such maintenance produces the best outcomes when it is combined with other psychiatric, psychological, and social services.¹⁸ In the absence of additional supportive services such as counseling, there is a higher risk that individuals will continue using alcohol, marijuana, or even heroin while taking methadone. Studies show that methadone is most effective when used for 12 months at a minimum, and some individuals continue to benefit from methadone maintenance treatment for a period of years.¹⁹

Buprenorphine is also a synthetic opioid and is a partial antagonist medication. It is a DEA Schedule III drug. Buprenorphine may be prescribed by individual practitioners, pursuant to a DEA waiver. To qualify for a waiver, physicians must meet certain educational criteria (such as a subspecialty board certification in addiction psychiatry; or, alternatively, not less than eight hours of training in the treatment and management of opioid-addicted patients).²⁰ Physicians can treat a maximum of 100 patients with buprenorphine.

Buprenorphine is available in two forms: (1) a pure form of the drug, and (2) a more commonly prescribed formulation called Suboxone that combines buprenorphine with naloxone. The addition of naloxone produces severe withdrawal effects if an individual attempts to inject suboxone, thereby reducing the likelihood the medication will be abused or diverted.²¹ Buprenorphine carries a “ceiling effect,” meaning that the effects of the medication plateau at a certain point regardless of whether the dose is increased. This contributes to the

¹⁶ 42 C.F.R. Part 8.

¹⁷ National Institutes of Health Consensus Development Program, *Effective Medical Treatment of Opiate Addiction* (Nov. 17-19, 1997).

¹⁸ CDC, *Methadone Maintenance Treatment* (online at www.cdc.gov/idu/facts/Methadone.htm).

¹⁹ *Id.*

²⁰ 21 U.S.C. § 823(g)(2).

²¹ SAMHSA, *About Buprenorphine Therapy* (online at buprenorphine.samhsa.gov/about.html).

lower risk of abuse or side effects.²² For patients with a high level of physical dependence on opioids, however, buprenorphine may not be as effective as methadone.

Naltrexone is a synthetic opioid antagonist. It is not a narcotic and is not a scheduled substance. Naltrexone is available as a generic oral medication and, in the last several years, as a branded injectable medication. The injectable version, Vivitrol, has largely taken over in use because it only has to be taken once a month. The oral version must be taken daily. In either case, it can only be taken after a patient has been off opioids for about a week, or it causes extreme withdrawal symptoms. Vivitrol has been particularly successful when used in prison settings, with inmates who have already been off drugs due to their incarceration.

C. Overdose Reversal Medication

Naloxone is an opioid antagonist used to counteract the effect of an opioid overdose. Considered a “rescue drug,” rather than a treatment drug, naloxone works by reversing opioid depression of the central nervous and respiratory systems. It is a non-addictive, prescription medication often administered by emergency response personnel, and it has proven effective in reducing drug overdoses. As of December 2014, 27 states and the District of Columbia have passed laws to expand access to and the use of naloxone by non-specialists.²³

D. Control Substances Act, Formal Scheduling, and Drug Addiction Treatment Act of 2000

i. Controlled Substances Act

The Controlled Substances Act (CSA), enacted as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (P.L. 91-513), regulates the manufacture, possession, use, importation, and distribution of controlled substances. The Drug Enforcement Agency (DEA) administers and enforces the CSA.

Controlled substances are drugs or other substances (other than alcohol or tobacco) with a potential for abuse, e.g., because of how they make the user feel. They also may lead to psychological or physical dependence.²⁴ Examples are narcotics, stimulants, depressants, hallucinogens, and anabolic steroids.

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

²²*Id.*

²³ The Network for Public Health Law, *Legal Interventions to Reduce Overdose Mortality: Naloxone Access and Overdose Good Samaritan Laws* (2015) (online at <https://www.networkforphl.org/asset/qz5pvn/network-naloxone-10-4.pdf>).

²⁴ 21 USC § 802(6) (online at <http://www.deadiversion.usdoj.gov/21cfr/21usc/802.htm>); 21 USC 812 (online at <http://www.deadiversion.usdoj.gov/21cfr/21usc/812.htm>).

substance inventories and transactions, as well as establish adequate security controls to minimize theft or diversion. There are criminal penalties, including, for some uses, mandatory minimum prison sentences associated with the unlawful manufacture, possession, and distribution of controlled substances.

ii. Formal Scheduling

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.

The process for adding, removing or changing the schedule of a substance can be initiated by the DEA, the U.S. Department of Health and Human Services (HHS), or by petition by any interested person. Following receipt of a petition, DEA will conduct an investigation of the substance. However, DEA may also initiate an investigation at any time in response to information received from law enforcement, state and local regulatory agencies, or other sources of information. After DEA's initial investigation, the DEA Administrator requests a scientific and medical evaluation and recommendation as to whether the substance should be controlled or removed from control from the Assistant Secretary of Health at HHS. Working with the FDA and the National Institute on Drug Abuse (NIDA), the Assistant Secretary of Health compiles the information, evaluations, and recommendations and submits to DEA the medical and scientific evaluation and recommendation as to whether the substance should be controlled, and into what schedule the substance should be placed. Congress may also add a substance to a schedule through legislation.

Schedule I substances have a high potential for abuse. They are distinguished from the other schedules by having no currently accepted medical use in the U.S.; whereas, Schedules II – V substances all have a currently accepted medical use in treatment in the U.S. There is also no requirement that Schedule I substances have a potential for psychological or physical dependence. 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. Additionally, their use may lead to severe psychological or physical dependence. Examples of Schedule II substances include: Vicodin, cocaine, methamphetamine, methadone, hydromorphone, oxycodone, fentanyl, Adderall, and Ritalin.

Schedule III substances have a moderate or low potential for physical dependence or a high potential for psychological dependence. Examples of Schedule III substances include: Tylenol with codeine, anabolic steroids, and testosterone.

Schedule IV drugs have a low potential for abuse and low risk of dependence. Examples of Schedule IV drugs include: Xanax, Darvocet, Valium, Ativan, Ambien, and Tramadol.

Schedule V substances have a lower potential for abuse than Schedule IV substances and consist of preparations containing limited quantities of certain narcotics. Schedule V substances are generally used for antidiarrheal, antitussive, and analgesic purposes.

iii. Drug Addiction Treatment Act (DATA) of 2000

The Drug Addiction Treatment Act of 2000 or DATA 2000, which passed as section 3502 of the Children's Health Act of 2000 (P.L. 106-310), amended the Controlled Substances Act to allow physicians to treat individuals with opiate dependence with Schedule III, IV, or V drugs or combinations of such medications for maintenance or detoxification treatment in their offices. The DEA and Substance Abuse and Mental Health Services Administration (SAMHSA) administer the DATA 2000 waiver.

DATA 2000 waives the statutory requirement for separate DEA registration as an Opioid Treatment Program (OTP) if both the physician and the medication meet specific criteria. The purpose of the DATA 2000 law was to expand access to Schedule III, IV, or V opioid medications for the maintenance or detoxification treatment of opiate-dependent patients.²⁵ Prior to the passage of DATA 2000, opiate dependence treatment was largely limited to methadone, which was dispensed in limited quantities and from a very limited number of OTPs throughout the U.S.²⁶

To qualify for a waiver and become a DATA-waived physician (DWP), a physician must: notify the Secretary of HHS of his or her intent to dispense Schedule III, IV, or V or combinations of such drugs to patients for opiate maintenance or detoxification treatment; certify to the Secretary that he or she is a qualifying physician; and certify that he or she will comply with the limit or cap on the number of patients that may be treated.

A qualifying physician is defined as a physician who is licensed under state law and meets at least one of the conditions listed in the statute. These conditions include: holding a subspecialty board certification in addiction psychiatry from the American Board of Medical Specialties; holding an addiction certification from the American Society of Addiction Medicine; holding a subspecialty board certification in addiction medicine from the American Osteopathic Association; having obtained at least eight hours of training with respect to the treatment and management of opiate-dependent patients; having been an investigator in a clinical trial leading to the FDA approval of a schedule III, IV, or V drug for maintenance or detoxification treatment of opiate-dependent patients; having such training or experience that the state medical licensing

²⁵U.S. Food and Drug Administration (FDA), *Subutex and Suboxone Approved to Treat Opiate Dependence*, (Oct. 8, 2002) (online at www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm191521.htm).

²⁶ *Id.*

board or the Secretary considers to demonstrate the ability of the physician to treat and manage opiate-dependent patients.²⁷

Currently under the DATA 2000, DWPs may treat up to 30 patients during the first year and thereafter may increase to treating up to 100 patients. At this time, nurse practitioners and physician assistants cannot qualify for a DATA waiver to treat opiate-dependent patients with Schedule III, IV, or V maintenance or detoxification medications.²⁸

A medication is eligible to be prescribed under a DATA waiver if it is a schedule III, IV, or V medication or combination of such drug, is FDA-approved for use in detoxification or maintenance treatment, and has not been the subject of an adverse determination. An adverse determination is a determination made by the Secretary of Health and Human Services (the Secretary, or HHS), in consultation with the Attorney General (AG) that a provider needs to meet more qualifications to provide treatment with the drug or the drug requires standards for the amount that may be provided for unsupervised use. At this time, buprenorphine, which was approved by the FDA in 2002,²⁹ is the only medication that meets the DATA 2000 waiver requirements.

E. Federal Response to Substance Abuse

HHS is leading the federal response to the opioid abuse epidemic. In March 2015, the Secretary announced an initiative to combat the opioid abuse epidemic. This new initiative focuses broadly on three areas: 1) opioid prescribing practices; 2) the expanded use of naloxone to treat opioid overdoses; and 3) expanded use of MAT to treat opioid abuse disorders.³⁰

More recently, the Secretary also announced on September 17, 2015, that HHS will be revising the current caps on the number of patients that can be treated by physicians certified to prescribe buprenorphine for MAT. Additional details on HHS's new initiative as well as other federal programs to address the opioid abuse epidemic are provided below.

SAMHSA: The Secretary's opioid abuse initiative proposes increased SAMHSA funding for the expanded use of naloxone. Currently, states may use some of their substance abuse block grant funds to purchase naloxone and provide training on its use. The President's fiscal year (FY) 2016 budget proposes \$12 million in SAMHSA grants to states to purchase naloxone, equip first responders in high-risk communities, and provide education.

The Secretary's opioid abuse initiative also proposes expanding SAMHSA support for MATs. In FY 2015, SAMHSA will provide \$12 million to grantees in 39 states through a

²⁷ 21 U.S.C. § 823(g)(2)(G)

²⁸ 21 U.S.C. § 823(g)(2)(B)

²⁹ *Id.*

³⁰ Department of Health and Human Services (HHS), Assistant Secretary for Planning and Evaluation, *Opioid Abuse in the U.S. and HHS Actions to Address Opioid-Drug Related Overdoses and Deaths* (Mar. 26, 2015).

demonstration program to expand treatment services for opioid dependence. Grantees will provide accessible, effective, comprehensive, coordinated and evidence-based medication-assisted treatment and recovery support services including the use of methadone, buprenorphine, and naltrexone. The FY 2016 President's Budget proposes an additional \$13 million expansion of this program to increase the number of states that would receive targeted funding.

CDC: The Secretary's opioid abuse initiative also proposes increasing CDC funding to address the epidemic. CDC received \$20 million in FY 2015 and has launched the Prescription Drug Overdose (PDO) Prevention for States program, which provides grants to states to expand state-level interventions focused on improving opioid prescribing practices and enhancing state PDMPs.³¹ The President's FY 2016 budget requests an additional increase of \$48 million to expand the PDO Prevention program to all 50 states, as well as fund monitoring and evaluation efforts.³²

To improve clinical decision-making and reduce inappropriate prescribing, the CDC is also developing guidelines for opioid prescribing for chronic pain.³³ The guidelines are expected to address clinical practices involving: 1) when to initiate or continue opioids for chronic pain; 2) proper dosing, duration, and follow-up; and 3) practices to reduce the harms of opioid use, such as the use of urine drug testing, evaluation of risk factors for abuse, review of PDMP data, and considerations for concurrent use of opioids and benzodiazepines.³⁴

The Health Resources and Services Administration (HRSA): HRSA has provided \$100 million through a Funding Opportunity Announcement to 300 Community Health Centers to expand services for those with substance abuse disorders, including medication-assisted treatment.³⁵ In addition, through the Office of Rural Health Policy, HRSA will make available approximately \$1.8 million in grant awards to rural communities to purchase naloxone, train health care professions and emergency responders in the use of naloxone, and facilitate the referral of people with opioid use disorders to treatment.³⁶

³¹ HHS, Assistant Secretary for Planning and Evaluation, *Opioid Abuse in the U.S. and HHS Actions to Address Opioid-Drug Related Overdoses and Deaths* (Mar. 26, 2015).

³² HHS, CDC, *FY 2016 Justification of Estimates for Appropriation Committees* (online at www.cdc.gov/fmo/topic/Budget%20Information/appropriations_budget_form_pdf/FY2016_CD_C_CJ_FINAL.pdf).

³³ *Id.*

³⁴ CDC, *Draft CDC Guidelines for Prescribing Opioids for Chronic Pain* (online at www.cdc.gov/drugoverdose/prescribing/guideline.html).

³⁵ HHS, *HHS Increases Access to Substance Use Disorder Treatment* (July 25, 2015) (online at <http://www.hhs.gov/news/press/2015pres/07/20150725a.html>).

³⁶ HHS, *Grants Aim to Reduce Opioid Overdoses in Rural Communities* (Sept. 17, 2015) (online at <http://www.hhs.gov/news/press/2015pres/09/20150917b.html>).

The Office of National Drug Control Policy (ONDCP): ONDCP coordinates drug-control activities and related funding across the federal government. In 2011, ONDCP developed the nation’s first Prescription Drug Abuse Prevention Action Plan, which called for action in four areas: education for the general population and medical practitioners; monitoring through state prescription drug monitoring programs; proper medication disposal; and efforts to eliminate improper prescribing, illicit diversion, and unscrupulous pain management clinics.³⁷

The National Institute on Drug Abuse (NIDA): NIDA is currently supporting 90 projects related to MAT, including research into the development of new pharmacological therapies to treat opioid use disorders, incorporating MAT into comprehensive addiction treatment services, utilizing MAT within the criminal justice system and its impact on retention in treatment and recidivism, and recovery outcomes for extended-release naltrexone versus buprenorphine for opioid treatment.³⁸ NIDA is also conducting research into the efficacy of prescribing take-home naloxone for individuals at a high risk of opioid overdose.

The Centers for Medicare & Medicaid Services (CMS): CMS has taken steps to combat prescription drug abuse by strengthening oversight of drug utilization in the Medicare Part D program. The agency has implemented the Medicare Part D Overutilization Monitoring System, in which CMS analyzes prescription drug data and provides quarterly reports to plan sponsors on beneficiaries with potential opioid overuse issues; plan sponsors are required to respond within 30 days. It has also adopted an HHS-OIG recommendation to require that all prescribers of Part D drugs enroll in Medicare. Finally, it has strengthened the agency’s authorities to remove providers from Medicare for abusive prescribing practices and patterns, or based upon a suspension or revocation of the prescriber’s DEA certificate or state authority to prescribe drugs.³⁹

FDA: FDA has taken a number of actions to address the prescription opioid abuse epidemic, including: 1) encouraging the development of medications to treat opioid abuse, such as buprenorphine and naloxone; 2) encouraging development of abuse-deterrent formulations of opioid medications; and 3) requiring manufacturers to offer education to physicians on the proper prescribing and safe use of opioid medications through the risk evaluation and mitigation strategy (REMS) requirement for extended-release and long-acting opioids.⁴⁰

II. LEGISLATION

A. The Recovery Enhancement for Addiction Treatment Act (H.R. 2536)

³⁷ Office of National Drug Control Policy, *Epidemic: Responding to America’s Prescription Drug Abuse Crisis* (Apr. 19, 2011) (online at www.whitehouse.gov/sites/default/files/ondcp/issues-content/prescription-drugs/rx_abuse_plan.pdf).

i. Overview

The Recovery Enhancement for Addiction Treatment Act or TREAT Act was introduced by Representatives Higgins (D-NY), Hanna (R-NY), Tonko (D-NY), and Katko (R-NY) on May 21, 2015. The purpose of the legislation is to expand access to medication-assisted therapy, specifically buprenorphine and any future medication that qualify under the DATA 2000 requirements.

The TREAT Act would amend the CSA to increase the patient limits under the DATA waiver and increase the type of providers who qualify. It would allow physicians, nurse practitioners, and physician assistants to treat up to 100 patients in the first year and subsequently treat an unlimited number of patients. The legislation would also require the Government Accountability Office (GAO) to evaluate the effectiveness of the amendments to the CSA made by H.R. 2356 at two years after the first physician filed notified the Secretary of their intent to treat an unlimited number of patients with buprenorphine.

The qualifications that a physician would have to meet to qualify for a DATA waiver under H.R. 2356 would remain largely the same as under current law. One difference is that H.R. 2356 would add holding a board certification from the American Board of Addiction Medicine as a statutory condition that a physician could meet to qualify for a waiver. The other difference is that a State medical licensing board could no longer determine what training or experience would demonstrate a physician has the ability to treat and manage opiate-dependent patients.

To qualify for a DATA waiver, a nurse practitioner (NP) or physician assistant (PA) would have to be a licensed provider under State law, be licensed under State law to prescribe schedule III, IV, or V medications for pain, and meet at least one of the qualifying conditions listed in the legislation. Those conditions include having completed at least 24 hours of training on the treatment and management of opiate-dependent patients for substance use disorders, having such other training or experience as the Secretary determines will demonstrate NP or PA's ability to treat and manage opiate-dependent patients, or practicing under the supervision of a licensed physician with an active DATA waiver and who either holds certain addiction-related board certifications or addiction certifications or practices, along with the NP or PA, in a qualified practice setting as identified by the legislation.

Nurse practitioners also have an additional pathway to qualify for a DATA waiver under H.R. 2356. A NP would qualify for a DATA waiver if the NP is a licensed provider under state law, is licensed under State law to prescribe schedule III, IV, or V medications for pain, has training or experience that the Secretary determines demonstrates specialization in the ability to treat opiate-dependent patients, and can, in accordance with State law, prescribe opioid addiction therapy in collaboration with a physician who holds an active DATA waiver, and practices in a qualified practice setting as defined by the legislation.

ii. Discussion

There exists access problems with obtaining MAT. According to a recent study published in the American Journal of Public Health, while the rate of opioid abuse or dependence

was 891.8 per 100,000 people aged 12 years or older in 2012, the maximum potential buprenorphine treatment capacity and methadone treatment capacity was 420.3 and 119.9 respectively.⁴¹ That leaves a gap of approximately 351.1 people with opioid abuse or dependence per 100,000 people without access to buprenorphine or methadone. Additionally, in 2012, 96 percent of states and the District of Columbia had opioid abuse or dependence rates higher than their buprenorphine treatment capacity rates, and 38 states reported that at least 75 percent of the OTPs were operating at 80 percent or greater capacity.⁴²

Since the DATA waiver allows physicians to prescribe buprenorphine as part of the range of health care services offered in their practices, many believe that we can expand access to MAT by lifting or eliminating the buprenorphine cap. Unlike with pain medication, which are Schedule II and have been largely blamed for driving the current opiate crisis, prescribers of buprenorphine are limited in the patients that can be treated with buprenorphine. That cap is an anomaly in the prescribing of medications. It is the only instance of a numerical cap being applied to the number of patients a provider can prescribe an FDA-approved drug. There is concern that this disparate treatment is inhibiting our ability to treat individuals with opiate dependence.

Some have raised concerns that increasing the availability of buprenorphine may increase the amount that is diverted – meaning that amount that is obtained or used without a prescription. Most of the anecdotal evidence points to individuals using diverted buprenorphine to “treat” their opiate-dependence. A recent study that looked at risk factors for diverted buprenorphine in a rural Appalachian Kentucky county found that the greatest risk factor for use of diverted buprenorphine was the inability to access buprenorphine treatment.⁴³ Such evidence has led to divergent opinions about the public health consequences related to buprenorphine diversion. There is also the possibility that injectable and implantable buprenorphine formulations, which would not have the diversion concerns related to oral medications, may obtain FDA-approval in the coming years. If that occurs, those formulations would eliminate or significantly reduce concerns related to diversion.

B. Heroin and Prescription Drug Abuse Prevention, Education, and Enforcement Act of 2015 (H.R. 2805)

i. Overview

H.R. 2805 was introduced by Representatives Brooks (R-IN) and Kennedy (D-MA). This legislation would establish an interagency task force to develop best practices for pain

⁴¹ Christopher Jones, et. al., *National and State Treatment Need and Capacity for Opioid Agonist Medication-Assisted Treatment*, American Journal of Public Health (Aug. 2015).

⁴² *Id.*

⁴³ Michelle Lofwal and Jennifer Havens, *Inability to Access Buprenorphine Treatment as a Risk Factor for Using Diverted Buprenorphine*, Drug and Alcohol Dependence (Dec. 1, 2012).

management and prescription pain medication prescribing practices. It would also instruct the Secretary to conduct a national awareness campaign to educate the public about the association between prescription opioid abuse and heroin use, and bring greater public awareness to the dangerous effects of fentanyl when mixed with heroin. The bill would also authorize the AG, in coordination with the Secretary, to establish a naloxone demonstration grant program for first responders to administer naloxone.

The legislation also includes the National All-Schedules Prescription Electronic Reporting Reauthorization Act of 2015 which was already approved by the House on September 8, 2015, by voice vote. It would also reauthorize the Byrne Justice Assistance Grant Program through 2020.

C. Opioid Addiction Treatment Modernization Act (H.R. 2872)

i. Overview

The Opioid Addiction Treatment Modernization Act was introduced by Representatives Buschon (R-IN) and Womack (R-AR) on June 24, 2015. This legislation would make certain changes to the CSA in order to increase awareness and access to all treatment options for opioid addiction, overdose reversal, and relapse prevention. The legislation would amend the CSA to require all physicians to complete eight hours of training to address substance abuse treatment every two years in order to qualify for a DATA waiver. The legislation would eliminate the option for physicians to initially qualify for a DATA waiver by obtaining at least 8 hours of hours of training with respect to the treatment and management of opiate-dependent patients.

The legislation would also require a DWP to have the capacity to provide directly or by referral all FDA-approved drugs for the treatment of opioid addiction as well as appropriate counseling and ancillary services. The legislation would also require physicians to maintain a diversion control plan to reduce the likelihood of the diversion of controlled substances. The legislation would require DWPs to obtain in writing from each patient a signed written consent that the patient will be subject to medication adherence and substance use monitoring, understands available treatment options, including all FDA-approved drugs for the treatment of opiate dependence, and has an individual treatment plan. The legislation would require the Secretary to update the treatment improvement protocol containing best practice guidelines for the treatment of opiate dependence within one year of enactment. The legislation would grant the Secretary and the Attorney General the authority to inspect DWPs to ensure compliance with the requirements of this legislation. The legislation would also require GAO to issue regular reports to Congress related to provisions of this legislation.

ii. Discussion

Instead of increasing awareness and access to all treatment options for opioid addiction, overdose reversal, and relapse prevention, this legislation may actually reduce access to substance abuse treatment services.

Substance Abuse Treatment Landscape

Despite the stated goal that the intent is to modernize the regulation of substance abuse treatment, there is no evidence to suggest that there has been major changes in substance abuse treatment since the passage of DATA 2000. DATA 2000 was passed in anticipation of the first approval of a Schedule III, IV, or V drug for the treatment of opiate dependence. Since the passage, just one drug, buprenorphine, has obtained FDA approval and qualifies under the DATA 2000 waiver. Therefore, the questions of whether the regulatory regime for buprenorphine, a Schedule III drug, should be the same or different than that of OTPs which dispense methadone were just the type of questions that Congress would have considered during the passage of DATA 2000.

Additionally, prior to passage of DATA 2000, oral naltrexone had been available to treat addiction to opioids. FDA approved oral naltrexone for the treatment of addiction to opiates in 1984.⁴⁴ The possibility of an FDA-approved drug for the treatment of opiate abuse that was not a scheduled drug could have also factored into the consideration of passage of DATA 2000.

Amendments to the Controlled Substances Act

The legislation aims to expand access to all FDA-approved drugs for substance abuse treatment by amending the DATA waiver contained in the CSA. As discussed above, the DATA waiver only applies to physicians who obtain a waiver to prescribe buprenorphine. Therefore, none of the changes proposed by this legislation would affect OTPs that dispense methadone or physicians who prescribe Vivitrol. As a result, there are questions as to whether the bill will ensure access to all FDA-approved medications for the treatment of opiate dependence within the CSA.

Application of Facility Requirements to Physician Offices

The legislation attempts to apply similar requirements to those placed on OTPs, which are specialty clinics or facilities, to physician offices. While some Office-Based Opioid Treatment Programs (or OBOTs) may be physicians who specialize in substance abuse treatment, many DWPs provide buprenorphine treatment services within the context of their larger health care practices. For example, some providers who are DATA waived may be primary care physicians while others may be psychiatrists who provide the full range of behavioral health services. Additionally, under current law, physicians can apply to become OTPs and prescribe buprenorphine without any restriction of the number of patients that can be served. Because of the difficulty and expense with meeting the regulatory requirements of an OTP, less than 10 physicians have taken advantage of that options. Based on that evidence, applying regulations similar to OTPs to physician practices may reduce the already limited number of physicians who obtain a DATA waiver.

⁴⁴ Substance Abuse and Mental Health Services Administration, *Treatment Improvement Protocol (TIP) Series No. 49*, (2009) (online at <http://www.ncbi.nlm.nih.gov/books/NBK64042/>).

Additionally, the bill attempts to apply regulations related to safely dispensing methadone, a schedule II drug that may cause a serious or life-threatening breathing program,⁴⁵ to the requirements of buprenorphine, a schedule III drug without the same safety profile. The use of methadone for the treatment of substance use disorders is one of the most highly regulated uses for the drug. An indication of the tight control is that methadone can only be dispensed, and not prescribed, in the substance abuse treatment context. The different safety profile and drug scheduling of buprenorphine seems to support a different regulatory regime for the prescribing of buprenorphine compared to the dispensing of methadone.

Amendments to Obtaining and Maintaining a DATA Waiver

The legislation would make it tougher to initially qualify for and maintain a DATA waiver. However, there are currently not enough DWPs to meet the needs of opiate-dependent patients. To provide a sense of the scale of the shortage, while 850,000 physicians are registered with the DEA to prescribe controlled substances,⁴⁶ only 30,524 physicians have obtained a waiver to prescribe buprenorphine outside of OTPs, and only 9,801 physicians have requested and received the required waiver to treat up to 100 patients.⁴⁷ Additionally, as discussed above, in 2012, 96 percent of states and the District of Columbia had opioid abuse or dependence rates higher than their buprenorphine treatment capacity rates.⁴⁸

Under current law, a physician without an addiction-related board certification or addiction certification can qualify to prescribe buprenorphine by obtaining at least 8 hours of hours of training with respect to the treatment and management of opiate-dependent patients. This allows primary care physicians and other providers, who play a particularly important role in expanding access to MATs in rural and underserved areas, to qualify to prescribe buprenorphine after obtained such training. Eliminating this option would limit the number of DWPs.

Additionally, H.R. 2872 would require all physicians, even those with an addiction-related board certification or addiction certification, to obtain 8 hours of training every 2 years to address substance abuse treatment in order to maintain a DATA waiver. Since physicians are required to obtain continuing education training to maintain their board certifications, there is a question of whether this requirement would be burdensome to those physicians. For those without addiction-related board certification or addiction certification, they may choose to

⁴⁵ U.S. National Library of Medicine, *Medline Plus – Methadone* (online <https://www.nlm.nih.gov/medlineplus/druginfo/meds/a682134.html>).

⁴⁶ Senate Caucus on International Narcotics Control, Testimony of H. Westley Clark, *America's Addiction to Opioids: Heroin and Prescription Drug Abuse*, 113th Cong. (May 26, 2014).

⁴⁷ Substance Abuse and Mental Health Services Administration, *A Breakdown of U.S. DATA-Certified Physicians Providing Buprenorphine Treatment* (online at www.samhsa.gov/medication-assisted-treatment/physician-program-data).

⁴⁸ *Supra* note 41

terminate their waiver and therefore their ability to prescribe buprenorphine rather than comply with a requirement to obtain 8 hours of training every 2 years. It is particularly important to note that such training is not required to prescribe other types of medications, including schedule II pain medications that are largely attributed with driving the current crisis. While additional education and training may be beneficial, however, this approach may inadvertently reduce the number of providers who can prescribe buprenorphine and therefore access to buprenorphine.

Some Requirements May Be Impossible to Meet

The legislation would require physicians to be able to have the capacity to provide directly or by referral all FDA-approved drugs for the treatment of opioid addiction as well as appropriate counseling and ancillary services. Many communities do not have an OTP facility that can dispense methadone. In fact, the current footprint of the opiate crisis is different than the footprint of existing OTP facilities. OTP facilities are largely located in urban areas that were hit hard by the heroin epidemic in the 70s. The current crisis is largely a rural and suburban crisis – although there are urban communities affected – and therefore does not align with the locations of existing OTP facilities. Because a DWP cannot prescribe or dispense methadone and many will be in communities without OTPs, this requirement could prevent many physicians from qualifying for a DATA waiver. Additionally, there is a shortage of substance abuse counselors in the United States., so requiring that providers have the ability to directly provide or refer for counseling could also prove problematic.

D. Medical Controlled Substances Transportation Act of 2015 (H.R. 3014)

H.R. 3014 was introduced by Representative Sessions (R-TX) on July 9, 2015. This legislation would allow a physician to transport controlled substances to another practice setting or to a Presidentially-declared disaster area if the physician is registered to dispense controlled substances listed on schedules II, III, IV, or V, and the physician enters into a specific agreement with the DEA. The agreement would require a physician to provide advance notification to the DEA of any such transport, identify the controlled substances to be transported and the locations to and from which the controlled substances will be transported, the intended dates of transport, anticipated travel time and more. The physician is also required under the agreement to maintain records in the physician's primary practice setting on the dispensing of any controlled substance transported, including the location and quantity. Further, the duration of such transport is limited to no more than 72 consecutive hours.

Currently, physicians are prohibited from transporting controlled substances away from their registered practice locations to other locations. This legislation would allow, for example, athletic team physicians to transport a supply of controlled substances to athletic games in other states, or physicians to bring controlled substances to respond to a disaster.

E. Synthetic Drug Control Act of 2015 (H.R. 3537)

H.R. 3537 was introduced by Representatives Dent (R-PA), Himes (D-CT), Holmes Norton (D-DC), and Jolly (R-FL) on September 18, 2015. This legislation would add a list of 316 synthetic drugs identified by DEA to Schedule I of the CSA, broken out into nine different

classes including cannabinoids and opioids. The legislation would also make any compound that is chemically or pharmacologically similar to a controlled substance in Schedule I or II of the CSA to be legally treated as though it was listed in that same schedule. Currently, under the Controlled Substances Analogue Enforcement Act (the Analogue Act) substances must be substantially similar in chemical structure and pharmacologically similar to be considered as listed in Schedule I or II. The legislation would also narrow the Analogue Act so that it would only apply to the manufacture, importation, distribution, and sale of drugs, not possession. These changes are intended to assist with the prosecution of synthetic drug manufacturers and distributors and inhibit its use in the prosecution of people who are simply users of the drugs.

The synthetic drugs that are the target of the legislation are chemically modified versions of existing Schedule I drugs, modified to escape control by DEA while still retaining or enhancing their potential for abuse. For example, some are designed to mimic or enhance the effects of drugs such as marijuana, cocaine, or methamphetamine. The effects and potential dangers of these substances are not well known. However, the use of synthetic drugs is reportedly on the rise, leading some to call on Congress to legislatively schedule specific substances. In June 2012, Congress passed the Synthetic Drug Control Act of 2011, to among other things, schedule selected synthetic stimulants and other synthetic substances. Criticisms have been raised about scheduling substances legislatively. However, supporters argue that the current formal scheduling process is too laborious to schedule synthetic drugs, which chemists can manipulate and modify relatively quickly.

F. Improving Treatment for Pregnant and Postpartum Women Act of 2015 (H.R. _____)

This bill was introduced by Representative Lujan (D-NM). It reauthorizes the Pregnant and Postpartum Women (PPW) program, and creates a pilot program to allow for up to 25 percent of the grants to be made for outpatient treatment services. This will allow for greater flexibility for state substance abuse agencies to provide access to treatment, and address gaps in services furnished to pregnant women along the continuum of care.

The PPW program is a SAMHSA program that provides grants to residential treatment programs that treat pregnant and postpartum women with substance use disorders. Currently, grants can only be used for services provided to women on an inpatient basis. Services available to women include: outreach, engagement, pre-treatment, and assessment; detoxification, substance abuse education, treatment, and relapse-prevention; healthcare services, including mental health services; postpartum health care; testing, counseling and treatment of hepatitis, HIV/AIDS, and other sexually transmitted diseases; life skills training and education; and parenting education and intervention. Services available to children including screenings and diagnostic assessments regarding social, emotional, cognitive, and physical development, as well as interventions related to mental and behavioral health. Services for families include programs to support family strengthening, such as counseling.⁴⁹

⁴⁹ HHS, SAMHSA Fiscal Year 2016 Budget Justification.

The PPW program provides services not covered under most public and private insurance. In FY 2015, it was funded at \$15.9 million. The proposed legislation would increase the authorization to \$40 million.

G. Co-Prescribing to Reduce Overdoses Act of 2015 (H.R. 3680)

This bill, introduced by Representative Sarbanes (D-MD), creates a demonstration grant program for entities to establish programs for co-prescribing of naloxone to patients at an elevated risk of overdose. “Co-prescribing” is the practice of prescribing naloxone to patients at elevated risk of overdose, such as patients who are taking high doses of opioids for long-term management of chronic pain, patients who have had a history of substance abuse or non-medical use of prescription or illicit opioids, patients who are completing mandatory opioid detoxification or abstinence programs, as well as patients who have been discharged from emergency medical care following opioid intoxication or poisoning.⁵⁰ The bill would provide funding to eligible entities to train health care providers and pharmacists on co-prescribing, to establish mechanisms for tracking patients and their health outcomes for program evaluation, to purchase naloxone, to offset patient cost-sharing associated with naloxone, to conduct community outreach to raise awareness of co-prescribing practices, and to establish protocols to connect patients who have experienced a drug overdose with appropriate treatment.

Naloxone has been proven effective in reducing opioid overdoses, as well as cost-effective from a public health standpoint.⁵¹ Although current efforts to improve access to naloxone have focused on first responders and community-based organizations, providing naloxone to at-risk patients in a health care setting could also reduce overdoses and may encourage patients to be safer with their opioid use. The Veteran’s Administration has been successfully co-prescribing naloxone to patients who are at significant risk of overdose since 2013.⁵² However, there continue to be significant barriers to physicians prescribing naloxone more broadly, including limited knowledge about naloxone and uncertainty about whom to prescribe to due to a lack of applicable medical guidelines, fears of liability, concerns about misuse and safety, as well as physician discomfort with discussing naloxone with patients for fear of offending patients.⁵³

⁵⁰ Substance Abuse and Mental Health Services Agency, *Opioid Overdose Tool Kit* (online at [https://store.samhsa.gov/shin/content/SMA13-4742/Overdose Toolkit 2014 Jan.pdf](https://store.samhsa.gov/shin/content/SMA13-4742/Overdose_Toolkit_2014_Jan.pdf)).

⁵¹ Phillip O. Coffin and Sean D. Sullivan, *Cost-Effectiveness of Distributing Naloxone to Heroin Users for Lay Overdose Reversal*, *Annals of Internal Medicine* (Jan. 1, 2013).

⁵² Veterans Administration, *Saving Veterans Lives through Implementation of Opioid Overdose Education and Naloxone Distribution (OEND)* (July 1, 2015) (online at www.fda.gov/downloads/Drugs/NewsEvents/UCM454765.pdf).

⁵³ National Institute on Drug Abuse, *Prescribing Life-Saving Naloxone: Addressing Attitudes of Primary Care Clinicians* (June 9, 2015) (online at www.drugabuse.gov/news-events/news-releases/2015/06/prescribing-lifesaving-naloxone-addressing-attitudes-primary-care-clinicians); Ingrid Binswanger, *Facilitators and Barriers to Naloxone Prescribing in Three Large Health Systems* (July 1, 2015) (online at

The bill would also create a second grant program for State departments of health working in conjunction with State medical boards, city, county, and local health departments, and community stakeholder groups to develop naloxone co-prescribing guidelines. The bill authorizes \$4 million for each of fiscal years 2016 through 2020 for both programs combined.

III. WITNESSES

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www.fda.gov/downloads/Drugs/NewsEvents/UCM454769.pdf); The Network for Public Health Law, *Legal Interventions to Reduce Overdose Mortality: Naloxone Access and Good Samaritan Laws* (July 2015) (online at https://www.networkforphl.org/_asset/qz5pvn/network-naloxone-10-4.pdf).