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ONE HUNDRED THIRTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
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MEMORANDUM

March 24, 2014

To: Subcommittee on Oversight and Investigations Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: Hearing on "Examining the Growing Problems of Prescription Drug and Heroin Abuse: State and Local Perspectives"

On Thursday, March 26, 2014, at 10:00 a.m. in room 2123 of the Rayburn House Office Building, the Subcommittee on Oversight and Investigations will hold a hearing titled "Examining the Growing Problems of Prescription Drug and Heroin Abuse: State and Local Perspectives." The Subcommittee held a previous hearing in April 2014, on the factors leading to the growth of opioid abuse, the relationship between prescription drug and heroin abuse, and the most effective prevention, treatment, and law enforcement responses to the problem.[1]

I. SCOPE OF THE PROBLEM

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.[2] The Southwest and the Appalachian regions reported the highest drug overdose death rates.[3] In 2013, over 50% of all drug overdose deaths were related to pharmaceuticals. More than 70% of the overdoses involved opioid pain relievers.[4]

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[1] House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, *Examining the Growing Problems of Prescription Drug and Heroin Abuse* (Apr. 28, 2014).

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

[3] Centers for Disease Control and Prevention, *Policy Impact: Prescription Painkiller Overdoses* (July 2, 2013).

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

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.[5] The number of prescriptions for opioids (like hydrocodone and oxycodone) escalated from about 76 million in 1991 to about 207 million in 2013. 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.[6]

This 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. 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.[7] Between 1999 and 2010, the death rate from prescription opioids more than quadrupled, and in 2010 alone, prescription opioids were involved in 16,651 overdose deaths.[8]

II. 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).[9]

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 risks of infectious-disease transmission and of engagement in criminal activities.[10] Nevertheless,

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[5] Substance Abuse and Mental Health Services Administration, *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] Nora D. Volkow et. al., *Medication-Assisted Therapies – Tackling the Opioid Overdose Epidemic*, New England Journal of Medicine (May 29, 2014).

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

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

MATs were available in only 9 percent of all substance abuse treatment facilities nationwide in 2013.[11]

Physicians generally administer three FDA-approved medications for the treatment of opioid addiction:

- **Methadone**, approved nearly 50 years ago, is a synthetic opioid agonist medication. It is a U.S. Drug Enforcement Agency (DEA) Schedule II drug. Methadone is administered in all but three states through federally approved Opioid Treatment Programs (OTPs).

- **Buprenorphine** (Subutex®, Suboxone®) is a synthetic opioid partial agonist medication. It is a DEA Schedule III drug. Buprenorphine can be prescribed by physicians who have received approval from the DEA, but physicians are only permitted by law to treat a maximum of 100 patients with buprenorphine at a given time.

- **Naltrexone** is a synthetic opioid antagonist, meaning it blocks opioid receptors and prevents the euphoric effects of opioids. It is not a narcotic and is not a scheduled drug. Naltrexone is traditionally ingested orally and requires strict compliance with a daily treatment schedule. In the last several years, a long-acting injectable version of naltrexone, Vivitrol, has become available. It is administered monthly.[12]

In addition, Naloxone, which is not considered a treatment drug, is an opioid antagonist used to counteract the effect of an opioid overdose. Considered as a "rescue drug," naloxone works by reversing opioids' 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.[13] 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.[14]

III. THE AFFORDABLE CARE ACT (ACA) AND MENTAL HEALTH PARITY

According to the Department of Health and Human Services, since the ACA's coverage provisions have taken effect, approximately 16.4 million uninsured people have gained health

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

[12] National Institute on Drug Abuse, National Institutes of Health, *Principles of Drug Addiction Treatment: A Research-Based Guide (Third Edition*) (Dec. 2012).

[13] 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).

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

insurance coverage.[15] The ACA expands access to affordable care and treatment for individuals fighting substance abuse disorders primarily through the provision of subsidies on the state and federal healthcare exchanges, allowing children to remain on their parents' health insurance until the age of 26, and Medicaid expansion. The ACA also improves coverage for treatment of substance abuse disorders by requiring all non-grandfathered plans in the individual and small group markets to offer mental health and substance abuse disorder benefits through the Essential Health Benefits package.

Finally, the ACA extends the reach of the Mental Health Parity and Addiction Equity Act (MHPAEA) of 2008. MHPAEA prohibited large group insurance plans offering coverage for mental health or substance-use disorders from imposing treatment limitations and financial requirements that are more restrictive than the corresponding requirements applied to medical benefits under the plan. Under the ACA, parity is extended further, across plans in the individual and small group market, as well as to Medicaid Alternative Benefit plans for the Medicaid expansion population.[16]

IV. BARRIERS TO ADDRESSING OPIOID ADDICTION

Treatment experts have reported that serious impediments to widespread access remain, including a shortage of substance abuse providers and treatment beds nationwide.[17] 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 MAT remains a hurdle. Medicaid coverage for MAT 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 that require documentation that other therapies were ineffective.[18] These practices likely persist in the private insurance market as well.[19]

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

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

[16] Department of Health and Human Services, Assistance Secretary for Planning and Evaluation, *Affordable Care Act Expands Mental Health and Substance Use Disorder Benefits and Federal Parity Protections for 62 Million Americans* (Feb. 20, 2013).

[17] *Barriers Remain Despite Health Law's Push To Expand Access To Substance Abuse Treatment*, Kaiser Health News (Apr. 10, 2014).

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

[19] 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.[20]

V. WITNESSES

The following witnesses have been invited to testify:

Fred Wells Brason II
Executive Director
Project Lazarus

Dr. Sarah T. Melton
Associate Professor of Pharmacy Practice
Gatton College of Pharmacy at East Tennessee State University
Chair of the Board of Directors
OneCare of Southwest Virginia

Dr. Stefan R. Maxwell
Associate Professor, Pediatrics
WVU School of Medicine
Medical Director, NICU
Women & Children's Hospital

Rachelle Gardner
Chief Operating Officer
Hope Academy

Corporal Michael Griffin
Narcotics Unit Supervisor- K9 Handler
Special Investigations Division
Tulsa Police Department

Dr. Caleb Banta-Green
Senior Research Scientist
Alcohol and Drug Abuse Institute
University of Washington

Victor Fitz
Cass County, Michigan Prosecutor
President
Prosecuting Attorneys Association of Michigan (PAAM)

[20] 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).