

October 23, 2017

TO: Members, Full Committee

FROM: Committee Majority Staff

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

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## **I. INTRODUCTION**

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

## **II. WITNESSES**

- Scott Gottlieb, MD, Commissioner, Food and Drug Administration;
- Elinore McCance-Katz, MD, PhD, Assistant Secretary for Mental Health and Substance Use, Substance Abuse and Mental Health Services Administration;
- Anne Schuchat, MD (RADM, USPHS), Principal Deputy Director, Centers for Disease Control and Prevention;
- Nora Volkow, MD, Director, National Institute on Drug Abuse, National Institutes of Health; and
- Neil Doherty, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

## **III. BACKGROUND**

### **A. Overview of CARA and 21st Century Cures**

The Committee on Energy and Commerce has led a number of bipartisan initiatives to help address the opioid crisis. From groundbreaking strategies that are now law, like the *Comprehensive Addiction and Recovery Act* (CARA) and the *21st Century Cures Act*, resources are becoming available and important policy changes are being implemented. The *21st Century Cures Act* provided \$1 billion in funding to help states and territories combat addiction, the first half of which was made available in April 2017, through the State Targeted Response to the Opioid Crisis Grants administered by the Substance Abuse and Mental Health Services Administration (SAMHSA). CARA established a comprehensive strategy for improving evidence-based treatment for patients with substance-use disorders and made significant changes

to expand access to addiction services and overdose reversal medications. CARA contained the following initiatives:

- Requiring the Comptroller General of the United States to issue a report on neonatal abstinence syndrome (NAS), including the prevalence of NAS among children covered by Medicaid, NAS treatment services covered by Medicaid and the costs associated with that treatment, the settings in which Medicaid covered treatment for infants with NAS are provided, and any Federal barriers for treating infants with NAS.
- Authorizing the Secretary of the U.S. Department of Health and Human Services (HHS) to convene an inter-agency, multi-stakeholder task force to review, revise if appropriate, and disseminate best practices for chronic and acute pain management.
- Establishing a grant program for the co-prescribing of opioid reversal drugs for patients who are at a high risk of overdose, and creating opioid overdose reversal co-prescribing guidelines.
- Reauthorizing residential treatment programs for pregnant and postpartum women and establishing a pilot grant program for state substance abuse agencies to support family based services with a primary diagnosis of a substance use disorder, which would include opioid addiction.
- Authorizing a demonstration program to help streamline licensure requirements for veterans who have already completed military emergency medical technician training to more easily meet civilian emergency medical technician licensure requirements.
- Expanding access to medication-assisted treatment (MAT), while ensuring that patients receive the full array of quality evidence-based services and minimizing the potential for drug diversion.
- Directing the Centers for Disease Control and Prevention (CDC) to study information and resources are available to youth athletes and their families regarding the dangers of opioid use and abuse, non-opioid treatment options, and how to seek addiction treatment.
- Authorizing grants to states for developing standing orders for naloxone prescriptions and educating health care professionals regarding the dispensing of opioid overdose reversal medication without person-specific prescriptions.
- Amending the Controlled Substances Act (CSA) to clarify when a prescription for a drug listed on Schedule II of the CSA may be partially filled.
- Requiring the U.S. Food and Drug Administration (FDA) to work closely with expert advisory committees before making critical product approval and labeling decisions.

- Encouraging the FDA to enhance the development and approval of opioids with abuse-deterrent properties and make recommendations regarding education programs for prescribers of extended-release and long-acting opioids.
- Requiring the HHS Secretary, in consultation with the Drug Enforcement Administration (DEA) and experts in opioid use disorder research and treatment, to perform a thorough review of opioid use disorder treatment services in the United States, including services provided in opioid treatment programs and other specialty and non-specialty settings.

## **B. Current Investigations**

The Subcommittee on Oversight and Investigations has initiated multiple bipartisan investigations related to the opioid epidemic this year.

### “Pill Dumping” Investigation

- Pill dumping, or distributing large amounts of controlled substances to a small population, preys on vulnerable citizens. On May 8, 2017, bipartisan leaders of the Committee sent letters to the leading wholesale drug distributors and the Drug Enforcement Administration (DEA), requesting detailed information about unusually large shipments of opioids to West Virginia.<sup>1</sup> For example, the town of Kermit, West Virginia, which has a population of about 400, received nearly 9 million hydrocodone pills in a two-year period.
- On September 25, 2017, bipartisan leaders of the Committee sent a letter to a wholesale drug distributor, Miami-Luken, Inc., requesting information and documents related to allegations by the DEA that the firm failed to maintain effective controls against diversion, or failed to disclose suspicious orders when it shipped opioids to West Virginia.<sup>2</sup>
- On October 13, 2017, bipartisan leaders of the Committee sent a second letter to the DEA highlighting considerable increases in the amount of hydrocodone and oxycodone that distributors provided to certain areas of West Virginia based on DEA’s data.<sup>3</sup> The Committee requested that the DEA produce pharmacy-specific and distributor-specific data for these areas, and key documents referenced in DEA enforcement actions.

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<sup>1</sup> Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy & Commerce, et al., to Hon. Chuck Rosenberg, Act. Admin., Drug Enforcement Administration, May 8, 2017, *available at*: <https://archives-energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/documents/20170508DEA.pdf>

<sup>2</sup> Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy & Commerce, et al., to Michael Faul, President & Chief Executive Officer, Miami-Luken, Inc., et al., September 25, 2017, *available at*: [https://energycommerce.house.gov/wp-content/uploads/2017/09/2010925Miami\\_Luken.pdf](https://energycommerce.house.gov/wp-content/uploads/2017/09/2010925Miami_Luken.pdf).

<sup>3</sup> Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy & Commerce, et al., to Robert W. Patterson, Act. Administrator, Drug Enforcement Administration, October 13, 2017, *available at*: <https://energycommerce.house.gov/wp-content/uploads/2017/10/20171013DEA.pdf>.

### Patient Broker Investigation

- On July 13, 2017, bipartisan leaders of the Committee sent a letter to HHS regarding reports of “patient brokers” who are serving as intermediaries and profiting from recruiting patients seeking addiction treatment.<sup>4</sup>

## **IV. ISSUES**

This hearing will provide a status update and review implementation of the provisions in CARA and the initiatives funded by the Opioid State Targeted Response (STR) grants, authorized in the *21st Century Cures Act*. In addition, this hearing will review other federal efforts to address the opioid crisis, additional steps Congress can take to augment those efforts, and address new and emerging issues in the fight against opioid abuse. Members will also have the opportunity to ask questions related to the Committee’s ongoing investigations into allegations of pill dumping and patient brokering.

## **V. STAFF CONTACTS**

If you have any questions regarding this hearing, please contact Kristen Shatynski, Caleb Graff, Danielle Steele, Adam Buckalew, or Paul Edattel of the Committee staff at (202) 225-2927. If you have any questions regarding the Committee’s ongoing investigations as they relate to this hearing, please contact Alan Slobodin, Brittany Havens, or Jen Barblan of the Committee staff at (202) 225-2927.

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<sup>4</sup> Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy & Commerce, et al., to The Hon. Thomas E. Price, Sec’y, U.S. Department of Health and Human Services, July 13, 2017, *available at*: <https://archives-energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/documents/20170713HHS.pdf>.