GREG WALDEN, OREGON
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FIFTEENTH CONGRESS

Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (202) 225-2927
Minority (202) 225-3641

MEMORANDUM

May 8, 2018

To: Full Committee Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: Full Committee Markup of Opioids Legislation, ADAGDUFA, and H.R. 4606, H.R. 5174, H.R. 5175, H.R. 5239, and H.R. 5240

On **Wednesday, May 9, at 9:00 a.m., in room 2123 of the Rayburn House Office Building,** the Full Committee will hold a markup of the following bills forwarded by the Subcommittee on Energy: H.R. 5174, the "Energy Emergency Leadership Act;" H.R. 5175, the "Pipeline and LNG Facility Cybersecurity Preparedness Act;" H.R. 5239, the "Cyber Sense Act of 2018;" H.R. 5240, the "Enhancing Grid Security Through Public-Private Partnerships Act;" and H.R. 4606, the "Ensuring Small Scale LNG Certainty and Access Act." The markup will also include numerous bills forwarded by the Subcommittee on Health. The Committee will also markup 25 bills aimed at combatting the opioid crisis and the Animal Drug and Animal Generic Drug User Fee Amendments of 2018. For additional information, please refer to the hearing memos referenced herein.

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;

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. 5686, Medicare Clear Health Options in Care for Enrollees (CHOICE) Act;
28. H.R. 5582, Abuse Deterrent Access Act of 2018;
29. H.R. 5684, Protecting Seniors from Opioid Abuse 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, Animal Drug and Animal Generic Drug User Fee Amendments of 2018; and
33. H.R. 5687, Securing Opioids and Unused Narcotics with Deliberate Disposal and Packaging Act of 2018.

I. ENERGY LEGISLATION

A. H.R. 5174, ENERGY EMERGENCY LEADERSHIP ACT

Rep. Walberg (R-MI) and Rep. Rush (D-IL) introduced H.R. 5174, the Energy Emergency Leadership Act, on March 6, 2018.

The legislation amends Section 203(a) of the Department of Energy (DOE) Organization Act to create a new DOE Assistant Secretary position with jurisdiction over all energy emergency and security functions related to energy supply, infrastructure, and cybersecurity. The bill authorizes the new Assistant Secretary to provide, upon request of a State, local, or tribal government, DOE technical assistance, and support and response capabilities with respect to energy security threats, risks, and incidents.

The Subcommittee on Energy forwarded H.R. 5174 by voice vote on April 18, 2018.

B. H.R. 5175, PIPELINE AND LNG FACILITY CYBERSECURITY PREPAREDNESS ACT

Rep. Upton (R- MI) and Rep. Loebsack (D-IA) introduced H.R. 5175, the Pipeline and LNG Facility Cybersecurity Preparedness Act, on March 6, 2018. The bill requires the Secretary of Energy to carry out a program to establish policies and procedures that would improve the physical and cyber security of natural gas transmission and distribution pipelines, hazardous liquid pipelines, and liquefied natural gas (LNG) facilities.

Under this program, the Secretary would establish a program to coordinate Federal agencies, States, and the energy sector to ensure security and resiliency of pipelines and LNG facilities. The Secretary would coordinate response to, and recovery from, physical and cyber incidents affecting the energy sector. The Secretary would also develop advanced cybersecurity technologies, perform pilot demonstration projects, and establish workforce development security curricula for pipelines and LNG facilities. Finally, the Secretary would provide mechanisms to help the energy sector evaluate, prioritize, and improve security capabilities for such facilities.

The Subcommittee on Energy forwarded H.R. 5175 by voice vote on April 18, 2018.

C. H.R. 5239, CYBER SENSE ACT OF 2018

Rep. Latta (R-OH) and Rep. McNerney (D-CA) introduced H.R. 5239, the Cyber Sense Act of 2018, on March 9, 2018.

H.R. 5239 requires the Secretary of Energy to establish the Cyber Sense Program. This voluntary program would identify cyber-secure products that could be used in the bulk-power system. In addition to making DOE responsible for promoting cyber-secure products, this legislation requires DOE to determine a testing process for Cyber Sense products and establish a cybersecurity vulnerability reporting process and database.

Additionally, the bill requires DOE to provide technical assistance to electric utilities, manufacturers, and other relevant stakeholders related to cybersecurity vulnerabilities in products under the Cyber Sense program. The bill requires all cyber-secure products to be reviewed biennially to determine how such products respond to and prevent cyber threats. This legislation also requires DOE to solicit public comment before establishing or altering the Cyber Sense Program.

The Subcommittee on Energy forwarded H.R. 5239 by voice vote on April 18, 2018.

D. H.R. 5240, ENHANCING GRID SECURITY THROUGH PUBLIC-PRIVATE PARTNERSHIPS ACT

Rep. Latta (R-OH) and Rep. McNerney (D-CA) introduced H.R. 5240, the Enhancing Grid Security Through Public-Private Partnerships Act, on March 9, 2018. This legislation contains provisions to address the physical and cyber security of electric utilities.

H.R. 5240 directs the Secretary of Energy, in consultation with States, other Federal agencies, and industry stakeholders, to create and implement a program to enhance the physical and cyber security of electric utilities. Among other things, this program would develop voluntary implementation of methods for assessing security vulnerabilities. It would provide cybersecurity training to electric utilities, advance the cybersecurity of utility third-party vendors, and promote sharing best practices and data collection in the electric sector. The bill further directs the Secretary of Energy to submit a report to Congress on cybersecurity and distribution systems.

Finally, the bill instructs the Secretary of Energy to update the Interruption Cost Estimate (ICE) Calculator at least once, every two years. The ICE Calculator, developed by DOE's Lawrence Berkley Lab and Nexant, Inc., is an electric reliability planning tool for estimating electricity interruption costs and the benefits associated with reliability improvements.[1]

The Subcommittee on Energy forwarded H.R. 5240 by voice vote on April 18, 2018.

E. H.R. 4606, ENSURING SMALL SCALE LNG CERTAINTY AND ACCESS ACT

Rep. Johnson (R-OH) introduced H.R. 4606, the "Ensuring Small Scale LNG Certainty and Access Act," on December 11, 2017. The bill amends section 3(c) of the Natural Gas Act to deem applications for "importation or exportation of a volume of natural gas that does not exceed 0.14 billion cubic feet per day" to be in the public interest. [2]

---

[1] Department of Energy, Interruption Cost Estimate Calculator (www.icecalculator.com) (accessed Mar. 10, 2018).

[2] For background information on LNG exports and DOE's small scale LNG rule, please see the memo from the January 19, 2018 legislative hearing.

This bill is ostensibly intended to codify the Department of Energy's (DOE) small-scale liquefied natural gas (LNG) rule, yet as forwarded by the Subcommittee on Energy, it fails to include the proposed rule's requirement that applications qualify for a categorical exclusion from the National Environmental Policy Act (NEPA). According to the Congressional Research Service, Eagle LNG Partners Jacksonville LLC is the only project that does not merit a categorical exclusion but would still meet the capacity requirements of the small-scale LNG rule.[3] Since the bill does not include a categorical exclusion provision, Eagle LNG Partners Jacksonville LLC would be the only current project to benefit from this new expedited process. Even if H.R. 4606 did include all aspects of the proposed small-scale LNG rule, qualifying small-scale applications could be approved without any public notice or comment, or need for a public interest determination. Additionally, because there is no limit on the number of small-scale applications an entity could have, an applicant could skirt requirements for larger exports by breaking a proposal into smaller pieces. An unrestricted export policy could lead to even higher levels of LNG exports, which could have significant impacts on domestic natural gas prices and adversely affect American consumers and manufacturers.

The Subcommittee on Energy reported H.R. 4606 by a vote of 19-14 on April 18, 2018, with all Democratic members voting against forwarding the bill.

At the markup, Rep. Johnson and Rep. Green are expected to offer an amendment conforming the legislation to DOE's proposed rule by requiring that a project must qualify for a categorical exclusion from NEPA in order to take advantage of the bill's provisions.

II. HEALTH LEGISLATION

The Health Subcommittee held a series of three legislative hearings related to the opioid crisis, entitled *Combatting the Opioid Crisis: Helping Communities Balance Enforcement and Patient Safety*,[4] *Combatting the Opioid Crisis: Prevention and Public Health Solutions*,[5] *and Combatting the Opioid Crisis: Improving the Ability of Medicare and Medicaid to Provide Care for Patients*.[6] On March 14, 2018, the Subcommittee held a legislative hearing entitled

---

[3] Congressional Research Service, *U.S. Liquefied Natural Gas (LNG) Exports: Prospects for the Caribbean* (Nov. 1, 2027) (www.crs.gov/reports/pdf/R45006) (R45006).

[4] House Committee on Energy and Commerce, *Combatting the Opioid Crisis: Helping Communities Balance Enforcement and Patient Safety*, 115th Cong. (Feb. 28, 2018) (https://democrats-energycommerce.house.gov/committee-activity/hearings/hearing-on-combating-the-opioid-crisis-helping-communities-balance).

[5] House Committee on Energy and Commerce, *Combatting the Opioid Crisis: Prevention and Public Health Solutions*, 115th Cong. (Mar. 21-22, 2018) (https://democrats-energycommerce.house.gov/committee-activity/hearings/hearing-on-combating-the-opioid-crisis-prevention-and-public-health).

[6] House Committee on Energy and Commerce, *Combatting the Opioid Crisis: Improving the Ability of Medicare and Medicaid to Provide Care for Patients*, 115th Cong. (April 11-12, 2018)

Reauthorization of Animal Drug User Fees: ADUFA and AGDUFA.[7] On September 13, 2017, the Subcommittee held a legislative hearing entitled *Modernizing FDA's Regulation of Over-the-Counter Drugs*.[8]

From these legislative hearings, the Health Subcommittee held a markup on the opioid and ADUFA and AGDUFA legislation on April 24, 2018.[9] The Health Subcommittee held a markup on H.R. 5333, the Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2018 on January 17, 2018.[10]

Please refer to the memoranda from these legislative hearings and Subcommittee markups for background on the legislation under consideration. The information below summarizes major changes made to those versions of the legislation that were considered at the relevant Subcommittee markup.

A. CONTROLLED SUBSTANCE ACT

6. H.R. 4275, Empowering Pharmacists in the Fight Against Opioid Abuse Act

An amendment was adopted at Subcommittee that charges U.S. Department of Health and Human Services with developing the training and materials related to identifying prescriptions that are fraudulent, forged, or indicative of abuse or diversion. Such materials are to be developed in consultation with the Drug Enforcement Administration (DEA).

B. PUBLIC HEALTH SERVICE ACT

(https://democrats-energycommerce.house.gov/committee-activity/hearings/hearing-on-combating-the-opioid-crisis-improving-the-ability-of-medicare).

[7] House Committee on Energy and Commerce, *Reauthorization of Animal Drug User Fees: ADUFA and AGDUFA*, 115th Cong. (Mar. 14, 2018) (https://democrats-energycommerce.house.gov/committee-activity/hearings/hearing-on-reauthorization-of-animal-drug-user-fees-adufa-and-agdufa).

[8] House Committee on Energy and Commerce, *Modernizing FDA's Regulation of Over-the-Counter Drugs*, 115th Cong. (Sept. 13, 2017) (https://democrats-energycommerce.house.gov/committee-activity/hearings/hearing-on-modernizing-fda-s-regulation-of-over-the-counter-drugs).

[9] House Committee on Energy and Commerce, *Markup of Opioid and Other Public Health Legislation*, 115th Cong. (April 25, 2018) (https://democrats-energycommerce.house.gov/committee-activity/markups/markup-of-opioid-and-other-public-health-legislation-subcommittee-on).

[10] House Committee on Energy and Commerce, *Markup of H.R. 1876, H.R. 2026, and H.R. __, Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2018*, 115th Cong. (Jan. 17, 2018) (https://democrats-energycommerce.house.gov/committee-activity/markups/markup-of-hr-over-the-counter-monograph-safety-innovation-and-reform-act).

18. H.R. 5272, Reinforcing Evidence-Based Standards Under Law in Treating Substance Abuse Act of 2018

An amendment was adopted at Subcommittee that requires the Substance Abuse and Mental Health Services Administration (SAMHSA) to issue guidance for entities applying for SAMHSA grants. The guidance would encourage the funding of evidence-based practices, encourage the replication of promising or effective practices, and inform applicants on how to best articulate a rationale for the funding of a program or activity.

C. 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

H.R. 3331, introduced by Reps. Jenkins (R-KS) and Matsui (D-NY), amends title XI of the Social Security Act to specify that the Center for Medicare and Medicaid Innovation may test models to provide incentive payments to behavioral health providers for: (1) adopting electronic health records technology, and (2) using that technology to improve the quality and coordination of care. An AINS and an amendment to the AINS is expected that would make technical changes and would add nurse practitioners as a class of behavioral health providers that can participate in the program.

22. H.R. 5685, Medicare Opioid Safety Education Act

H.R. 5685, the Medicare Opioid Safety Education Act, introduced by Reps. Faso (R-NY) and Welch (D-VT) directs CMS to compile educational resources for beneficiaries regarding opioid use, pain management, and alternative pain management treatments, and include these resources in the "Medicare and You" Handbook. The introduced bill includes technical changes from the discussion draft that was marked up in Subcommittee.

D. 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

Following subcommittee markup, H.R. 5675 was introduced with revisions from the discussion draft favorably reported by the subcommittee. The introduced bill requires prescription drug plan sponsors to establish drug management programs for at-risk beneficiaries, while also ensuring beneficiary protections created in the Comprehensive Addiction Recovery Act (CARA) are preserved.

E. FEDERAL FOOD, DRUG, AND COSMETIC ACT

30. H.R. 5333, the Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2018

On March 19, 2018, Reps. Burgess (R-TX), Green (D-TX), Latta (R-OH), DeGette (D-CO), Guthrie (R-KY), and Dingell (D-MI) introduced the "Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2018." A discussion draft version of this legislation passed the Subcommittee on Health on January 17, 2018 by voice vote. H.R. 5333 authorizes the Over-the-Counter Monograph User Fee Act of 2018 and includes a number of reforms to the current monograph process, including: transitioning OTC monographs from a rulemaking process to an administrative order procedure; expediting administrative order procedures for OTC monograph drugs that pose an imminent hazard to public health or are associated with serious adverse events requiring safety label changes; outlining a procedure for minor changes to an administrative order for a OTC monograph drug; and, clarifying how sunscreens would be reviewed moving forward. The introduced bill incorporates technical assistance from the Food and Drug Administration, as well as industry and other stakeholders. In addition, the introduced legislation modifies the exclusivity provision that was considered at the Subcommittee from 24 months from effective date of final order, to 18 months from drug listing, which must take place on or before the date the drug is first commercially marketed.

31. H.R. 5554, Animal Drug and Animal Generic Drug User Fee Amendments of 2018

A Manager's amendment was adopted at Subcommittee that includes three additional provisions. One directing the Food and Drug Administration (FDA) to consider how the drug development tools included in 21st Century Cures could be applied to animal drugs, such as adaptive and novel clinical trial designs, real world evidence, and biomarkers and surrogate endpoints, among others. Another that would direct FDA to issue recommendations related to expanding conditional approval by September 30, 2019. And a final that would require FDA to consider foreign data in food additive decisions and provide the scientific rationale if the agency requires the sponsor to conduct additional studies, as well as report on the number of food additive petitions pending, how long they have been pending, and the number of study protocols that have been pending review for over fifty days. FDA would also have to put out guidance which details the manner and number of days by which it intends to review and respond to existing petitions. An amendment is expected to be considered at Full Committee that would expand conditional approval to major uses and major species, and would direct FDA to issue a plan as to how the agency will bring all medically important antimicrobial drugs intended for use in animals under veterinary oversight.

32. H.R. 5687, Securing Opioids and Unused Narcotics with Deliberate Disposal and Packaging Act of 2018

A discussion draft version of H.R. 5687 was passed by voice vote at Subcommittee. Prior to introduction, the sponsors of the legislation, Reps. Hudson (R-NC) and Butterfield (D-NC), made a number of changes to address the concerns raised by industry and Members at the mark-up. Such changes include: requiring FDA to take into consideration the specific risk of abuse or misuse of a drug and the impact on patient access when considering the technologies, controls, or

other measures that should be applied to such drug; modifying the compliance date to ensure agreement among FDA and sponsors; clarifying that FDA has the ability to approve generic drugs with packaging or disposal technologies, controls, or measures that are comparably effective to those of the approved brand drug product and that such labeling cannot be used to block approval of generic drug products; clarifying that FDA should also consult with patients and caregivers when making decisions related to disposal products or packaging technologies; and revising the GAO report to also require an assessment of packaging technologies.