

March 19, 2018

TO: Members, Subcommittee on Health

FROM: Committee Majority Staff

RE: Hearing entitled “Combating the Opioid Crisis: Prevention and Public Health Solutions”

I. INTRODUCTION

The Subcommittee on Health will hold a hearing on Wednesday, March 21, 2018, at 9:00 a.m. in 2123 Rayburn House Office Building. The hearing will continue Thursday, March 22, 2018 at 10:00 a.m. in 2123 Rayburn House Office Building. The hearing is entitled “Combating the Opioid Crisis: Prevention and Public Health Solutions.”

II. WITNESSES

The following panels of witnesses have been invited to testify. The makeup and order of the panels are subject to change.

MARCH 21, PANEL ONE

- Scott Gottlieb, MD, Commissioner, Food and Drug Administration;
- Anne Schuchat, MD (RADM, USPHS), Acting Director, Centers for Disease Control and Prevention; and
- Christopher M. Jones, PharmD, MPH, Director of the National Mental Health and Substance Use Policy Laboratory, Substance Abuse and Mental Health Services Administration.

MARCH 21, PANEL TWO

- Patrick J. Kennedy, former Member (RI), U.S. House of Representatives, Founder, The Kennedy Forum;
- Sue Thau, Public Policy Consultant, Community Anti- Drug Coalitions of America;
- Cartier Esham, Executive Vice President, Emerging Companies, Biotechnology Innovation Organization;
- Jeffrey Francer, Senior Vice President and General Counsel, Association for Accessible Medicines; and

- John W. Holaday, PhD, Chairman & Co-Founder, DisposeRx.

MARCH 22, PANEL ONE

- Eric C. Strain, MD, Director, Center for Substance Abuse Treatment and Research, Johns Hopkins University School of Medicine;
- Kenneth J. Martz, PsyD MBA, Special Projects Consultant, Gaudenzia, Inc.;
- Brad Bauer, Senior Vice President of New Business Development and Customer Relationship Management, Appriss Health;
- William Banner, MD, PhD, Medical Director, Oklahoma Center for Poison and Drug Information; Board President, American Association of Poison Control Centers; and
- Michael E. Kilkenny, MD, MS, Physician Director, Cabell-Huntington Health Department of West Virginia.

MARCH 22, PANEL TWO

- Jessica Hulsey Nickel, Founder, President and Chief Executive Officer, Addiction Policy Forum;
- Ryan Hampton, Recovery Advocate, Facing Addiction;
- Carlene Deal-Smith, Peer Support Specialist, Presbyterian Medical Services;
- Mark Rosenberg, DO, MBA, FACEP, FAAHPM, Chairman of Emergency Medicine and Chief Innovation Officer, St Joseph's Healthcare System; Board of Directors, American College of Emergency Physicians;
- Stacy Bohlen, CEO, National Indian Health Board; and
- Alexis Horan, Vice President of Government Relations, Clean Slate Centers.

III. BACKGROUND

On average, 115 Americans die from an opioid overdose every day.¹ 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).² The

¹ Rudd RA, Seth P, David F, Scholl L, Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–2015. *Morbidity and Mortality Weekly Report*. 65: 1445–1452 (2016). Available at <http://dx.doi.org/10.15585/mmwr.mm655051e1>.

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

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 initiative continued the Energy and Commerce Committee’s work to combat the opioid crisis, including the enactment of the Comprehensive Addiction and Recovery Act and the 21st Century Cures Act, and related hearings held the 115th Congress.

IV. LEGISLATION

The Subcommittee will review the following legislation:

- **H.R. 449, Synthetic Drug Awareness Act**, authored by Rep. Hakeem Jeffries (D-NY), will require the United States Surgeon General to submit a comprehensive report to Congress on the public health effects of the rise in synthetic drug use among youth aged 12 to 18 in order to further educate parents and the medical community on the health effects of synthetic drugs. Synthetic drugs, such as synthetic cannabinoids (Spice, K2), cathinones (Bath Salts), and psychedelic phenethylamines (N-Bomb) are produced in the lab and can have chemical structures that can be either identical to or different from naturally occurring drugs.³ Their effects are designed to mimic or even enhance those of natural drugs. Synthetic drugs can be modified to circumvent the Drug Enforcement Administration’s (DEA) scheduling regime. Fentanyl, a substance that is 50 times more potent than heroin and 100 times more potent than morphine, has numerous analogs.⁴ Before DEA’s recently issued order to schedule *all* fentanyl-related compounds under Schedule I, when the agency would temporarily control one given fentanyl substance, illicit manufacturers abroad would produce new analogs through minor structural modifications to be smuggled and distributed as a purportedly “noncontrolled substances.”
- **H.R. 5002, Advancing Cutting Edge (ACE) Research Act**, authored by Rep. Debbie Dingell (D-MI) and Rep. Fred Upton (R-MI), will provide the National Institutes of Health (NIH) with new, flexible authorities to conduct innovative research spur urgently needed research on new, non-addictive pain medications.
- **H.R. __, FDA Accelerated Approval and Breakthrough Therapy Status**, help make these pathways available to take on the opioid crisis. Several approaches have proven successful in speeding the availability of treatments for serious diseases through the Food and Drug Administration (FDA). The FDA accelerated approval program facilitates faster approval of medications using surrogate endpoints for serious conditions where there is an unmet medical need. The breakthrough therapy pathway is a process designed to expedite the development and review of drugs which may demonstrate substantial improvement over available therapy.

³ Sacco LN and Finklea K, Synthetic Drugs: Overview and Issues for Congress. *Congressional Research Service R42066*. May 3, 2016. Available at <http://www.crs.gov/reports/pdf/R42066>.

⁴ Centers for Disease Control & Prevention, Injury Prevention & Control. “Opioid Overdose, Synthetic Opioid Data.” December 16, 2016. Available at <https://www.cdc.gov/drugoverdose/data/fentanyl.html>.

- **H.R. __, FDA Opioid Sparing**, authored by Rep. Barbara Comstock (R-VA), will direct the Food and Drug Administration (FDA) to establish clear data collection methods for opioid-sparing labeling claims for products that may replace, delay, or reduce the use of opioid analgesics. While there may be alternatives to opioids for certain patients and conditions, there is a need for additional clarity and flexibility regarding what drug developers need to do to show that their products can spare certain patients from opioids as a part of their treatment regimen.
- **H.R. __, FDA Packaging and Disposal**, authored by Rep. Richard Hudson (R-NC), will direct the FDA to work with manufacturers to establish programs for efficient return or destruction of unused Schedule II drugs, with an emphasis on opioids. These methods could include mail-back pouches to secure facilities for incineration, or methods to immediately inactivate or render unattractive unused drugs. In addition, this bill will facilitate utilization of packaging that may reduce overprescribing of opioids. Finally, the bill will require the Government Accountability Office (GAO) to study new and innovative technologies that claim to be able to safely dispose of opioids and other unused medications. GAO would review and detail the effectiveness of these disposal methods. According to the Substance Abuse and Mental Health Services Administration (SAMHSA), about 10.7 million people aged 12 or older misused prescription pain relievers annually. Of those who misused, over half surveyed indicated they obtained the pain relievers from a friend or relative.⁵ Safe and proper disposal of opioids and other unused prescription drugs can prevent these substances from getting into the wrong hands.
- **H.R. __, FDA and International Mail**, authored by Rep. Marsha Blackburn (R-TN), will streamline and enhance FDA's tools to intercept illegal products. Illicit or unapproved drugs enter the U.S. supply chain through International Mail Facilities (IMFs) and pose serious public health threats to individuals across the country.
- **H.R. __, FDA Misuse/Abuse**, authored by Rep. Gene Green (D-TX), will strengthen FDA's authority to consider the misuse and abuse of a controlled substance when determining if its overall benefits outweigh the risks. Under current law, FDA evaluates drugs for safety and efficacy for their intended use when reviewing new drug applications. Clarifying FDA's authority to consider misuse and abuse as part of the drug approval and assessment process for opioids would augment the Agency's capacity to take necessary action to minimize the public health consequences of opioid misuse and abuse.
- **H.R. __, FDA Long-term Efficacy**, authored by Rep. Jerry McNerney (D-CA), will enhance FDA's authorities and enforcement tools to ensure timely post-marketing studies for chronically administered opioids. Currently, there is limited data on the long-term efficacy of opioids, their increased addictive tendencies over time, and their overall place in the treatment of pain.

⁵ Lipari RN and Hughs, A. How People Obtain the Prescription Pain Relievers They Misuse. *National Survey on Drug Use and Health CBHSQ Report*. January 12, 2017. Available at https://www.samhsa.gov/data/sites/default/files/report_2686/ShortReport-2686.html.

- **An Amendment in the Nature of a Substitute (AINS) to H.R. 4284, Indexing Narcotics, Fentanyl, and Opioids (INFO) Act**, authored by Rep. Bob Latta (R-OH), will direct the Department of Health and Human Services (HHS) to create a public and easily accessible electronic dashboard linking to all of the nationwide efforts to combat the opioid crisis. The AINS will also create an Interagency Substance Use Disorder Coordinating Committee to review and coordinate opioid use disorder (OUD) and other substance use disorder (SUD) research, services, and prevention activities across all relevant Federal agencies, evaluate the effectiveness of these activities, and make specific recommendations for actions that agencies can take to better coordinate the administration of services for patients with OUD and SUD.
- **H.R. 5272, Reinforcing Evidence-Based Standards Under Law in Treating Substance Abuse (RESULTS) Act**, authored by Rep. Steve Stivers (R-OH) and Rep. Eliot Engel (D-NY), will require that entities applying for Federal funding used to support programs or activities that address mental health or SUD, submit materials to HHS demonstrating that the programs or activities are evidence-based.
- **H.R. 5009, Jessie’s Law**, authored by Rep. Tim Walberg (R-MI), Rep. Debbie Dingell (D-MI), and Rep. Bob Latta (R-OH), will ensure medical professionals have access to a consenting patient’s complete health information when making treatment decisions by requiring HHS to develop and disseminate best practices regarding the prominent display of SUD history in records of patients who have previously provided this information to a health care provider.
- **AINS to H.R. 3545, Overdose Prevention and Patient Safety Act**, authored by Rep. Markwayne Mullin (R-OK), will permit SUD records to be shared without patient consent, in accordance with the Health Insurance Portability and Accountability Act (HIPAA), for the purposes of treatment. The bill will also enhance the penalties in the event of disclosure SUD records, add breach notification requirements, and provide discrimination prohibitions to protect people seeking and receiving SUD treatment. Federal confidentiality law and regulations (42 CFR Part 2, or “Part 2”) were enacted over three decades ago after Congress recognized that stigma associated with SUD and fear of prosecution deterred people from entering treatment.
- **H.R. __, to enhance and improve state-run prescription drug monitoring programs**, authored by Rep. Morgan Griffith (R-VA) and Rep. Frank Pallone (D-NJ) will improve current Federal support for state-run prescription drug monitoring programs (PDMPs) by authorizing the CDC to carry out certain controlled substances overdose prevention and surveillance activities in order to improve data collection and integration into physician clinical workflow so that timely, complete, and accurate information will get into the hands of providers and dispensers so that they can make the best clinical decisions for their patients.
- **H.R. __, Poison Center Network Enhancement Act**, authored by Rep. Susan Brooks (R-IN) and Rep. Eliot Engel (D-NY), will reauthorize the national network of Poison

Control Centers that offer free, confidential, expert medical advice 24 hours a day, seven days a week, oftentimes serving as the primary resource for poisoning information, and helping reduce ER visits through in-home treatment. Over two million poisonings are reported annually to poison control centers.⁶ The National Poison Data System has reported year over year increases in all analgesic exposures, including opioids and sedatives, with 9,039 opioid exposures reported to poison control centers in one month alone.⁷

- **H.R. __, Eliminating Opioid-Related Infectious Diseases Act**, authored by Rep. Leonard Lance (R-NJ), Rep. Joe Kennedy (D-MA), Rep. Chris Collins (R-NY), Rep. Anna Eshoo (D-CA), Rep. Joe Barton (R-TX), and Rep. Doris Matsui (D-CA), will authorize the CDC to undertake an injection drug use-associated infection elimination initiative and work with states to improve education, surveillance, and treatment of infections associated with injection drug-use. Injection drug use is a well-known route for the transmission of blood borne infections, particularly human immunodeficiency virus (HIV) and hepatitis. According to the CDC, in the United States, approximately 7 percent of new HIV cases, 50 percent of new hepatitis C virus (HCV) cases, and 2 percent of hepatitis A cases are associated with illicit injection of drugs.^{8,9} Within the course of one year in the state of Indiana, HIV infection was diagnosed in 181 patients, most of whom (87.8 percent) reported having injected the extended-release formulation of the prescription opioid oxycodone, and 92.3 percent were coinfecting with HCV.¹⁰
- **H.R. __, to improve fentanyl testing and surveillance**, authored by Rep. Anne Kuster (D-NH), will authorize grants to Federal, state, and local agencies for the establishment or operation of public health laboratories to detect fentanyl, its analogs, and other synthetic opioids.
- **H.R. 5261, Treatment, Education, And Community Help (TEACH) to Combat Addiction Act**, authored by Rep. Bill Johnson (R-OH) and Rep. Paul Tonko (D-NY), will authorize HHS to designate and support Centers of Excellence, or institutions of learning that have championed SUD treatment and pain management education to improve how health professionals are taught about both SUD and pain. According to the National Academies of Sciences, Engineering, and Medicine, schools for health professional education, professional societies, and state licensing boards should develop

⁶ Gummin DD, Mowry JB, Spyker DA, Brooks DE, Fraser MO, Banner W, 2016 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 34th Annual Report. *Clinical Toxicology*. 55: 1072-1252 (2017). Available at <https://www.ncbi.nlm.nih.gov/pubmed/29185815>.

⁷ American Association of Poison Control Centers. "Opioid Exposures." January 1, 2018. Available at <http://www.aapcc.org/alerts/opioids/>.

⁸ Belani H, et al, Integrated Prevention Services for HIV Infection, Viral Hepatitis, Sexually Transmitted Diseases, and Tuberculosis for Persons Who Use Drugs Illicitly: Summary Guidance from CDC and the U.S. Department of Health and Human Services. *Morbidity and Mortality Weekly Report*. 61: 1-40 (2012). Available at https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6105a1.htm?s_cid=rr6105a1_w.

⁹ Spiller MW, Broz D, Wejnert C, Nerlander L, Paz-Bailey G, HIV Infection and HIV-Associated Behaviors Among Persons Who Inject Drugs — 20 Cities, United States, 2012. *Morbidity and Mortality Weekly Report*. 64: 270-275 (2015). Available at <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6410a3.htm>.

¹⁰ Peters PJ, et al, HIV Infection Linked to Injection Use of Oxycodone in Indiana, 2014–2015. *The New England Journal of Medicine*. 375: 229-239 (2016). Available at <http://www.nejm.org/doi/full/10.1056/NEJMoa1515195>.

evidence-based approaches to pain education and provide basic training in the treatment of opioid use disorder for health care providers.¹¹

- **H.R. __, Comprehensive Opioid Recovery Centers Act**, a discussion draft authored by Rep. Brett Guthrie (R-KY) and Rep. Gene Green (D-TX) will help support the establishment of Comprehensive Opioid Recovery Centers (CORCs) to serve as models for comprehensive treatment and recovery. CORCs would utilize the full range of FDA-approved medications and evidence-based treatments, have strong linkages with the community, generate meaningful outcomes data, and dramatically improve the opportunities for individuals to establish and maintain long-term recovery as productive members of society.
- **H.R. 4684, Ensuring Access to Quality Sober Living Act**, authored by Rep. Judy Chu (D-CA), Rep. Mimi Walters (R-CA), Rep. Gus Bilirakis (R-FL), and Rep. Raul Ruiz (D-CA), will authorize SAMHSA to develop, publish, and disseminate best practices for operating recovery housing that promotes a safe environment and sustained recovery from SUD. Recovery housing can provide a safe, structured, and supportive environment for people in recovery from an SUD. These alcohol- and drug-free housing arrangements typically take the form of “ordinary housing, located in residentially zoned areas and distinguished only by the residents” shared commitment not to use alcohol or other drugs.¹² Unfortunately, an increasing number of reports have revealed the nefarious practice of patient brokering where individuals known as “patient brokers” treat men and women with SUD as a commodity by pushing them to seek treatment at certain outpatient facilities and to live at affiliated recovery residences while undergoing treatment. In exchange for steering patients towards said facilities and/or housing, patient brokers receive generous financial kickbacks. Usually, the recovery residence and the treatment center involved in the kickback scheme lack any oversight, transparency, and accountability.
- **H.R. __, to support the peer support specialist workforce**, authored by Rep. Ben Ray Lujan (D-NM) and Rep. Bill Johnson (R-OH), will enhance the Comprehensive Addiction and Recovery Act’s Building Communities of Recovery Program and authorize HHS to award grants to peer support specialist organizations for the development and expansion of recovery services. Peer support specialists/peer recovery coaches are health workers who are in recovery from an SUD. New programs are emerging across the country to use peers in a range of settings, including hospitals, to provide immediate and ongoing support and treatment linkages to individuals who have overdosed from opioids, or support individuals newly in recovery.
- **H.R. 5176, Preventing Overdoses While in Emergency Rooms (POWER) Act**, authored by Rep. David McKinley (R-WV) and Rep. Michael Doyle, will provide

¹¹ National Academies of Sciences, Engineering, and Medicine. “Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use.” July 13, 2017. Available at <http://nationalacademies.org/hmd/Reports/2017/pain-management-and-the-opioid-epidemic.aspx>

¹² Wittman, FD, Affordable Housing for People with Alcohol and Other Drug Problems. *Contemporary Drug Problems*. 541 (1993). Available at <http://heinonline.org/HOL/LandingPage?handle=hein.journals/condp20&div=35&id=&page=>.

resources for hospitals to develop protocols on discharging patients who have presented with an opioid overdose. These protocols would address the provision of naloxone upon discharge, connection with peer-support specialists, and the referral to treatment and other services that best fit the patient's needs. SAMHSA has identified individuals discharged from emergency medical care following opioid poisoning as a very vulnerable patient group in terms of opioid risks. For patients brought to the emergency room (ER) with uncontrolled blood pressure, asthma, or neglected diabetes, doctors often start treatment immediately. This is usually not the case for patients with SUD presenting with an opioid overdose. Having protocols in place that connect the patient to SUD treatment is a cost-effective way to treat patients in hospital emergency rooms.¹³

- **H.R. 5197, Alternatives to Opioids (ALTO) in the Emergency Department Act**, authored by Rep. Bill Pascrell, Jr (D-NJ) and Rep. David McKinley, will establish a demonstration program to test alternative pain management protocols to limit to use of opioids in hospital emergency departments. According to the CDC, emergency physicians have a “unique opportunity to engage in prevention of a future overdose, particularly for patients who may not have had other contact with the health care system.”¹⁴ By promoting the use of non-opioid alternatives to manage pain, ERs can importantly serve as one of the first lines of defense against the opioid crisis.
- **H.R. 5140, Tribal Addiction and Recovery Act of 2018 (TARA)**, authored by Rep. Markwayne Mullin (R-OK), will make tribes, like states, eligible to be direct grantees of this funding to fight the opioid epidemic in Indian Country. Tribes would receive their own \$25 million allocation, which they could apply directly to the Federal government to receive, instead of having to go through their states. The 21st Century Cures Act authorized \$1 billion over two years in State Targeted Response to the Opioid Crisis Grants to help states offer prevention, treatment, and recovery services to those in need¹⁵. However, American Indian and Alaska Native communities are currently unable to directly access these resources.
- **H.R. 5102, Substance Use Disorder Workforce Loan Repayment Act**, authored by Rep. Katherine Clark (D-MA), Rep. Harold Rogers (R-KY), Rep. John Sarbanes (D-MD), and Rep. Brett Guthrie (R-KY), will create a loan repayment program for SUD treatment providers. The bill will offer student loan repayment of up to \$250,000 for participants who agree to work as a SUD treatment professional in areas most in need of their services. The program will be available to a wide range of direct care providers, including physicians, registered nurses, social workers, and other behavioral health professionals. Serious workforce shortages exist for health professionals and paraprofessionals across the United States. According to SAMHSA, in 2012, the turnover rates in the addiction services workforce ranged from 18.5 percent to over 50

¹³ Busch SH, et al, Cost-effectiveness of emergency department-initiated treatment for opioid dependence. *Addiction*. 112: 2002–2010 (2017). Available at

<http://onlinelibrary.wiley.com/doi/10.1111/add.13900/abstract;jsessionid=C64B00FAE33F1920471223B396D1FD53.f03t03>.

¹⁴ Axeen S, Seabury SA, Menchine M, Emergency Department Contribution to the Prescription Opioid Epidemic. *Annals of Emergency Medicine*. (2018) DOI: 10.1016/j.annemergmed.2017.12.007.

¹⁵ Public Law No: 114-255

percent.¹⁶ In a recent survey, nearly half of clinical directors in agencies specializing in SUD treatment acknowledged that they had difficulty filling open positions, primarily because of a lack of qualified applicants.¹⁷

- **AINS to H.R. 3692, Addiction Treatment Access Improvement Act**, authored by Rep. Paul Tonko (D-NY) and Rep. Ben Ray Lujan (D-NM), will expand access to medication-assisted treatment (MAT) by allowing clinical nurse specialists, certified nurse midwives, and certified registered nurse anesthetists to prescribe buprenorphine and permanently authorize non-physician providers to prescribe buprenorphine. The bill would also codify regulations that increased the cap on the number of patients a physician can treat with buprenorphine to 275 patients. SUD treatment remains largely segregated from the rest of health care and serves only a fraction of those in need of treatment. Only about 10 percent of those with SUD receive any type of specialty treatment.¹⁸

V. STAFF CONTACTS

If you have any questions regarding this hearing, please contact Paul Edattel, Kristen Shatynski, or Danielle Steele of the Committee staff at (202) 225-2927.

¹⁶ Substance Abuse and Mental Health Services Administration. "Workforce." September 15, 2017. Available at <https://www.samhsa.gov/workforce>.

¹⁷ Addiction Technology Transfer Center Network. "Vital Signs: Taking the Pulse of the Addiction Treatment Profession." September 28, 2012. Available at <http://attcnetwork.org/documents/VitalSignsReport.pdf>.

¹⁸ Ahrnsbrak R, Bose J, Hedden SL, Lipari RN, Park-Lee E. Key substance use and mental health indicators in the United States: Results from the 2016 National Survey on Drug Use and Health. *National Survey on Drug Use and Health Series H-52*. September 2017. Available at <https://www.samhsa.gov/data/sites/default/files/NSDUH-FFR1-2016/NSDUH-FFR1-2016.pdf>.