

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

April 21, 2015

To: Subcommittee on Oversight and Investigations Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: Hearing on “Combating the Opioid Abuse Epidemic: Professional and Academic Perspectives”

On Thursday, April 23, 2015, at 10:15 a.m. in room 2322 of the Rayburn House Office Building, the Subcommittee on Oversight and Investigations will hold a hearing titled “Combating the Opioid Abuse Epidemic: Professional and Academic Perspectives.” The hearing will focus on medical experts’ views on the treatment and prevention of opioid addiction, and it is the second in a series of hearings on the opioid abuse epidemic.

I. BACKGROUND

The Centers for Disease Control and Prevention (CDC) has called prescription drug abuse in the United States an epidemic and has found drug overdose to be the leading cause of injury death in the United States.¹ In 2013, over 50% of all drug overdose deaths were related to prescription pharmaceuticals. More than 70% of these overdoses involved opioid pain relievers.²

The Substance Abuse and Mental Health Services Administration (SAMHSA) found that between 2000 and 2010, there was a fourfold increase in the use of prescribed opioids for the treatment of pain.³ The greater availability of opioids and their misuse have had adverse public health consequences. Between 1999 and 2010, the death rate from prescription opioids more

¹ Office of National Drug Control Policy, *Prescription Drug Abuse* (online at www.whitehouse.gov/ondcp/prescription-drug-abuse) (accessed Mar. 17, 2015).

² Centers for Disease Control and Prevention, *Prescription Drug Overdose in the United States: Fact Sheet* (Mar. 2, 2015).

³ Substance Abuse and Mental Health Services Administration, *SAMHSA Opioid Overdose Prevention Toolkit* (2014).

than quadrupled, and in 2010 alone, prescription opioids were involved in 16,651 overdose deaths.⁴

The Subcommittee held a hearing on March 26, 2015, at which state and local experts offered their perspectives on the opioid epidemic and some of the responses that have been taken in their communities.⁵ Additional information relating to that hearing is available online [here](#).

II. OPIOID PRESCRIBING PRACTICES

The opioid addiction and abuse epidemic is inextricably tied to the overprescribing of these drugs for the treatment and management of pain.⁶ Opioid analgesics are primarily prescribed for acute pain in hospitalized patients, for pain in cancer patients, and for chronic non-cancer pain. Increased opioid consumption over the past few decades has been driven largely by greater use for chronic non-cancer pain. However, there is limited scientific evidence supporting the safety and efficacy of opioid analgesics for chronic non-cancer pain.⁷ There is also limited evidence of the maintenance of pain relief or improved physical function in the long-term, possibly due to the development of pharmacologic tolerance.⁸ Studies have also shown that use of opioid analgesics above a certain dosage to treat chronic non-cancer pain is associated with increased morbidity and mortality.⁹

Prescribing rates for chronic non-cancer pain over the past few decades suggests that many physicians are unaware of the scope of the risks associated with opioid analgesics and the lack of evidence supporting their effectiveness for the treatment of chronic pain. Some professional societies are now warning clinicians to avoid prescribing opioid analgesics for common chronic conditions, such as lower back pain.¹⁰

⁴ Nora D. Volkow et. al., *Medication-Assisted Therapies – Tackling the Opioid Overdose Epidemic*, New England Journal of Medicine (May 29, 2014).

⁵ House Committee on Energy and Commerce, *Hearing on Examining the Growing Problems of Prescription Drug and Heroin Abuse: State and Local Perspectives*, 114th Cong. (Mar. 26, 2015).

⁶ Laxmaiah Manchikanti et. al., *Opioid Epidemic in the United States*, Pain Physician (July 2012).

⁷ 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).

⁸ Gary M. Franklin, *Opioids for Chronic Noncancer Pain: A Position Paper of the American Academy of Neurology*, Neurology (Sept. 30, 2014).

⁹ Kate M. Dunn et. al., *Overdose and Prescribed Opioids: Associations Among Chronic Non-Cancer Pain Patients*, Annals Of Internal Medicine (Jan. 19, 2010).

¹⁰ Gary M. Franklin, *Opioids for Chronic Noncancer Pain: A Position Paper of the American Academy of Neurology*, Neurology (Sept. 30, 2014).

There are currently no mandatory federal guidelines or continuing medical education (CME) requirements for physicians who prescribe opioid analgesics, although registration with the Drug Enforcement Agency (DEA) is required to dispense controlled substances. Yet, there is evidence that mandating CME has been effective in changing physician prescribing patterns and reducing opioid prescriptions.¹¹ More than a handful of states, including Iowa, Kentucky, Massachusetts, Ohio, New Mexico, Tennessee, and Utah, have passed legislation mandating CME on addiction and pain management. Washington State has further adopted mandatory prescribing guidelines for opioid analgesics.¹²

Additionally, evidence suggests that state Prescription Drug Monitoring Programs (PDMPs) may be effective in reducing opioid prescribing.¹³ Individuals with opioid abuse disorders may receive prescriptions from multiple physicians, a practice known as “doctor shopping.” PDMPs can help physicians identify doctor shoppers, detect opioid addiction, and refer individuals for addiction treatment. However, major challenges remain to PDMPs’ effectiveness, including a lack of resources, low provider use of the data, a lack of timeliness, consistency, and completeness of PDMP data, and a lack of interoperability between most states’ systems.¹⁴

III. 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).¹⁵

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% 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

¹¹ Joanna G. Katzman et. al., *Rules and Values: A Coordinated Regulatory and Educational Approach to the Public Health Crises of Chronic Pain and Addiction*, American Journal of Public Health (Aug. 2014).

¹² Washington State Department of Health, *Pain Management* (online at www.doh.wa.gov/ForPublicHealthandHealthcareProviders/HealthcareProfessionsandFacilities/PainManagement) (accessed Apr. 16, 2015).

¹³ 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).

¹⁴ Congressional Research Service, *Prescription Drug Monitoring Programs* (Mar. 24, 2014).

¹⁵ National Institute on Drug Abuse, National Institutes of Health, *Treating Prescription Drug Addiction* (Nov. 2014).

risks of infectious-disease transmission and of engagement in criminal activities.¹⁶ Nevertheless, MATs were available in only 9% of all substance abuse treatment facilities nationwide in 2013.¹⁷

There is consensus among the medical community that MATs play a critical role in opioid addiction therapy. There continues to be debate over long-term use of MATs and how much treatment plans should focus on tapering patients off medication.¹⁸ Currently, minimal data exists on best practices for successful long-term treatment of opioid addiction. Data is also lacking in predicting which medication will be most effective for any given patient with opioid dependence.¹⁹

There are three 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.²⁰

Methadone, approved nearly 50 years ago, is a synthetic opioid agonist medication. It is a DEA Schedule II drug. 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.²¹

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

¹⁶ Nora D. Volkow et. al., *Medication-Assisted Therapies – Tackling the Opioid Overdose Epidemic*, *New England Journal of Medicine* (May 29, 2014).

¹⁷ Substance Abuse and Mental Health Services Administration, *National Survey of Substance Abuse Treatment Services: 2013* (Sept. 2014).

¹⁸ Office of National Drug Control Policy Healthcare Brief, *Medication-Assisted Treatment for Opioid Addiction* (Sept. 2012).

¹⁹ Substance Abuse and Mental Health Services Administration, *Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs* (online at www.ncbi.nlm.nih.gov/books/NBK64168) (accessed Apr. 17, 2015); Substance Abuse and Mental Health Services Administration, *An Introduction to Extended-Release Injectable Naltrexone for the Treatment of People with Opioid Dependence* (Winter 2012); and World Health Organization, *Treatment of Opioid Dependence* (online at www.who.int/substance_abuse/activities/treatment_opioid_dependence/en) (accessed Apr. 17, 2015).

²⁰ National Institute on Drug Abuse, National Institutes of Health, *Treatment Approaches for Drug Addiction* (Sept. 2009).

²¹ 42 C.F.R. Part 8.

opioid dependence was also found to substantially reduce the rates of criminal activity and reduce transmission of infectious diseases.²²

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.²³ 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.²⁴

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).²⁵ 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.²⁶ 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 lower risk of abuse or side effects.²⁷ 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 drug. It has no potential for abuse and it is not addictive. Naltrexone is traditionally taken orally daily or three times a week, yet noncompliance with the treatment schedule is a common problem. In the last several years, a long-acting injectable version of naltrexone, Vivitrol, has been FDA-approved for treatment of opioid addiction. It is administered monthly. Vivitrol

²² National Institutes of Health Consensus Development Program, *Effective Medical Treatment of Opiate Addiction* (Nov. 17-19, 1997).

²³ Centers for Disease Control and Prevention, *Methadone Maintenance Treatment* (online at www.cdc.gov/idu/facts/Methadone.htm) (accessed Apr. 16, 2015).

²⁴ *Id.*

²⁵ 21 U.S.C. § 823(g)(2).

²⁶ Substance Abuse and Mental Health Services Administration, *About Buprenorphine Therapy* (online at buprenorphine.samhsa.gov/about.html) (accessed Apr. 16, 2015).

²⁷ *Id.*

should only be administered to patients who have been medically detoxified from opioids for at least seven to 14 days.²⁸

Naloxone, which is not considered a treatment drug, is an opioid antagonist used to counteract the effect of an opioid overdose. Considered a “rescue 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.²⁹ 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.³⁰

IV. BARRIERS TO ADDRESSING OPIOID ADDICTION

Treatment experts have reported that serious impediments to widespread access remain, including a shortage of substance abuse treatment providers and treatment beds nationwide.³¹ Additional barriers include cultural and social stigmas attached to substance abuse disorders, lack of health coverage, high out-of-pocket costs for treatment, and physician shortages.

Even for those who have access to public or private insurance, the issue of insurance coverage for MATs remains a hurdle. Medicaid coverage for MATs varies greatly from state to state, with some states not covering all FDA-approved medications, limiting dosages, imposing prior authorization and reauthorization requirements, and imposing “fail first” criteria requiring documentation that other therapies were ineffective.³² These practices likely persist in the private insurance market as well.³³

Physician shortages also pose problems for those seeking medication-assisted treatment. While 850,000 physicians are registered with the DEA to prescribe controlled substances, only

²⁸ Food and Drug Administration, *Vivitrol Medication Guide* (online at www.fda.gov/downloads/Drugs/DrugSafety/UCM206669.pdf) (accessed Apr. 17, 2015).

²⁹ 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).

³⁰ The Network for Public Health Law, *Legal Interventions to Reduce Overdose Mortality: Naloxone Access and Overdose Good Samaritan Laws* (Dec. 2014).

³¹ *Barriers Remain Despite Health Law’s Push To Expand Access To Substance Abuse Treatment*, Kaiser Health News (Apr. 10, 2014).

³² American Society of Addiction Medicine, *Advancing Access to Addiction Medications* (June 2013).

³³ Kelsey N. Barry et. al., *A Tale of Two States: Do Consumers See Mental Health Insurance Parity When Shopping on State Exchanges?*, *Psychiatry Online* (Mar. 2, 2015).

26,143 physicians have obtained a waiver to prescribe buprenorphine outside of OTPs, and only 7,745 physicians have requested and received the required waiver to treat up to 100 patients.³⁴

V. WITNESSES

The following witnesses have been invited to testify:

Dr. Robert L. DuPont
President
Institute for Behavior and Health

Dr. Marvin D. Seppala
Chief Medical Officer
Hazelden Betty Ford Foundation

Dr. Laurence M. Westreich
President
American Academy of Addiction Psychiatry

Dr. Anna Lembke
Assistant Professor of Psychiatry and Behavioral Sciences
Stanford University Medical Center, Psychiatry Department

Dr. Adam Bisaga
Columbia University Medical Center
NYS Psychiatric Institute

Dr. Patrice Harris
Board Member
American Medical Association

³⁴ 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).