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ONE HUNDRED FOURTEENTH 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

April 19, 2016

To: Subcommittee on Health Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: Subcommittee on Health Markup of Twelve Opioid Bills

On **Wednesday, April 20, 2016, the Subcommittee on Health will convene at 1:30 p.m. in room 2322 of the Rayburn House Office Building** to hold a markup of the following twelve bills:

- H.R. 4641, a bill to provide for the establishment of an inter-agency task force to review, modify, and update best practices for pain management and prescribing pain medication;
- H.R. 3250, the DXM Abuse Prevention Act of 2015;
- H.R. 3680, the Co-Prescribing to Reduce Overdose Act of 2015;
- H.R. 3691, the Improving Treatment for Pregnant and Postpartum Women Act of 2015;
- H.R. __, the Opioid Use Disorder Treatment Expansion and Modernization Act;
- H.R. 1818, the Veteran Emergency Medical Technician Support Act of 2015;
- GAO Study on Neonatal Abstinence Syndrome;
- H.R. 4599, the Reducing Unused Medications Act of 2016;
- H.R. 4976, the Opioid Review Modernization Act;
- H.R. 4586, a bill to provide for a grant program to develop standing orders for naloxone prescriptions;
- H.R. 4969, a bill to direct the Centers for Disease Control and Prevention to provide informational materials to educate and prevent addiction in teenagers and adolescents who are injured playing youth sports and subsequently prescribed an opioid; and
- H.R. __, Examining Opioid Treatment Infrastructure Act of 2016.

Additional information will be provided if amendments in the nature of a substitute are offered for consideration.

I. H.R. 4641, INTER-AGENCY TASK FORCE TO REVIEW, MODIFY, AND UPDATE BEST PRACTICES FOR PAIN MEDICATION

Representatives Joseph Kennedy (D-MA) and Susan Brooks (R-IN) introduced H.R. 4641 on February 26, 2016. This legislation was adapted from Section 3 of H.R. 2805, the Heroin and Prescription Drug Abuse Prevention, Education, and Enforcement Act of 2015. The subcommittee held a legislative hearing on H.R. 2805 on October 8, 2015.

H.R. 4641 would create an Inter-Agency Task Force, comprised of representatives of federal agencies and departments as well as external stakeholders, to review, modify, and update best practices for pain management and prescribing pain medication. The task force would also submit a report to Congress detailing the strategy for disseminating these best practices, the feasibility of linking best practices to receiving and renewing DEA registration to prescribe scheduled substances, and recommendations on how to effectively apply best practices at medical facilities.

II. H.R. 3250, DXM ABUSE PREVENTION ACT OF 2015

Dextromethorphan (DXM) is an antitussive, or cough suppressant, agent found in over 100 over-the-counter cough and cold medicines. DXM, which was first approved by the Food and Drug Administration in 1958, is available in pills, gel capsules, lozenges, liquids, and syrups, either alone or in combination with other analgesics, antihistamines, decongestants, and expectorants. It can also be purchased in bulk powder.

Currently, DXM is not scheduled under the Controlled Substances Act. While not known to be addictive, the 2015 National Institute on Drug Abuse (NIDA) Monitoring the Future study found that approximately three percent of, or one in 30, teenagers admit to abusing DXM to get high.[1] Further, teens report taking 25 times or more of the recommended dose of these medicines.[2] According to the FDA, abuse of DXM can cause brain damage, seizure, loss of consciousness, irregular heartbeat, and death.[3] Nine states (California, New York, Arizona, Louisiana, Virginia, Tennessee, Kentucky, Washington, and New Jersey) have passed legislation restricting sales of DXM to individuals 18 and under including civil penalties.

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[1] Lloyd D. Johnston, et. al, *Monitoring the Future, 2015 Overview, Key Findings on Adolescent Drug Use* (Feb. 2016) (online at http://www.monitoringthefuture.org/pubs/monographs/mtf-overview2015.pdf).

[2] Community Anti-Drug Coalitions of America (CADCA), *Fact Sheet: Teen Medicine Abuse* (online at http://www.preventrxabuse.org/wp-content/uploads/2015/09/FactSheet-Teens.pdf).

[3] Food and Drug Administration (FDA), *Overview of the September 14, 2010, DSaRM Advisory Committee Meeting to Discuss the Drug Enforcement Administration (DEA) Request for an Abuse Potential Evaluation and Scheduling Recommendation for Dextromethorphan (DXM)* (Aug. 23, 2010) (online at http://www.fda.gov/downloads/advisorycommittees/drugs/ucm224446.pdf).

H.R. 3250, introduced by Representatives Doris Matsui (D-CA) and Bill Johnson (R-OH), would establish national requirements to prevent those under the age of 18 from purchasing DXM. To restrict such purchases, this legislation would require retailers to have verification systems in place to ensure those under the age 18 cannot purchase DXM, and to prevent the possession, receipt, and distribution of unfinished DXM by entities not registered or licensed with the federal or state government. Violations would result in escalating civil monetary penalties. This legislation is supported by American Association of Poison Control Centers (AAPCC), Community Anti-Drug Coalitions of America (CADCA), Consumer Healthcare Products Association (CHPA), Drug Abuse Resistance Education (D.A.R.E.), National Association for Alcoholism and Drug Abuse Counselors (NAADAC), National Association of School Nurses (NASN), and the Partnership for Drug-Free Kids, among others.

III. H.R. 3680, CO-PRESCRIBING TO REDUCE OVERDOSE ACT OF 2015

Representative John Sarbanes (D-MD) introduced H.R. 3680, the Co-Prescribing to Reduce Overdose Act, on October 1, 2015. The subcommittee held a legislative hearing on this legislation on October 8, 2015.

H.R. 3680 would create a demonstration grant program for entities to establish programs for the prescribing of naloxone to patients at an elevated risk of overdose as well as to a close relative of such patient The bill would provide grant funding to eligible entities to train health care providers and pharmacists on co-prescribing, to establish mechanisms for tracking patients and their health outcomes for program evaluation, to purchase naloxone, to offset patient cost-sharing associated with naloxone, to conduct community outreach to raise awareness of naloxone prescribing practices, and to establish protocols to connect patients who have experienced a drug overdose with appropriate treatment. The bill would authorize $4,000,000 in annual appropriations for each of fiscal years 2016 through 2020.

IV. H.R. 3691, IMPROVING TREATMENT FOR PREGNANT AND POSTPARTUM WOMEN ACT OF 2015

Representative Ben Ray Lujan (D-NM) introduced H.R. 3691, the Improving Treatment for Pregnant and Postpartum Women Act of 2015 on October 6, 2015. The subcommittee held a legislative hearing on this legislation on October 8, 2015.

H.R. 3691 would reauthorize the Pregnant and Postpartum Women (PPW) program. The bill also creates a pilot program to allow for up to 25 percent of those grants made under the program to be made for outpatient treatment services. Such an allowance would enable state substance abuse agencies to proceed with greater flexibility in providing access to treatment, and addressing gaps in services furnished to pregnant women along the continuum of care. The bill would increase the authorization of this program to $40,000,000 for each of fiscal years 2016 through 2020.

V. H.R. __ OPIOID USE DISORDER TREATMENT EXPANSION AND MODERNIZATION ACT

Representatives Paul Tonko (D-NY) and Larry Buschon (R-IN) introduced H.R. ___ on April 18, 2016. This legislation was adapted from H.R. 2536, the Recovery Enhancement for Addiction Treatment Act, and H.R. 2872, the Opioid Addiction Treatment Modernization Act. The Subcommittee held a legislative hearing on H.R. 2536 and H.R. 2872 on October 8, 2015. The bill would expand access to buprenorphine by lifting the current cap on the number of patients physicians can treat with buprenorphine from 100 to 250 and by allowing nurse practitioners and physician assistants to treat up to 100 patients with buprenorphine. The legislation does not apply any new standards on the treatment of patients under the existing cap limit of 100 but includes new requirements on physicians who treat patients above 100 to ensure those providers maintain quality treatment practices while treating an increased buprenorphine treatment load.

VI. H.R. 1818, VETERAN EMERGENCY MEDICAL TECHNICIAN SUPPORT ACT OF 2015

Representatives Lois Capps (D-CA) and Adam Kinzinger (R-IL) introduced H.R. 1818, the Veteran Emergency Technician Support Act of 2015, on April 15, 2015. The subcommittee held a legislative hearing on the draft version of this legislation on January 27, 2016. Additionally, during the 113th Congress, the Committee passed this bill by voice vote on February 12, 2013.

H.R. 1818 would authorize a demonstration grant program for states to inform government and other stakeholders on ways to streamline certification and licensure requirements for returning veterans with military emergency medical technician (EMT) training, to become emergency medical technicians in their states.

VII. GAO STUDY ON NEONATAL ABSTINENCE SYNDROME

This legislation, introduced by Representatives Cheri Bustos (D-IL) and Lynn Jenkins (R-KS), authorizes a GAO study to assess the prevalence of Neonatal Abstinence Syndrome (NAS) in the Medicaid program. This study will also examine available treatments for NAS, cost of treatment, and any access barriers to treatment. The GAO is directed to complete the study within one year of enactment.

VIII. H.R 4599, THE REDUCING UNUSED MEDICATIONS ACT OF 2016

The National Institute on Drug Abuse (NIDA) estimates that over 70 percent of adults who misuse prescription opioids obtain these medications from friends or relatives, either for free or by purchasing them.[4] This is often due to many patients filling legitimate prescriptions for opioids and not using the entirety of the prescription. Partial fill policies allow providers, pharmacists, and patients the option to dispense a portion of a prescription with the option of filling the total amount of the prescription at a later time. Supporters of partial fill policies believe they can help to reduce the amount of unused opioid medications in the home.

[4] Centers for Disease Control and Prevention (CDC), *Injury Prevention and Control: Opioid Overdose, Data Overview* (Mar. 14, 2016) (online at http://www.cdc.gov/drugoverdose/data/).

Current Drug Enforcement Administration regulations allow pharmacists to partially fill prescriptions for Schedule III, IV, and V substances; however, Schedule II substances can only be partially filled in long term care settings or to terminally ill patients when the full prescription cannot be supplied.[5,6] While these regulations do not prohibit partially filling prescriptions for Schedule II substances in other situations, the DEA has acknowledged that applicable regulations may need to be amended for greater clarity as to when partial fill of Schedule II substances is allowed.[7] H.R. 4599, introduced by Representatives Katherine Clark (D-MA) and Steve Stivers (R-OH), would clarify when Schedule II prescriptions may be partially filled under the Controlled Substances Act.

IX. H.R. 4976, OPIOID REVIEW MODERNIZATION ACT

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 regarding a recommendations for a framework for pediatric opioid labeling before any new labeling is approved; updating the Risk Evaluation and Mitigation Strategy (REMS) program for extended-release and long-acting opioids regarding prescriber training; strengthening post-market requirements; and expanding access to abuse-deterrent formulations, among other steps.[8]

H.R. 4976, the Opioid Review Modernization Act, introduced by Representatives Sean Patrick Maloney (D-NY) and Leonard Lance (R-NJ), would require FDA to work closely with expert advisory committees before making critical product approval and labeling decisions, and to make recommendations regarding education programs for prescribers of extended-release and long-acting opioids. Further, it would encourage the development and approval of generic opioids with abuse-deterrent properties.

X. H.R. 4586, GRANT PROGRAM TO DEVELOP STANDING ORDERS FOR NALOXONE

This legislation, led by Representatives Katherine Clark (D-MA) and. Bob Dold (R-IL) creates a grant program for states to develop standing orders and to educate health care professionals regarding the dispensing of opioid overdose reversal medications without person-

[5] 21 CFR §1306.23.

[6] 21 CFR §1306.13.

[7] Letter from Matthew J. Strait, Section Chief, Congressional Affairs Section, U.S. Department of Justice, Drug Enforcement Administration to Senators Warren, Capito, Markey, Blumenthal and Ayotte (Feb. 26, 2016).

[8] FDA, *Fact Sheet – FDA Opioids Action Plan* (Feb. 5, 2016) (online at http://www.fda.gov/NewsEvents/Newsroom/FactSheets/ucm484714.htm).

specific prescriptions. To be eligible for grant funding, the state must have authorized standing orders regarding opioid overdose medications. Preference is given to states that (1) have not issued standing orders regarding opioid overdose reversal medications; (2) authorize standing orders that permit community-based organizations, substance abuse programs, or other nonprofit entities to acquire, dispense, or administer opioid overdose reversal medication; (3) authorize standing orders that permit emergency responders to administer opioid overdose reversal medication; (4) have a higher per capita rate of opioid overdoses than other applicant states; or (5) meet any other criteria deemed appropriate by the Secretary. It authorizes $10,815,000 for the period of fiscal years 2016 through 2019 for these purposes.

XI. H.R. 4969, TO PROVIDE INFORMATION ON THE DANGERS OF OPIOID ADDICTION TO PARTICIPANTS IN YOUTH SPORTS

This legislation, led by Representative Patrick Meehan (R-PA) directs the Secretary of the Department of Health and Human Services (HHS), acting through the Centers for Disease Control and Prevention (CDC), to issue a report determining the extent to which informational materials and resources are available to teenagers and adolescents who play youth sports about youth sports injuries for which opioids could be prescribed and the ensuing risks of addiction; the dangers of opioid use and misuse; treatment options for injuries that do not involve the use of opioids; and how to seek treatment for addiction. The legislation further directs the Secretary to develop and disseminate such informational materials, taking into consideration the findings of the report.

XII. H.R. __, EXAMINING OPIOID TREATMENT INFRASTRUCTURE ACT OF 2016

This legislation, led by Representatives Bill Foster (D-IL) and Ranking Member Frank Pallone, Jr., directs GAO to conduct a study on the inpatient and outpatient treatment capacity of the U.S. within 24 months. To the extent that data is available, the bill would directs GAO to examine or assess:

- the capacity of acute residential or inpatient detoxification programs, inpatient clinical stabilization programs
- transitional residential support services and residential rehabilitation programs
- geographic differences in the availability of residential and outpatient treatment and recovery programs for substance use disorders
- the availability of residential and outpatient treatment programs that offer treatment options based on reliable scientific evidence of efficacy for the treatment of substance use disorders, including the use of FDA-approved medications
- the number of patients in residential and specialty outpatient treatment services for substance use disorders, and
- the need for residential and outpatient treatment for substance use disorders across the continuum of care.