

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

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MEMORANDUM

March 19, 2018

To: Subcommittee on Health Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: Hearing on “Combatting the Opioid Crisis: Prevention and Public Health Solutions”

On **Wednesday, March 21st, at 9:00 a.m. in Room 2123 of the Rayburn House Office Building**, the Subcommittee will hold a legislative hearing titled “Combatting the Opioid Crisis: Prevention and Public Health Solutions.” Following the first two panels, the hearing will reconvene on Thursday, March 22nd, at 10:00 a.m. in Room 2123 of the Rayburn House Office Building. The hearing will examine 25 bills:

- H.R. 449, Synthetic Drug Awareness Act (Panel I and II)
- H.R. 5002, Advancing Cutting Edge Research Act (Panel I and II)
- H.R. 5009, Jessie’s Law (Panel I and III)
- H.R. 5102, Substance Use Disorder Workforce Loan Repayment Act (Panel I and IV)
- H.R. 5140, Tribal Addiction and Recovery Act (Panel I and IV)
- H.R. 5176, Preventing Overdoses While in Emergency Rooms Act (Panel I and IV)
- H.R. 5197, Alternatives to Opioids in the Emergency Department Act (Panel I and IV)
- H.R. 5261, Treatment, Education, and Community Help to Combat Addiction Act (Panel I and IV)
- H.R. 5272, Reinforcing Evidence-Based Standards Under Law in Treating Substance Abuse Act (Panel I)
- Discussion Draft of H.R. __, Poison Center Network Enhancement Act (Panel I and III)
- Discussion Draft of H.R. __, A Bill to Improve Fentanyl Testing and Surveillance (Panel I and III)
- Discussion Draft of H.R. __, Eliminating Opioid-Related Infectious Diseases Act (Panel I and III)

- Discussion Draft of H.R. __, Comprehensive Opioid Recovery Centers Act (Panel I and IV)
- Discussion Draft of H.R. __, A Bill to Enhance and Improve State-run Prescription Drug Monitoring Programs (Panel I and III)
- Discussion Draft of H.R. __, A Bill to Support the Peer Support Specialist Workforce (Panel I and IV)
- Discussion Draft of H.R. __, FDA Accelerated Approval and Breakthrough Therapy Status (Panel I and II)
- Discussion Draft of H.R. __, FDA and International Mail (Panel I and II)
- Discussion Draft of H.R. __, FDA Opioid Sparing (Panel I and II)
- Discussion Draft of H.R. __, FDA Packaging and Disposal (Panel I and II)
- Discussion Draft of H.R. __, FDA Long-term Efficacy (Panel I and II)
- Discussion Draft of H.R. __, FDA Misuse/Abuse (Panel I and II)
- H.R. 4684, Ensuring Access to Quality Sober Living Act (Panel I and IV)
- Amendment in the Nature of a Substitute to H.R. 3692, Addiction Treatment Access Improvement Act (Panel I and IV)
- Amendment in the Nature of a Substitute to H.R. 3545, Overdose Prevention and Patient Safety Act (Panel I and III)
- Amendment in the Nature of a Substitute to H.R. 4284, Indexing Narcotics, Fentanyl, and Opioids Act (Panel I)

I. H.R. 449, SYNTHETIC DRUG AWARENESS ACT OF 2017

Introduced by Reps. Jeffries (D-NY), Collins (R-NY), Butterfield (D-NC), Gowdy (R-SC), and Meehan (D-PA), H.R. 449 would require the Surgeon General to report on the public health impacts of synthetic drug use and abuse by adolescents between the ages of 12 and 18.

II. H.R. 5002, ADVANCING CUTTING EDGE (ACE) RESEARCH ACT

Introduced by Reps. Dingell (D-MI) and Upton (R-MI), H.R. 5002 would extend the National Institutes of Health (NIH) existing other transactions authority to projects related to the prevention, diagnosis, or treatment of diseases and disorders, or research urgently needed to respond to a public health threat.

III. H.R. 5009, JESSIE’S LAW

Introduced by Reps. Walberg (R-MI) and Dingell (D-MI), H.R. 5009 would require the Department of Health and Human Services (HHS) to convene appropriate stakeholders to develop best practices for displaying opioid use disorder history prominently on a patients’ medical records, when requested by a patient.

IV. H.R. 5102, SUBSTANCE USE DISORDER WORKFORCE LOAN REPAYMENT ACT OF 2018

Introduced by Reps. Clark (D-MA), Rogers (R-KY), Sarbanes (D-MD), and Guthrie (R-KY), H.R. 5102 would create a substance abuse disorder workforce loan repayment program.

The bill would provide loan repayment for providers who serve in Mental Health Professional Shortage Areas or a county where the running three-year average of mean overdose death rate is higher than the national average. Providers can receive loan repayment for up to six years of service and up to a total of \$250,000. The bill also authorizes \$25 million per year for fiscal years 2019 through 2028.

V. H.R. 5140, TRIBAL ADDICTION AND RECOVERY ACT

Introduced by Rep. Mullin (R-OK), H.R. 5140 would amend the State Targeted Response to the Opioid Abuse Crisis program created by the 21st Century Cures Act to provide \$25 million in funding for grants to Indian tribes and tribal organizations.

VI. H.R. 5176, PREVENTING OVERDOSES WHILE IN EMERGENCY ROOMS ACT

Introduced by Reps. McKinley (R-WV) and Doyle (D-PA), H.R. 5176 would require HHS to award grants to not more than 20 eligible health care sites to establish protocols and procedures that result in a “warm” handoff between an emergency department and substance abuse treatment provider for patients treated in the emergency department for non-fatal overdose.

VII. H.R. 5197, ALTERNATIVES TO OPIOIDS (ALTO) IN THE EMERGENCY DEPARTMENT ACT

Introduced by Reps. Pascrell (D-NJ), McKinley (R-WV), DeGette (D-CO), and Tipton (R-CO), H.R. 5197 would direct the Substance Abuse and Mental Health Services Administration (SAMHSA) to award grants to hospitals and emergency departments to develop and implement alternative pain management protocols that limit the use of opioids in hospital-based emergency departments. The bill authorizes \$10 million per year for fiscal years 2019 through 2021.

VIII. H.R. 5261, TREATMENT, EDUCATION, AND COMMUNITY HELP TO COMBAT (TEACH) ADDICTION ACT

Introduced by Reps. Johnson (R-OH) and Tonko (D-NY), H.R. 5261 would require HHS to enter into cooperative agreements to establish Regional Centers of Excellence for Substance Use Disorder Education. These centers would develop, evaluate, and distribute evidence-based curriculum on pain management and substance use disorders for health professional schools. The bill would codify NIH’s Centers of Excellence in Pain Education. The bill would provide \$2 million each year for fiscal years 2019 through 2023 for each program.

IX. H.R. 5272, REINFORCING EVIDENCE-BASED STANDARDS UNDER LAW IN TREATING SUBSTANCE ABUSE (RESULTS) ACT

Introduced by Reps. Stivers (R-OH) and Engel (D-NY), H.R. 5272 would require HHS treatment and prevention programs for mental health or substance use disorders to be evidence-based unless HHS provides a waiver. Such waivers can be provided to emergent and innovative

programs that will contribute to the knowledge that is needed for programs to become evidence based.

X. DISCUSSION DRAFT OF H.R. ___, POISON CENTER NETWORK ENHANCEMENT ACT OF 2018

Authored by Reps. Brooks (R-IN) and Engel (D-NY), the discussion draft would reauthorize the Health Resources and Services Administration's (HRSA) Poison Control Center program. The proposal would authorize \$700,000 for each of fiscal years 2020 through 2024 for the establishment and maintenance of a national toll-free number, reauthorize the Nationwide Public Awareness Campaign by providing \$800,000 for each of fiscal years 2020 through 2024, and reauthorize the Poison Control Center grant program by providing \$29,600,000 for each of fiscal years 2020 through 2024.

XI. DISCUSSION DRAFT OF H.R. ___, A BILL TO IMPROVE FENTANYL TESTING AND SURVEILLANCE

Authored by Rep. Kuster (D-NH), the discussion draft would provide \$15 million in grants to federal, state, and local agencies to establish or operate public health laboratories to detect fentanyl, its analogues, or other synthetics. The proposal would authorize \$10 million to enhance and expand the Centers for Disease Control and Prevention's (CDC) drug surveillance program to all 50 states and to increase detection and surveillance of fentanyl, its analogues, or other synthetics. The proposal would also authorize \$5 million to establish a pilot program to test point-of-care fentanyl testing. Each program will be authorized for each of fiscal years 2018 through 2022.

XII. DISCUSSION DRAFT OF H.R. ___, ELIMINATING OPIOID-RELATED INFECTIOUS DISEASES ACT

Authored by Rep. Lance (R-NJ), the discussion draft would authorize \$40 million for fiscal years 2019 through 2023 for the CDC to improve surveillance of infections associated with intravenous drug use (IVDU), such as HIV and Hepatitis C, develop and distribute public educational materials on risks associated with IVDU, and improve the education and training of healthcare professionals on the detection and treatment of IVDU associated infections.

XIII. DISCUSSION DRAFT OF H.R. ___, COMPREHENSIVE OPIOID RECOVERY CENTERS ACT OF 2018

Authored by Rep. Guthrie (R-KY), the discussion draft would require SAMHSA to provide grants for the purpose of developing comprehensive opioid recovery centers. Centers that receive such grants will have to provide or coordinate the provision of certain outreach, treatment, or recovery activities.

XIV. DISCUSSION DRAFT OF H.R. ___, A BILL TO ENHANCE AND IMPROVE STATE-RUN PRESCRIPTION DRUG MONITORING PROGRAMS

Authored by Reps. Griffith (R-VA) and Pallone (D-NJ), the discussion draft would codify the CDC's Prevention for States Program and Enhanced Surveillance of Controlled Substance Overdose Program. The proposal would also integrate the National All Scheduled Prescription Electronic Reporting (NASPER) Act into the CDC program.

XV. DISCUSSION DRAFT OF H.R. ___, A BILL TO SUPPORT THE PEER SUPPORT SPECIALIST WORKFORCE

Authored by Reps. Luján (D-NM) and Johnson (R-OH), the discussion draft would amend the Communities of Recovery program authorized by the Comprehensive Addiction and Recovery Act (CARA) such that all funding is to be used to establish regional technical assistance centers to implement regionally driven, peer delivered addiction recovery support services, establish recovery community organizations, establish recovery community centers, and provide overdose reversal medication training and dissemination. The proposal would reauthorize the program at \$15 million for each of fiscal years 2019 through 2023.

XVI. DISCUSSION DRAFT OF H.R. ___, FDA ACCELERATED APPROVAL & BREAKTHROUGH THERAPY STATUS

The discussion draft would direct the Food and Drug Administration (FDA) to issue guidance as to how FDA will provide for accelerated approval or breakthrough therapy designation for medicines developed to treat pain or addiction.

XVII. DISCUSSION DRAFT OF H.R. ___, FDA AND INTERNATIONAL MAIL

Authored by Rep. Blackburn (R-TN), the discussion draft would provide FDA with additional enforcement authorities to address illegal and illicit products entering the United States from international mail facilities. Specifically, the discussion draft would enable FDA to refuse admission and destroy articles identified to be of concern to the Drug Enforcement Administration (DEA) and FDA, streamline seizure proceedings, and debar individuals or organizations that repeatedly violate federal laws from being able to import into the U.S.

XVIII. DISCUSSION DRAFT OF H.R. ___, FDA OPIOID SPARING

Authored by Reps. Comstock (R-VA) and Luján (D-NM), the discussion draft would direct FDA to update or issue guidance related to data collection on opioid sparing for purposes of including such information on product labeling.

XIX. DISCUSSION DRAFT OF H.R. ___, FDA PACKAGING AND DISPOSAL

Authored by Rep. Hudson (R-NC), the discussion draft would provide FDA with the authority to issue orders directing manufacturers of controlled substances to implement or modify technologies, controls, or measures related to the packaging or disposal of such drug for purposes of reducing the risk of abuse or misuse. Such requirements could include unit dose packaging, disposal systems, or other technologies identified by FDA related to packaging and disposal. In addition, the discussion draft would require the Government Accountability Office

(GAO) to study the effectiveness of controlled substance disposal technologies, current federal oversight of disposal technologies, and recommendations as to the federal government's role in evaluating and promoting these technologies.

XX. DISCUSSION DRAFT OF H.R. ___, FDA LONG-TERM EFFICACY

Authored by Rep. McNerney (D-CA), the discussion draft would provide FDA with the authority to require post-market studies related to the effectiveness of controlled substances.

XXI. DISCUSSION DRAFT OF H.R. ___, FDA MISUSE/ABUSE

Authored by Rep. Gene Green (D-TX), the discussion draft would authorize FDA to consider the potential for misuse and abuse when assessing the risks and benefits of controlled substances for purposes of approval.

XXII. H.R. 4684, ENSURING ACCESS TO QUALITY SOBER LIVING ACT OF 2017

Introduced by Reps. Chu (D-CA), Murphy (D-FL), Bustos (D-IL), Gonzalez (D-TX), Frankel (D-FL), Kuster (D-NH), Maloney (D-NY), Ruiz (D-CA), Bilirakis (R-FL), and Walters (R-CA), H.R. 4684 would direct SAMHSA to develop and publish best practices for operating a recovery house. The bill would authorize \$3 million for fiscal years 2018 through 2020 to disseminate best practices for recovery houses and provide technical assistance to the states.

XXIII. AINS TO H.R. 3692, ADDICTION TREATMENT ACCESS IMPROVEMENT ACT OF 2017

The AINS to H.R. 3692, introduced by Reps. Tonko (D-NY) and Luján (D-NM), would make the policy passed in CARA that allows Nurse Practitioners and Physician Assistants to treat patients with opioid use disorder with buprenorphine permanent.¹ This new proposal also would allow all other advanced practice nurses, including Clinical Nurse Specialists (CNS), Certified Nurse Midwives (CNM), and Certified Registered Nurse Anesthetists (CRNA), to treat patients with opioid use disorder with buprenorphine. The bill would also codify the existing physician cap of 275 patients and allow providers to start treating a minimum of 100 patients if they hold additional credentialing specified in statute or practice in a qualified practice setting.

XXIV. AINS TO H.R. 3545, OVERDOSE PREVENTION AND PATIENT SAFETY ACT

The AINS to H.R. 3545, introduced by Rep. Mullin (R-OK), would no longer require patient consent for substance use disorder treatment records to be shared between covered

¹ House Committee on Energy and Commerce, *Federal Efforts to Combat the Opioid Crisis: A Status Update on CARA and Other Initiatives*, 115th Congress (October 23, 2017) (<https://democrats-energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/Dem-Memo-FC-Hrg-on-Federal-Efforts-to-Combat-the-Opioid-Crisis-A-Status-Update-on-CARA-2017-10-25.pdf>).

entities or between a covered entity and a non-covered entity for purposes of treatment, as long as those disclosures and redisclosures are made in accordance with the Health Insurance Portability and Accountability Act (HIPAA). The bill would allow disclosure of de-identified substance use disorder treatment records to public health authorities. The bill contemplates excluding from evidence any substance abuse treatment record used in a legal proceeding that was not obtained in accordance with the court order that this privacy statute requires, as well as requiring automatic dismissal of legal proceedings wherein such a record was offered. The bill would apply certain penalties to the disclosure of protected substance abuse treatment records. The bill contemplates prohibiting discrimination based on the information contained in substance abuse treatment records in health care admission or treatment, employment, housing, and access to courts. The bill would apply HIPAA breach notification requirements to substance abuse treatment records covered by the privacy requirements governing confidentiality of such records. The bill would require HHS to develop and disseminate model training programs for providers, patients, and families relating to privacy requirements related to confidentiality of such records.

XXV. AINS TO H.R. 4284, INDEXING NARCOTICS, FENTANYL, AND OPIOIDS (INFO) ACT

The AINS to H.R. 4284, introduced by Rep. Latta (R-OH), would establish a substance use disorder information dashboard and the Interagency Substance Use Disorder Coordinating Committee.

XXVI. WITNESSES

Wednesday, March 21st

Panel I:

Scott Gottlieb, MD

Commissioner

Food and Drug Administration

Anne Schuchat, MD (RADM, USPHS)

Principal Deputy Director

Centers for Disease Control and Prevention

Christopher M. Jones, PharmD, MPH

Director of the National Mental Health and Substance Use Policy Laboratory

Substance Abuse and Mental Health Services Administration

Panel II:

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

William Simpson

Director and President
DisposeRx

Thursday, March 22nd

Panel III:

Patrick J. Kennedy

Former U.S. Representative (RI)
Founder, The Kennedy Forum

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

Michael E. Kilkenny, MD, MS

Physician Director
Cabell-Huntington Health Department of West Virginia

Panel IV:

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

Beverly Cook
Chief, St. Regis Mohawk Tribe
Nashville Area Representative, National Indian Health Board

Alexis Horan
Vice President of Government Relations
Clean Slate Centers