

ONE HUNDRED FIFTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (202) 225-2927
Minority (202) 225-3641

MEMORANDUM

October 23, 2017

To: Committee on Energy and Commerce Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: Hearing on “Federal Efforts to Combat the Opioid Crisis: A Status Update on CARA and Other Initiatives”

On **Wednesday, October 25, 2017 at 10:00 a.m. in room 2123 of the Rayburn House Office Building**, the full Committee on Energy and Commerce will hold a hearing titled “Federal Efforts to Combat the Opioid Crisis: A Status Update on CARA and Other Initiatives.”

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 91 deaths per day occur from opioid overdoses resulting in over 33,000 deaths per year. Nearly half of these overdose deaths are due to a prescription opioid.¹

The increased consumption of opioids has been driven by many factors. 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, have led to higher opioid utilization rates.² In 2016, almost half a million Americans used heroin and an estimated

¹ National Institute on Drug Abuse, *Overdose Death Rates*. (Sept. 2017) (<https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates>).

² National Academies of Sciences, Engineering, Medicine, *Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use*, The National Academies Press (<https://www.nap.edu/read/24781/chapter/1>) (Accessed on Oct. 12, 2017).

3.3 million Americans misused prescription pain relievers.³ There is a strong correlation between increases in heroin use and the rise of opioid prescriptions.⁴ In fact, prescription opioids may serve as a gateway to heroin use.

II. TREATMENT AND PREVENTION OF OPIOID USE DISORDERS

Current research indicates the most effective treatment for Opioid Use Disorders (OUDs) and opioid addiction is a combination of medication assisted treatment (MAT), such as methadone, buprenorphine, or naltrexone and behavioral therapy (e.g. counseling and supportive services).⁵ MATs has proven to be effective at 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, an estimated 21 million people aged 12 years or older needed substance abuse treatment, but only approximately 11 percent (2.2 million) received specialized substance abuse treatment.⁶ Naloxone, an opioid antagonist that can be utilized as a rescue medication, works by reversing the effects of opioids.

Prevention of OUDs can be achieved in a variety of ways. CDC recommends many approaches to help prevent individuals from developing opioid use disorders. Tools, such as Prescription Drug Monitoring Programs (PDMPs), can assist providers in determining which patients may be at risk for misuse, abuse, or overdose of opioid prescription medications. Provider and patient education can help improve awareness of the dangers of opioid use, the risk of overdose, and alternative, non-opioid methods to treat pain.

III. CONGRESSIONAL ACTION

The Affordable Care Act (ACA) significantly increased health insurance coverage for millions of previously uninsured individuals. The ACA expanded access to affordable care and treatment for individuals fighting substance use disorders through the provision of subsidies on the state and federal healthcare exchanges, allowing children to remain on their parents' health

³ Substance Abuse and Mental Health Services Administration, *Key Substance Use and Mental Health Indicators in the United States: Results from the 2016 National Survey on Drug Use and Health* (Sept. 2017).

⁴ National Institute on Drug Abuse, *Prescription opioid use is a risk factor for heroin use* (Dec. 2015) (<https://www.drugabuse.gov/publications/research-reports/relationship-between-prescription-drug-heroin-abuse/prescription-opioid-use-risk-factor-heroin-use>).

⁵ 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>).

⁶ Substance Abuse and Mental Health Services Administration, *Key Substance Use and Mental Health Indicators in the United States: Results from the 2016 National Survey on Drug Use and Health* (Sept. 2017).

insurance until the age of 26, and Medicaid expansion.⁷ The ACA also improved 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.

Building upon the coverage expansions provided by the ACA, Congress took steps towards addressing the national opioid crisis in 2016 with the passage of the *Comprehensive Addiction and Recovery Act* (CARA) and the *21st Century Cures Act* (CURES). CARA included initiatives to help respond to the opioid abuse epidemic. For example, 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 the adoption of coprescribing practices to individuals at high risk for overdose and their families. In addition, CARA extended the waiver authority that allows providers to prescribe buprenorphine to individuals with opioid use disorder to nurse practitioners and physician assistants. CARA also took steps to reduce the amount of opioids that are prescribed by permitting pharmacists to partially fill a Schedule II controlled substance prescription at the request of a patient or health care provider.

CURES 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 provides \$1 billion over two years to states to develop prevention, treatment, and recovery activities for opioid use disorder.

IV. FDA ACTION

On February 4, 2016, the Food and Drug Administration (FDA) announced an action plan that outlines the role the agency will play in helping to combat the opioid abuse crisis. These steps include:

- Convening an expert advisory committee before approving any new drug application for an opioid that does not have abuse-deterrent properties;
- Consulting with the Pediatric Advisory Committee for recommendations to develop a framework for pediatric opioid labeling prior to new labeling approval;
- Updating the Risk Evaluation and Mitigation Strategy (REMS) program for extended-release and long-acting (ER/LA) opioids regarding prescriber training with the goal of increasing the number of providers trained in pain management and safe opioid prescribing practices;
- Developing better warning labels and safety information for immediate-release (IR) as well as ER/LA opioids;

⁷ Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, *Health Insurance Coverage and the Affordable Care Act* (Mar. 16, 2015).

- Strengthening post-market requirements to guide the use of opioids and develop evidence on the risks for abuse associated with long-term use of opioids;
- Expanding access to abuse-deterrent formulations to discourage abuse;
- Supporting better treatment options, such as making naloxone over-the-counter and developing new classes of medicines to treat pain that do not have the same risks as opioids; and
- Reassessing the risk-benefit approval framework for opioid use and incorporating the public health impact of opioid abuse on approval decisions for opioid medications.⁸

In September 2017, FDA Commissioner Scott Gottlieb, M.D. announced new REMS requirements for immediate-release (IR) opioids. The REMS will require training on safe prescribing practices and non-opioid alternatives for pain for healthcare providers who prescribe opioids, and will subject IR opioids to the same regulatory requirements as ER/LA opioids. This will expand the number of opioids under the REMS requirements from 64 ER/LA opioids to 277 IR opioid analgesics.⁹ The REMS educational “Blueprint” will also be updated to include principles for treating acute and long-term pain, non-opioid and non-pharmacologic alternatives for pain management, such as physical therapy, and information on the safe use of opioids, OUDs, and addiction medicine. The REMS materials will be made available for additional healthcare providers, including nurses and pharmacists. Commissioner Gottlieb also stated that a final guidance for applicants seeking FDA approval for generic formulations of abuse-deterrent medications for opioid drugs will be released soon.¹⁰

Finally, FDA’s Opioid Policy Steering Committee (OPSC) is determining whether education for healthcare providers about opioids and OUDs should be mandatory and if so, how the agency should pursue this goal. FDA released a public notice requesting public comments for 70 days concerning this decision on September 29, 2017.¹¹

V. DEA ACTION

As a federal law enforcement agency, the Drug Enforcement Administration (DEA) works to prevent, detect, and identify diversion of controlled substances while also balancing the need for patient access to these substances. DEA conducts education conferences and events for DEA registrants, including pharmacists, manufacturers, importers and exporters, and distributors. These events are intended to educate registrants on how to prevent and respond to diversion, and how to identify invalid prescriptions and suspicious orders. DEA has also taken

⁸ Food and Drug Administration, *Fact Sheet – FDA Opioids Action Plan* (Jul. 11, 2017) (<https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm484714.htm>).

⁹ Food and Drug Administration, *FDA Takes Important Steps to Stem the Tide of Opioid Misuse and Abuse* (Sept. 28, 2017) (<https://blogs.fda.gov/fdavoices/index.php/2017/09/fda-takes-important-steps-to-stem-the-tide-of-opioid-misuse-and-abuse/>).

¹⁰ *Id.*

¹¹ Food and Drug Administration, *Opioid Policy Steering Committee; Establishment of a Public Docket; Request for Comments*. 82 Fed. Reg. 45597 (Sept. 29, 2017).

steps to address unused, expired, or unwanted prescription drugs through its National Drug Take Back Initiative, which encourages individuals to bring unused medications to state or local law enforcement partners, and through regulations detailing safe drug disposal methods through drop-boxes at pharmacies and law enforcement agencies, mail back programs, and drug deactivation processes. On the enforcement side, DEA's Tactical Diversion Squads continue to investigate and take down diversion schemes such as prescription forgery rings and pill mills. The agency has also employed the "360 Strategy", which leverages law enforcement, diversion control, and community relations and has been piloted in four cities – West Memphis Arkansas; St. Louis, Missouri; Pittsburgh, Pennsylvania; and Milwaukee, Wisconsin. This initiative strives to target violence related to drug trafficking, educate DEA registrants on how to prevent diversion, and provide assistance to communities to identify and work through drug abuse issues.

VI. SAMHSA ACTION

SAMHSA has awarded millions in grant funding to expand access to treatment and recovery support services, expand access to naloxone, and expand the behavioral health workforce. Last month, for example, SAMHSA awarded \$9.8 million in funding for the State Pilot Grant for Treatment of Pregnant and Postpartum Women, and \$4.6 million to the Building Communities of Recovery program; these programs were authorized in CARA. Additionally, SAMHSA provided \$34.4 million in grants to improve treatment for adolescent and/or transitional aged youth with substance use disorders and/or co-occurring substance use and mental health disorders as well as \$44.6 million in grants to develop the Addiction Technology Transfer Center Cooperative, which develops the healthcare workforce to treat substance use disorders and support recovery.

VII. CDC ACTION

CDC has bolstered surveillance efforts to provide more timely and comprehensive data on how the crisis is affecting individuals and communities. CDC has also provided grant funding to states such as through the Prescription Drug Overdose: Prevention for States (PFS) to enhance their Prescription Drug Monitoring Programs (PDMPs). In 2016, CDC released the *Guidelines for Prescribing Opioids for Chronic Pain* that focused on the prescription of opioid pain relievers in primary care settings. Finally, CDC has created tools, including mobile apps, which make these guidelines easy to understand and use by primary care providers.

VIII. NIH ACTION

The National Institutes of Health (NIH) recently established a public-private partnership to promote development of new and innovative medications to treat opioid addiction and prevent and reverse overdose. The partnership is also promoting development of safe and effective non-addiction strategies to manage chronic pain and increase our understanding of the neurobiology of chronic pain. NIH also funds research and hosts scientific meetings on related topics that are helping to improve our understanding of how to prevent and treat opioid use disorder as well as how to prevent and treat chronic pain.

IX. WITNESSES

Scott Gottlieb, M.D.

Commissioner
Food and Drug Administration

Anne Schuchat, M.D.

Principal Deputy Director
Centers for Disease Control and Prevention

Elinore McCance-Katz, M.D., Ph.D.

Assistant Secretary for Mental Health and Substance Use
Substance Abuse and Mental Health Services Administration

Nora Volkow, M.D.

Director
National Institute on Drug Abuse
National Institutes of Health

Neil Doherty

Deputy Assistant Administrator
Office of Diversion Control
Drug Enforcement Administration