

February 26, 2018

TO: Members, Subcommittee on Health

FROM: Committee Majority Staff

RE: Hearing entitled “Combating the Opioid Crisis: Helping Communities Balance Enforcement and Patient Safety”

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## **I. INTRODUCTION**

The Subcommittee on Health will hold a hearing on Wednesday, February 28, 2018, at 1:00 p.m. in 2123 Rayburn House Office Building. The hearing is entitled “Combating the Opioid Crisis: Helping Communities Balance Enforcement and Patient Safety.”

## **II. WITNESSES**

### PANEL ONE

- Susan A. Gibson, Deputy Assistant Attorney, Diversion Control Division, Drug Enforcement Administration.

### PANEL TWO

- Frank L. Fowler, Chief of Police, Syracuse Police Department;
- Patrick M. Beardsley, Ph.D., Professor, Department of Pharmacology and Toxicology, Virginia Commonwealth University;
- John Mulder, M.D. F.A.A.H.P.M. H.M.D.-C., Director, Trillium Institute;
- Ponni Subbiah, M.D., Chief Medical Officer, Indivior PLC;
- David Y. Kan, M.D., President, California Society of Addiction Medicine;
- Richard J. Nance, L.C.S.W., Director, Utah County Department of Drug and Alcohol Prevention and Treatment;
- Thomas J. Cosgrove, Partner, Covington and Burling LLP;
- Andrew Kolodny, M.D., Co-Director, Opioid Policy Research, Brandeis University; and,
- Richard N. Logan, Jr., Pharm.D., Owner, L&S Pharmacy.

### III. BACKGROUND

Every day, an average of 115 Americans die from an opioid overdose.<sup>1</sup> In 2016, opioid overdose deaths—from both prescription and illicit drugs—were five times higher than in 1999, according to the latest data from the Centers for Disease Control and Prevention (CDC).<sup>2</sup> This same report found that West Virginia, Ohio, New Hampshire, Pennsylvania, and Kentucky are the five hardest hit states across the country. But no state is immune to the opioid epidemic.

The Subcommittee on Health held a Member day on October 11, 2017, where over 50 Members of Congress—Democratic and Republican—shared local and personal stories to highlight potential legislative solutions to combat the opioid crisis. This hearing is a continuation of the Energy and Commerce Committee’s previous and ongoing work, including enactment of the Comprehensive Addiction and Recovery Act, resources authorized to combat the opioid crises as part of 21st Century Cures, and hearings held in 2017 by the full Energy and Commerce Committee, Health Subcommittee, and Oversight and Investigation Subcommittee focused on combatting the opioid crises.

Specifically, the legislative hearing will focus on the Controlled Substances Act (CSA). Subsequent hearings will focus on legislation related to public health and prevention as well as insurance coverage-related bills.

### IV. ISSUES

The following issues may be examined at the hearing:

- **H.R. 2851, Stop the Importation and Trafficking of Synthetic Analogues (SITSA) Act**, authored by Rep. John Katko (R-NY), will give law enforcement tools to help get illicit synthetic drugs, like fentanyl, off our streets without compromising important public health and research protections. H.R. 2851 will also modernize scheduling guidelines to keep pace with the fast-changing nature of synthetic drugs. The language noticed for the hearing was approved by the House Committee on the Judiciary on July 12, 2017. The two areas of ongoing discussion are the desire of the public health community to maintain U.S. Food and Drug Administration (FDA) involvement in the scheduling process as well as accommodating legitimate exemptions for Drug Enforcement Administration (DEA) license holders who may be conducting research on scheduled substances or housing certain analogue substances within their chemical library without prior knowledge.
- **H.R. 5041, Safe Disposal of Unused Medication Act**, authored by Rep. Tim Walberg (R-MI) and Rep. Debbie Dingell (D-MI), will help reduce the number of unused controlled substances at risk of diversion or misuse by allowing hospice workers to safely

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<sup>1</sup> Rudd RA, Seth P, David F, Scholl L. Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–2015. *MMWR Morb Mortal Wkly Rep.* ePub: 16 December 2016. DOI: <http://dx.doi.org/10.15585/mmwr.mm655051e1>.

<sup>2</sup> Centers for Disease Control and Prevention. “Drug Overdose Death Data.” December 19, 2017. Retrieved from: <https://www.cdc.gov/drugoverdose/data/statedeaths.html>.

dispose of these medications in patients' homes. Areas of focus include clarifying the definition of hospice employee and hospice volunteer; reviewing licensing and training standards; and, considering record keeping requirements.

- **H.R. \_\_, Ensuring Patient Access to Substance Use Disorder Treatments Act of 2018**, a discussion draft written by Rep. Ryan Costello (R-PA) and Rep. Rick Nolan (D-MN) will update federal law to improve dispensing of implantable and injectable therapies – developed to make abuse, misuse, and diversion more difficult.
- **H.R. \_\_, Special Registration for Telemedicine Clarification Act of 2018**, a discussion draft written by Rep. Buddy Carter (R-GA) and Rep. Cheri Bustos (D-IL) will clarify telemedicine waivers. Federal law permits the Attorney General to issue a special registration to health care providers to prescribe controlled substances via telemedicine in legitimate emergency situations, such as a lack of access to an in-person specialist. Unfortunately, the waiver process has never been implemented through regulation, and some patients do not have the emergency access they need to treatment. This bipartisan draft directs the Attorney General, with the Secretary of Health and Human Services, to promulgate interim final regulations within 30 days of passage of the law.
- **H.R. \_\_, Improving Access to Remote Behavioral Health Treatment Act of 2018**, a discussion draft written by Rep. Gregg Harper (R-MS) and Rep. Doris Matsui (D-CA) will expand access for patients in rural and underserved communities who may live near community mental health or addiction treatment centers, but not a hospital or state-licensed clinic. Without a DEA registration, these health facilities do not qualify for the Ryan Haight Act's telemedicine exception, and are unable to provide care to patients in need. This proposal would direct the Attorney General, with the Secretary of Health and Human Services, to promulgate interim final regulations within 120 days of passage of the law for these treatment facilities to register with the DEA to engage in the practice of telemedicine. The discussion draft amends section 102(54) of the CSA, which is the definition of "practice of telemedicine." Members may consider if it is also necessary to amend 309(e) of the CSA, pertaining to controlled substances delivered, distributed, or dispensed by means of the Internet.
- **H.R. \_\_, Tableting and Encapsulating Machine Regulation Act of 2018**, authored by Rep. David Kustoff (R-TN), will make it tougher to traffick synthetic drugs. This bill will give the DEA the authority to regulate the use of tableting and encapsulating machines with requirements for the maintenance of records, inspections for verifying location and stated use, and security provisions. The intent of the discussion draft is to end the use of pill presses to produce counterfeit drugs and not create a burden on legitimate industries. This is a recommendation of The President's Commission on Combating Drug Addiction and the Opioid Crisis.<sup>3</sup>

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<sup>3</sup> The President's Commission on Combatting Drug Addiction and the Opioid Crisis. November 1, 2017. Retrieved from: [https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final\\_Report\\_Draft\\_11-15-2017.pdf](https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-15-2017.pdf).

- **H.R. 2063, Opioid Preventing Abuse through Continuing Education (PACE) Act of 2017**, authored by Rep. Brad Schneider (D-IL), aims to improve provider understanding of pain management treatment guidelines and best practices, early detection of opioid addiction, and the treatment and management of opioid-dependent patients by requiring 12 hours of continuing medical education on the topic every three years. Members may inquire whether decisions on continuing medical education curriculum and course selection should be made at the state or federal level.
- **H.R. 4275, Empowering Pharmacists in the Fight Against Opioid Abuse Act**, authored by Rep. Mark DeSaulnier (D-CA) and Rep. Buddy Carter (R-GA), will help pharmacists detect fraudulent prescriptions. H.R. 4275 will help develop and disseminate materials, giving pharmacists greater understanding and ability to decline to fill controlled substances when they suspect the prescriptions are fraudulent, forged, or appear to be for abuse or diversion. Some members have questioned if the Secretary of Health and Human Services is better equipped than the Administrator of the DEA to originate this information.

#### **V. STAFF CONTACTS**

If you have any questions regarding this hearing, please contact Paul Edattel, Josh Trent, or Adam Buckalew of the Committee staff at (202) 225-2927.