U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY AND COMMERCE

May 7, 2018

TO: Members, Committee on Energy and Commerce

FROM: Committee Majority Staff

RE: Full Committee Markup

I. INTRODUCTION

The Committee on Energy and Commerce will meet in open markup session on Wednesday, May 7, 2018, at 9:00 a.m. in 2123 Rayburn House Office Building to consider the following:

Energy Legislation

1. H.R. 4606, Ensuring Small Scale LNG Certainty and Access Act;
2. H.R. 5174, Energy Emergency Leadership Act;
3. H.R. 5175, Pipeline and LNG Facility Cybersecurity Preparedness Act;
4. H.R. 5239, Cyber Sense Act;
5. H.R. 5240, Enhancing Grid Security through Public-Private Partnerships Act

Health Legislation

Controlled Substance Act

6. H.R. 4275, Empowering Pharmacists in the Fight Against Opioid Abuse Act;
7. H.R. 5041, Safe Disposal of Unused Medication Act;
8. H.R. 5202, Ensuring Patient Access to Substance Use Disorder Treatments Act of 2018;
9. H.R. 5483, Special Registration for Telemedicine Clarification Act of 2018;

Public Health Service Act

10. H.R. 449, Synthetic Drug Awareness Act of 2017;
11. H.R. 4284, INFO Act of 2017;
12. H.R. 5002, ACE Research Act;
13. H.R. 5009, Jessie's Law;
14. H.R. 5102, Substance Use Disorder Workforce Loan Repayment Act of 2018;
15. H.R. 5176, Preventing Overdoses While in Emergency Rooms Act of 2018;
16. H.R. 5197, Alternatives to Opioids (ALTO) in the Emergency Department Act;
17. H.R. 5261, TEACH to Combat Addiction Act of 2018;
18. H.R. 5272, Reinforcing Evidence-Based Standards Under Law in Treating Substance Abuse Act of 2018;
19. H.R. 5327, Comprehensive Opioid Recovery Centers Act 2018;
20. H.R. 5353, Eliminating Opioid-Related Infectious Diseases Act of 2018;

Medicare Part B

21. H.R. 3331, To amend title XI of the Social Security Act to promote testing of incentive payments for behavioral health providers for adoption and use of certified electronic health record technology;

22. H.R. 5685, Medicare Opioid Safety Education Act;
23. H.R. 5603, Access to Telehealth Services for Opioid Use Disorders;
Medicare Part D
24. H.R. 3528, Every Prescription Conveyed Securely Act;
25. H.R. 4841, Standardizing Electronic Prior Authorization for Safe Prescribing Act of 2018;
26. H.R. 5675, To amend title XVIII of the Social Security Act to require prescription drug plan sponsors under the Medicare program to establish drug management programs for at-risk beneficiaries;
27. H.R. 5582, Abuse Deterrent Access Act of 2018;
28. H.R. 5684, Protecting Seniors from Opioid Abuse Act;
29. H.R. 5686, Medicare Clear Health Options in Care for Enrollees (CHOICE) Act;
Federal Food, Drug, and Cosmetic Act
30. H.R. 5333, the Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2018;
31. H.R. 5473, Better Pain Management Through Better Data Act of 2018;
32. H.R. 5554, To amend the Federal Food, Drug, and Cosmetic Act to reauthorize user fee programs relating to new animal drugs and generic new animal drugs; and
33. H.R. 5687, Securing Opioids and Unused Narcotics with Deliberate Disposal and Packaging Act of 2018

In keeping with Chairman Walden's announced policy, Members must submit any amendments they may have two hours before they are offered during this markup. Members may submit amendments by email to peter.kielty@mail.house.gov. Any information with respect to an amendment's parliamentary standing (e.g., its germaneness) should be submitted at this time as well.

II. ENERGY LEGISLATION

1. H.R. 4606, Ensuring Small Scale LNG Certainty and Access Act: H.R. 4606 provides that applications under the Natural Gas Act (NGA) for the importation or exportation of small volumes of natural gas shall be granted without modification or delay. Section 2 amends section 3(c) of the NGA by inserting "or the importation or exportation of a volume of natural gas that does not exceed 0.14 billion cubic feet per day" after "natural treatment for trade in natural gas."

The Committee anticipates an amendment to ensure that the review required under the National Environmental Policy Act (NEPA) is completed as part of DOE's review of the application. The amendment provides that DOE may grant the application provided that two criteria are met: the application proposed to export no more than 0.14 billion cubic feet per day, and the proposed export qualifies for a categorical exclusion under DOE's NEPA regulations.

2. H.R. 5174, Energy Emergency Leadership Act: H.R. 5174 amends the Department of Energy Organization Act to include energy emergency and energy security among the functions that the Secretary of the Department of Energy (DOE) shall assign to an Assistant

Secretary; provides that these functions include responsibilities with respect to infrastructure, cybersecurity, emerging threats, supply and emergency planning, coordination, response, and restoration; and provides that these functions also include the provision of technical assistance, support, and response capabilities with respect to energy security threats, risks, and incidents to State, local, and tribal governments and the energy sector.

3. H.R. 5175, Pipeline and LNG Facility Cybersecurity Preparedness Act: H.R. 5175 requires the Secretary of Energy to carry out a program to coordinate Federal agencies, States, and the energy sector to ensure the security, resiliency, and survivability of natural gas pipelines, hazardous liquid pipelines, and liquefied natural gas facilities. The bill also requires the Secretary to coordinate response and recovery to physical and cyber incidents impacting the energy sector, develop advanced cybersecurity applications and technologies, perform pilot demonstration projects, develop workforce development curricula relating to physical and cybersecurity, and provide mechanisms to help the energy sector evaluate, prioritize, and improve physical and cybersecurity capabilities.

The Committee anticipates an amendment to clarify that the advanced cybersecurity applications, technologies, and technical tools developed are for voluntary use. The amendment also includes a savings clause to clarify that nothing in the Act shall be construed to modify the authority of any other Federal agency relating to physical security or cybersecurity for pipelines or liquefied natural gas facilities.

4. H.R. 5239, Cyber Sense Act: H.R. 5239 establishes a voluntary Department of Energy (DOE) program that tests the cybersecurity of products and technologies intended for use in the bulk-power system, including products related to industrial control systems. H.R. 5239 instructs DOE to provide technical assistance to electric utilities, product manufacturers, and other electricity sector stakeholders to help mitigate cybersecurity vulnerabilities. In addition, the bill requires the Secretary of Energy to establish cybersecurity vulnerability reporting processes and maintain a related database.

H.R. 5239 requires the Secretary to biennially review products and technologies tested under the Cyber Sense program for cybersecurity vulnerabilities and provide analysis on how such products and technologies respond to and mitigate cyber threats. H.R. 5239 instructs the Secretary to develop guidance for electric utilities regarding procurement of products and technologies. The Secretary will utilize analysis and testing results under the Cyber Sense program in developing this guidance.

H.R. 5239 directs the Secretary to provide reasonable notice and solicit comments from the public prior to establishing or revising the Cyber Sense testing process. H.R. 5239 provides that any cybersecurity vulnerability reported pursuant to this program, the disclosure of which the Secretary of Energy reasonably foresees would cause harm to critical electric infrastructure, shall be deemed "critical electric infrastructure information" as defined by section 215A(d) of the Federal Power Act. H.R. 5239 includes Federal Government liability protections by noting that nothing shall be construed to authorize the commencement of an action against the United States government with respect to the testing of a product or technology under the Cyber Sense program.

5. H.R. 5240, Enhancing Grid Security through Public-Private Partnerships Act: H.R. 5240 requires the Secretary of Energy to establish a program to facilitate and encourage public-private partnerships to promote and advance physical security and cybersecurity of electric utilities. The Secretary, in consultation with State regulatory authorities, industry stakeholders, and other Federal agencies the Secretary determines appropriate, shall carry out a program to (1) develop, and provide for voluntary implementation of, maturity models, self-assessments, and auditing methods for assessing the physical security and cybersecurity of electric utilities; (2) provide training and technical assistance to electric utilities to address and mitigate cybersecurity supply chain management risks; (3) increase opportunities for sharing best practices and data collection within the electric sector; (4) assist with cybersecurity training for electric utilities; (5) advance the cybersecurity of third-party vendors that work in partnerships with electric utilities; and (6) provide technical assistance for electric utilities subject to the program.

The Secretary is required to take into consideration different sizes of electric utilities and the regions they serve and to prioritize electric utilities with fewer available resources. Any information an electric utility provides to the Federal Government through this program will be exempt from public disclosure under Federal, State, or tribal law.

H.R. 5240 instructs the Secretary of Energy, in consultation with State regulatory authorities, industry stakeholders, and other Federal agencies the Secretary determines appropriate, to submit to Congress a report addressing cybersecurity as it relates to electric distribution systems. The bill directs the Secretary to assess priorities, policies, procedures, and actions for enhancing the physical and cybersecurity of electric distribution systems, including an estimate of potential costs and benefits of implementing these priorities, policies, procedures, and actions, including any public-private cost-sharing opportunities. Any information an electric utility provides to the Federal government through this study will be exempt from public disclosure under Federal, State, or tribal law.

Finally, H.R. 5240 directs the Department of Energy to update the Interruption Cost Estimate Calculator, a tool designed for and utilized by electric reliability planners at electric utilities, government organizations, and other entities that are interested in estimating interruption costs and benefits associated with infrastructure improvements.

The Committee anticipates an amendment to insert “electric reliability organization” to the list of entities the Secretary must consult with in carrying out a program to facilitate and encourage public-private partnerships to promote and advance physical and cybersecurity of electric utilities.

III. HEALTH LEGISLATION

Controlled Substances Act

6. H.R. 4275, Empowering Pharmacists in the Fight Against Opioid Abuse Act: H.R. 4275, 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 education materials, giving pharmacists greater understanding and ability to detect prescriptions that are fraudulent, forged, or appear to be for abuse or diversion.

7. H.R. 5041, Safe Disposal of Unused Medication Act: H.R. 5041, 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 dispose of these medications in patients' homes safely.

8. H.R. 5202, Ensuring Patient Access to Substance Use Disorder Treatments Act of 2018: H.R. 5202, authored 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.

9. H.R. 5483, Special Registration for Telemedicine Clarification Act of 2018: This legislation, authored 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 bill directs the Attorney General, with the Secretary of Health and Human Services, to promulgate interim final regulations within 1 year of passage of the law.

Public Health Service Act

10. H.R. 449, Synthetic Drug Awareness Act: H.R. 449, 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 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 labs and can have chemical structures that can be either identical to or different from naturally occurring drugs.[1] Their effects are designed to mimic or 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

[1] 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.

numerous analogs.[2] 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."

11. H.R. 4284, INFO Act of 2017: H.R. 4284, 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. H.R. 4284 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

12. H.R. 5002, ACE Research Act: H.R. 5002, authored by Rep. Debbie Dingell (D-MI) and Rep. Fred Upton (R-MI), will provide the National Institutes of Health (NIH) with new authorities to conduct research on innovative non-addictive pain medications.

13. H.R. 5009, Jessie's Law: H.R. 5009, 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 the Department of Health and Human Services (HHS) to develop and disseminate best practices regarding the prominent display of Substance Use Disorder (SUD) history in records of patients who have previously provided this information to a health care provider.

14. H.R. 5102, Substance Use Disorder Workforce Loan Repayment Act: H.R. 5102, 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 Substance Abuse and Mental Health Services Administration (SAMHSA), in 2012, the turnover rates in the addiction services workforce ranged from 18.5 percent to over 50 percent.[3] 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.[4]

15. H.R. 5176, Preventing Overdoses While in Emergency Rooms (POWER)

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[2] 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.
[3] Substance Abuse and Mental Health Services Administration. "Workforce." September 15, 2017. Available at https://www.samhsa.gov/workforce.
[4] 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.

Act: H.R. 5176, authored by Rep. David McKinley (R-WV) and Rep. Michael Doyle (D-PA), will provide 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.[5]

16. H.R. 5197, Alternatives to Opioids (ALTO) in the Emergency Department Act: H.R. 5197, authored by Rep. Bill Pascrell, Jr. (D-NJ) and Rep. David McKinley (R-WV), will establish a demonstration program to test alternative pain management protocols to limit the use of opioids in hospital emergency departments. According to the Centers for Disease Control and Prevention (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."[6] By promoting the use of non-opioid alternatives to manage pain, ERs can serve as one of the first lines of defense against the opioid crisis.

17. H.R. 5261, Treatment, Education, And Community Help (TEACH) to Combat Addiction Act: H.R. 5261, 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 evidence-based approaches to pain education and provide basic training in the treatment of opioid use disorder for health care providers.[7]

18. H.R. 5272, Reinforcing Evidence-Based Standards Under Law in Treating Substance Abuse (RESULTS) Act: H.R. 5272, 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. An amendment in the nature of a substitute will instead direct SAMHSA to provide guidance for entities applying for grants, including guidance on how best to articulate the rationale for a given program or activity; encourage the funding of evidence-based interventions; and encourage the replication of promising or effective

[5] 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.
[6] 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.
[7] 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

practices.

19. H.R. 5327, Comprehensive Opioid Recovery Centers Act: H.R. 5237, 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 Food and Drug Administration (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.

20. H.R. 5353, Eliminating Opioid-Related Infectious Diseases Act: H.R. 5353, 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 oxymorphone, and 92.3 percent were coinfected with HCV.[10]

Medicare Part B

21. H.R. 3331, to amend title XI of the Social Security Act: H.R. 3331, authored by Rep. Lynn Jenkins (R-KS), will promote the testing of incentive payments for behavioral health providers for adoption and use of certified electronic health record technology.

22. H.R. 5685, Medicare Opioid Safety Education Act: This bill, authored by Rep. John Faso (R-NY), Rep. Peter Welch (D-VT), and Rep. Jim Renacci (R-OH), will direct the Centers for Medicare and Medicaid Services (CMS) to compile education resources for beneficiaries regarding opioid use, pain management, and alternative pain management treatments, and include these resources in the "Medicare and You" handbook.

23. H.R. 5603, Access to Telehealth Services for Opioid Use Disorders: This bill, authored by Rep. Doris Matsui (D-CA), will instruct CMS to evaluate the utilization of telehealth

[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 Oxymorphone 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.

services in treating opioid use disorder.

Medicare Part D

24. H.R. 3528, Every Prescription Conveyed Securely Act: H.R. 3528, authored by Rep. Katherine Clark (D-MA) and Rep. Markwayne Mullin (R-OK), will require e-prescribing, with exceptions, for coverage of prescribed controlled substances under the Medicare Part D program.

25. H.R. 4841, Standardizing Electronic Prior Authorization for Safe Prescribing Act: H.R. 4841, authored by Rep. David Schweikert (R-AZ), seeks to standardize electronic prior authorization for prescription drugs under Medicare Part D.

26. H.R. 5675, To amend title XVIII of the Social Security Act to require prescription drug plan sponsors under the Medicare program to establish drug management programs for at-risk beneficiaries: This bill, authored by Rep. Gus Bilirakis (R-FL), Rep. Ben Ray Lujan (D-NM), Rep. Peter Roskam (R-IL), and Rep. Sander Levin (MI), will build off of work done in the Comprehensive Addiction Recovery Act (CARA), and will require prescription drug plan sponsors under the Medicare program to establish drug management programs for at-risk beneficiaries.

27. H.R. 5582, Abuse Deterrent Access Act of 2018: H.R. 5582, authored by Rep. Buddy Carter (R-GA), Rep. David Loebsack (D-IA), and Rep. Tom Reed (NY), will direct CMS to evaluate the use of abuse-deterrent opioids in Medicare plans.

28. H.R. 5684, Protecting Seniors from Opioid Abuse Act: This bill, authored by Rep. Mike Kelly (R-PA), Rep. Cathy McMorris Rodgers (R-WA), Rep. Mike Thompson (D-CA), and Rep. Michael Doyle (D-PA), will add beneficiaries at risk for prescription drug abuse to the list of targeted beneficiaries to be eligible for Medication Therapy Management under Part D.

29. H.R. 5686, Medicare Clear Health Options in Care for Enrollees (CHOICE) Act: This bill, authored by Rep. Erik Paulsen (R-MN), Rep. Chris Collins (R-NY), Rep. Terri Sewell (D-AL), and Rep. Connor Lamb (D-PA), will require prescription drug plans under Medicare Part D to include information on the adverse effects of opioid overutilization and coverage of non-pharmacological therapies and non-opioid medications or devices used to treat pain.

Federal Food, Drug, and Cosmetic Act

30. H.R. 5333, the Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2018: This bill, authored by Rep. Bob Latta (R-OH), Rep. Michael Burgess (R-TX), Rep. Gene Green (D-TX), Rep. Diana DeGette (D-CO), Rep. Brett Guthrie (R-KY), and Debbie Dingell (D-MI), would add new sections to the Federal Food, Drug, and Cosmetic Act (FDCA) to modernize and complete the over-the-counter (OTC) monograph system that was established by the FDA in 1972 to review the safety and efficacy of OTC ingredients in the

marketplace. The bill would enact the following reforms: (1) include by reference OTC Review Final Monographs and Tentative Final Monographs in statute; (2) create a system for future changes to Monographs through an administrative order procedure with the opportunity for development meetings or other consultations, comment on proposed orders, and dispute resolution protections; (3) create a mechanism for faster safety label changes; (4) create a pathway for innovations under Monographs; and, (5) include a clause to not prejudice either the new drug approval pathway or nonprescription drugs otherwise marketed under existing enforcement discretion. H.R. 5333 would also authorize facility fees totaling $22 million for fiscal year 2019 and incrementally increase said fees to $34 million in fiscal year 2023. The bill included a 5-year authorization.

31. H.R. 5473, Better Pain Management Through Better Data Act of 2018: This bill, authored by Rep. Barbara Comstock (R-VA), will direct the 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.

32. H.R. 5554, To amend the Federal Food, Drug, and Cosmetic Act to reauthorize user fee programs relating to new animal drugs and generic new animal drugs: The FDA collects user fees from the animal drug industry to accelerate the development of animal drugs, reduce application review times, and create a more predictable, streamlined process for drug development and approval. This bill, authored by Rep. Markwayne Mullin (R-OK) and Rep. Kurt Schrader (D-OR), reauthorizes FDA's authority to collect fees from pioneer and generic animal drug manufacturers for a period of five years.

33. H.R. 5687, Securing Opioids and Unused Narcotics with Deliberate Disposal and Packaging Act of 2018: This bill, authored by Rep. Richard Hudson (R-NC), Rep. G.K Butterfield (D-NC), and Ted Budd (R-NC), will direct the FDA to work with manufacturers to establish programs for efficient return or destruction of unused Schedule II or III opioids. These methods could include mail-back pouches to secure facilities for incineration, or methods to inactivate immediately or render unattractive unused drugs. In addition, this bill will facilitate utilization of packaging that may reduce overprescribing, diversion, or abuse of opioids. Finally, the bill will require the Government Accountability Office (GAO) to study new and innovative technologies that claim to be able to dispose of opioids safely and other unused medications. GAO would review and detail the effectiveness of these disposal methods. According to 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.[11] Safe and proper disposal of opioids and other unused prescription drugs can prevent these substances from getting into the wrong hands.

[11] 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.

IV. STAFF CONTACTS

If you have questions regarding the energy legislation, please contact Mary Martin, Brandon Mooney, or Annelise Rickert of the Committee staff. If you have questions regarding the health legislation, please contact Paul Edattel, Josh Trent, Kristen Shatynski, Caleb Graff, James Paluskiewicz, Jay Gulshen, Danielle Steele, or Adam Buckalew of the Committee staff. All Committee staff can be contacted at (202) 225-2927.