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ONE HUNDRED FIFTEENTH CONGRESS

Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
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MEMORANDUM

June 6, 2017

To: Committee on Energy and Commerce Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: Full Committee Markup of H.R. 338, H.R. 627, H.R. 723, H.R. 1109, H.R. 446, H.R. 447, H.R. 951, H.R. 2122, H.R. 2274, H.R. 2292, H.R. 2457, H.R. 1222, H.R. 1492, H.R. 2410, and H.R. 2430

On **Wednesday, June 7, 2017, at 10:00 a.m. in room 2123 of the Rayburn House Office Building** the Committee on Energy and Commerce will convene for opening statements and a markup of the following 15 legislative measures:

- H.R.338, To Promote a 21st Century Energy and Manufacturing Workforce;
- H.R. 627, Streamlining Energy Efficiency for Schools Act of 2017;
- H.R. 723, Energy Savings Through Public-Private Partnerships Act of 2017;
- H.R. 1109, To Amend Section 203 of the Federal Power Act;
- H.R. 446, To Extend the Deadline for Commencement of Construction of a Hydroelectric Project (Flanagan, VA);
- H.R. 447, To Extend the Deadline for Commencement of Construction of a Hydroelectric Project (Gathright, VA);
- H.R. 951, To Extend the Deadline for Commencement of Construction of a Hydroelectric Project (W. Kerr Scott, NC);
- H.R. 2122, To Reinstate and Extend the Deadline for Commencement of Construction for a Hydroelectric Project Involving Jennings Randolph Dam (West Virginia);
- H.R. 2274, HYdropower Permit Extension (HYPE) Act;
- H.R. 2292, To Extend a Project of the Federal Energy Regulatory Commission Involving the Cannonsville Dam;
- H.R. 2457, J. Bennett Johnston Waterway Hydropower Extension Act of 2017;
- H.R. 1222, the Congenital Heart Futures Reauthorization Act of 2017;
- H.R. 1492, the Medical Controlled Substances Transportation Act of 2017;

- H.R. 2410, the Sickle Cell Disease Research, Surveillance, Prevention, and Treatment Act of 2017; and
- H.R. 2430, the Food and Drug Administration Reauthorization Act.

This memorandum supplements information provided in memoranda from prior- and related legislative hearings and markups.

I. H.R. 338, A BILL TO PROMOTE A 21ST CENTURY ENERGY AND MANUFACTURING WORKFORCE

H.R. 338, a bill to promote a 21st century energy and manufacturing workforce was introduced by Rep. Rush (D-IL) on January 5, 2017. The Committee reported similar legislation to the House during the last Congress. That legislation subsequently passed the House by voice vote.

The 21st Century Workforce directs the Secretary of Energy to prioritize education and training for underrepresented groups (e.g., minorities, women, veterans) and displaced and unemployed energy and manufacturing workers in order to increase the number of skilled candidates trained to work in these related fields. Elements of this new program include:

- Strengthening and more fully engaging Department of Energy (DOE) programs and national labs in carrying out the Department's workforce development initiatives including the Minorities in Energy Initiative;
- Establishment of a clearinghouse of information and resources on training and workforce development programs for energy and manufacturing-related jobs;
- Collaboration with schools, community colleges, universities (including minority serving institutions), workforce training organizations, national laboratories, state energy offices, workforce investment boards, and the energy and manufacturing industries to develop and implement training programs;
- Outreach to minority-serving educational institutions, with the objective of increasing the number of minorities, women, and veterans trained to work in the energy and manufacturing-related job sector; and
- Work with industry and community-based workforce organizations to help identify candidates from underrepresented and unemployed communities to enroll into training and apprenticeship programs, with the objective of increasing their opportunities for employment within the energy and manufacturing job sectors

II. H.R. 627, STREAMLINING ENERGY EFFICIENCY FOR SCHOOLS ACT OF 2017

This bill, authored by Rep. Cartwright (D-PA), amends the Energy Policy and Conservation Act to direct the Department of Energy's Office of Energy and Renewable Energy to establish a clearinghouse to disseminate information regarding available programs and financing mechanisms for energy efficiency projects for schools. Such information includes that which may be used to help initiate, develop, and finance energy efficiency, distributed generation, and energy retrofitting projects. The language requires DOE to consult with

appropriate agencies to develop a list of programs and financing mechanisms that are, or may be, used for the projects. It also requires the Office to coordinate with appropriate agencies to develop a collaborative education and outreach effort to streamline communications and promote the programs and financing mechanisms. Similar legislation passed the House by voice vote in the previous Congress.

III. H.R. 723, ENERGY SAVINGS THROUGH PUBLIC-PRIVATE PARTNERSHIPS ACT OF 2017

This legislation, sponsored by Rep. Kinzinger (R-IL), makes several clarifying improvements to the implementation of Energy Savings Performance Contracts (ESPCs). ESPCs allow the federal government to contract for energy-saving and water-saving improvements in federal buildings that are paid for with the resulting energy and water savings over the life of the contract. Similar language was included in the original, bipartisan subcommittee markup of comprehensive energy legislation during the 114th Congress (H.R. 8).

IV. H.R. 1109, A BILL TO AMEND SECTION 203 OF THE FEDERAL POWER ACT

H.R. 1109, a bill to amend section 203 of the Federal Power Act (FPA), was introduced by Reps. Walberg and Dingell on February 16, 2017. The Committee reported similar legislation last Congress, which subsequently passed the House by voice vote.

From its enactment in 1935, the FPA has required the Federal Energy Regulatory Commission (FERC) authorization for mergers or consolidations of any electric utility or parts of such a utility. Prior to 2006, FERC interpreted the statute to provide for a *de minimu*s exemption for such activities with a monetary value of less than $50,000. The FPA, together with the Securities and Exchange Commission-administered Public Utility Holding Company Act of 1935 (PUHCA), provided for strict, structural regulation of electric utilities and their holding companies.

The Energy Policy Act of 2005 (EPACT05) made significant changes to FERC's enforcement authorities as part of an overall revamp of federal electricity regulation and regulation of the utility industry. EPACT05 effectively repealed PUHCA and replaced its structural regulation of the utilities industry with increased direct enforcement authority and a broad prohibition on energy market manipulation.

One aspect of this overhaul included altering the authorities in FPA section 203 to address perceived regulatory gaps posed by the repeal of PUHCA. In particular, EPACT05 significantly revised and expanded section 203(a), adding five additional paragraphs. A version of the contents of the original section 203(a) was re-designated as section 203(a)(1) and divided into four subparagraphs, each addressing a specific activity requiring review and prior authorization by FERC. Three of the four activities outlined provided for an exemption from FERC review for transactions with a value of less than $10 million. However, Congress included no such *de minimus* exemption in the subparagraph (B) dealing with mergers and consolidations.

H.R. 1109 would amend section 203(a)(1)(B) of the FPA to include a $10 million threshold to trigger FERC review of a merger or consolidation. In addition, section 2 of the legislation amends section 203(a) to require any public utility seeking to merge or consolidate FERC-jurisdictional facilities, pursuant to subsection 203(a)(1)(B) of the FPA, to notify the Commission within 30 days after the date on which the transaction is consummated if the facilities have a value in excess of $1,000,000 but less than $10,000,000.

V. H.R. 446, A BILL TO EXTEND THE DEADLINE FOR COMMENCEMENT OF CONSTRUCTION OF A HYDROELECTRIC PROJECT

This bill, authored by Rep. Griffith (R-VA), authorizes FERC to extend for six years the date by which the licensee is required to commence construction of a hydroelectric facility at the Gathright Dam in Alleghany County, Virginia. Similar legislation passed the House of Representatives by voice vote during the 114th Congress.

VI. H.R. 447, A BILL TO EXTEND THE DEADLINE FOR COMMENCEMENT OF CONSTRUCTION OF A HYDROELECTRIC PROJECT

This bill, also sponsored by Rep. Griffith (R-VA) authorizes FERC to extend for six years the date by which the licensee is required to commence construction of a hydroelectric facility at the Flannagan Dam in Virginia. Similar legislation passed the House of Representatives by voice vote in the 114th Congress.

VII. H.R. 951, A BILL TO EXTEND THE DEADLINE FOR COMMENCEMENT OF CONSTRUCTION OF A HYDROELECTRIC PROJECT INVOLVING THE W. KERR SCOTT DAM

H.R. 951 is legislation sponsored by Rep. Foxx (R-NC) to extend the deadline for commencement of construction of a hydroelectric project involving the W. Kerr Scott Dam.

On July 17, 2012, FERC licensed the W. Kerr Scott Hydropower project to be located at the Corps' W. Kerr Scott Dam on the Yadkin River in Wilkes County, North Carolina. The licensee for the W. Kerr Scott Hydropower project was not able to commence construction by the already extended deadline of July 17, 2016. Legislation is required to extend the construction commencement deadline.

The bill would authorize FERC to extend for six years the date by which the licensee is required to commence construction. Similar legislation passed the House during the 114th Congress by a vote of 406-3.

VIII. H.R. 2122, A BILL TO REINSTATE AND EXTEND THE DEADLINE FOR COMMENCEMENT OF CONSTRUCTION OF A HYDROELECTRIC PROJECT INVOLVING JENNINGS RANDOLPH DAM

This legislation, sponsored by Rep. McKinley (R-WVa), authorizes FERC to extend for six years the date by which the licensee is required to commence construction of a hydroelectric

facility at the Jennings Randolph Dam located on the North Branch of the Potomac River in Maryland and West Virginia. Similar legislation passed the House of Representatives by a 418-2 vote during the 114th Congress.

IX. H.R. 2274, HYDROPOWER PERMIT EXTENSION (HYPE) ACT

The HYdropower Permit Extension (HYPE Act) is legislation recently introduced by Rep. Peters (D-CA) to provide FERC with the authority to grant longer periods for preliminary and construction permits and associated extensions under Sections 5 and 13 of the FPA. The FPA requires licensees to commence construction of hydroelectric projects within the time fixed in the license --no more than two years from the issuance of the license. Current law requires an act of Congress to extend construction permits for hydropower projects. The bill gives projects an extra year on their initial permit to begin construction. The bill lengthens preliminary construction permits for hydropower projects from three years to four years and also increases from two years to four years the extension that FERC can grant to projects that experience delays.

X. H.R. 2292, A BILL TO EXTEND A PROJECT OF THE FEDERAL ENERGY REGULATORY COMMISSION INVOLVING THE CANNONSVILLE DAM

H.R. 2292, a bill to extend the deadline for commencement of construction of a hydroelectric project involving the Cannonsville Dam, was introduced by Rep. Faso (R-NY) on May 2, 2017.

On May 13, 2014, FERC licensed the construction of a hydroelectric facility at the Cannonsville Reservoir located on the West Branch of the Delaware River in Delaware County, New York. The licensee for the Cannonsville Reservoir project was not able to commence construction by the deadline in May 2016. The additional reviews and repairs to the dam which are necessary to commence construction of the hydroelectric project will delay commencement of construction beyond the expiration date of the original license and the two year extension which FERC is authorized to grant. Legislation is required to extend the construction commencement deadline in light of these circumstances.

The bill would authorize FERC to extend for eight years the date by which the licensee is required to commence construction. Similar legislation passed the House during the 114th Congress by a vote of 417-2.

XI. H.R. 2457, J. BENNETT JOHNSTON WATERWAY HYDROPOWER EXTENSION ACT OF 2017

H.R. 2457, the J. Bennett Johnston Waterway Hydropower Extension Act of 2017, was introduced by Rep. Mike Johnson (R-LA) on May 16, 2017. The bill would extend the time period during which the licensee is required to commence the construction of its project for up to three consecutive 2-year periods from the date of the expiration of the original extension. Additionally, the legislation defers the obligation on the licensee to pay any annual charges required under FPA section 10(e) until the project actually commences construction. Finally, the

legislation allows for the prospective reinstatement of the license should that license expire prior to the legislation's date of enactment.

XII. H.R. 1222, THE CONGENITAL HEART FUTURES REAUTHORIZATION ACT OF 2017

Rep. Bilirakis (R-FL) and Rep. Schiff (D-CA) introduced H.R. 1222, the Congenital Heart Futures Reauthorization Act of 2017 on February 27, 2017. H.R. 1222 builds on existing efforts by requiring the Centers for Disease Control and Prevention (CDC) to enhance and expand its research, surveillance infrastructure, and public outreach and education programs relating to congenital heart disease (CHD). The bill also directs CDC to submit one or more reports to Congress on a study to improve knowledge of the epidemiology of congenital heart disease. Finally, the bill requires the National Institutes of Health (NIH) to issue a report outlining current and future research plans with respect to CHD.

XIII. H.R. 1492, THE MEDICAL CONTROLLED SUBSTANCES TRANSPORTATION ACT OF 2017

H.R. 1492 was introduced by Rep. Sessions (R-TX) on March 10, 2017. This legislation would allow a physician registered with the Drug Enforcement Administration (DEA) to transport controlled substances to another practice setting if the physician is registered to dispense controlled substances listed on schedules II, III, IV, or V, and the physician applies for registration for such purposes. To be registered for such purposes, the registrant would be required to: be licensed, registered or otherwise permitted by the state to administer controlled substances, limit transport and administration to a 72 hour time period, and maintain records regarding the transportation and administration of the controlled substances.

Currently, physicians are prohibited from transporting controlled substances away from their registered practice locations to other locations. This legislation would allow, for example, athletic team physicians to transport a supply of controlled substances to athletic games in other states, or physicians to bring controlled substances to respond to a disaster.

Last Congress, the Medical Controlled Substances Transportation Act of 2017 passed out of full Committee on November 18, 2015, by a voice vote.

XIV. H.R. 2410, THE SICKLE CELL DISEASE RESEARCH, SURVEILLANCE, PREVENTION, AND TREATMENT ACT OF 2017

Rep. Davis (D-IL) and Rep. Burgess (R-TX) introduced H.R. 2410, the Sickle Cell Disease Research, Surveillance, Prevention, and Treatment Act of 2017 on May 11, 2017. This legislation would reauthorize the Sickle Cell Disease Treatment Demonstration Program and allow up to 25 eligible entities to receive grants under the program. H.R. 2410 also would allow the Secretary of Health and Human Services (HHS) to conduct or support research to help increase understanding of sickle cell disease. Finally, this legislation would allow the Secretary to create a grant program that would support states in conducting surveillance on the prevalence

and distribution of the disease, conducting public health initiatives, or identifying and evaluating prevention and treatment strategies.

XV. H.R. 2430, THE FOOD AND DRUG ADMINISTRATION REAUTHORIZATION ACT OF 2017

A. Summary of Changes to H.R. 2430

A bipartisan draft of the Food and Drug Administration Reauthorization Act of 2017 was reported out of the health subcommittee by a voice vote following passage of four bipartisan amendments. Below is a summary of the amendments made to H.R. 2430. Additional technical edits to specific provisions will be considered by the Committee in a manager's amendment.

B. Drug Diversion and Counterfeit Crackdown Act of 2017

Counterfeit and diverted prescription drugs present dangerous disruptions in the U.S. drug supply chain. Many unapproved, foreign-made, counterfeit drugs are imported to the U.S. by illegitimate online pharmacies and wholesalers that often sell them at extremely low prices. While these drugs are marketed as safe, legal, and cheap, the drugs may in fact contain harmful ingredients, contain the incorrect amount of active ingredients, or have been transported or stored in unsanitary or otherwise improper conditions. For example, the drugs may be expired or may have been produced in unsanitary environments.

Under current law, the penalties for illegally diverting drugs into the U.S. that were manufactured abroad and intended for foreign markets are significantly less severe than if the drugs were initially manufactured in the U.S. Further, the penalties for counterfeiting are much lower than for diversion. There is no public health or patient safety rationale for these arbitrary distinctions.

Introduced by Rep. Lance (R-NJ), Rep. Dingell (D-MI), Rep. Burgess (R-TX), and Rep. Green (D-TX), the Drug Diversion and Counterfeit Crackdown Act of 2017, provides the same penalties for diverting drugs made outside the U.S. and intended for a foreign market as the penalties for diverting drugs made inside the U.S. and intended for a foreign market. Further, any person who knowingly makes, sells, or dispenses a counterfeit drug is subject to a fine in accordance with title 18 and not more than 10 years of prison. This amendment was adopted by a voice vote during health subcommittee consideration.

C. Over-The-Counter Hearing Aid Act of 2017

Introduced by Rep. Kennedy (D-MA), Rep. Carter (R-GA), and Rep. Blackburn (R-TN), the amendment establishes a category for over-the-counter (OTC) hearing aids. No later than three years after enactment, HHS must propose regulations to establish a separate category for the regulation of OTC hearing aids. Final regulations shall be issued no later than 180 days after the close of the public comment period. These regulations should include requirements to provide reasonable assurances of safety and efficacy, to establish or adopt output limits appropriate for OTC hearing aids, for appropriate labeling of OTC hearing aids, and under which

sale of OTC hearing aids is permitted. HHS must also determine whether OTC hearing aids require premarket notification. The amendment prevents state or local governments from establishing any law that would restrict or interfere with the sale and use of OTC hearing aids. Finally, the amendment directs HHS to finalize the draft guidance entitled "Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products", which will clarify the products that meet the definition of a personal sound amplification product. This amendment was adopted by a voice vote during health subcommittee consideration.

D. Risk-Based Medical Device Inspections

Introduced by Rep. Bucshon (R-IN), Rep. Brooks (R-IN), Rep. Peters (D-CA) and Rep. Butterfield (D-NC), the amendment aims to improve the process for Food and Drug Administration (FDA) inspections of medical device establishments and for granting export certificates to foreign countries.

The amendment directs FDA to inspect device establishments using a risk-based inspection schedule. In establishing the risk-based schedule, HHS must consider previously established device risk factors and consider the participation of the device establishment in international device audit programs. FDA is also directed to adopt a process and set of standards for inspecting device establishments. The process will include notification of the agent in charge of the establishment of the type and nature of the inspection, as well as announcing the inspection of the establishment within a reasonable time before inspection. For inspections other than for-cause inspections, FDA must provide a reasonable estimate of the timeframe for the inspection and maintain daily communications with the agent in charge of the establishment regarding inspection status. Finally, the amendment establishes a timeline to receive feedback from FDA once the inspection report has been received by the establishment. Not later than one year after the date of enactment, HHS must issue draft guidance that specifies how FDA will implement the new inspection process, provide necessary templates for communication, develop a standard timeframe for inspection, and identify practices for investigators. Final guidance must be issued no later than 18 months after the date of enactment.

With regards to foreign export certificates, FDA will provide a written justification for the denial of any export certificate and detail specific deficiencies leading to denial. FDA must also provide a process for review of a denied certification to allow establishments to address those deficiencies. HHS must issue guidance on the process within one year after enactment. This amendment was adopted by a voice vote during health subcommittee consideration.

E. Generic Drug Access and Competition

Generic drugs are an important option because they are lower-cost drugs that increase treatment access for the public. Eighty-eight (88) percent of prescription drugs dispensed in the United States are generic drugs, and from 2005 to 2014, generics saved the U.S. health system

$1.68 trillion.[1] Increasing generic competition can be an effective way to lower prescription drug costs and increase accessibility to treatment.

Introduced by Rep. Bilirakis (R-FL) and Rep. Schrader (D-OR), the amendment intends to speed the review of applications for generic drugs for which there is little to no competition. Specifically, it allows generic drugs to be classified as a "Competitive Generic Therapy" if there is not more than one approved version of the drug actively marketed, as listed in the FDA's Orange Book. Sponsors of Competitive Generic Therapies will have access to pre-submission meetings and ongoing consultation with FDA to assist in creating complete generic drug applications. Further, FDA must update the sponsors of generic drug applications with the status of the application upon request.

The amendment would also extend six months of exclusivity to a competitive generic therapy where there are no blocking patents or exclusivities. It would also address the loophole in the Neglected Tropical Disease Priority Review Voucher (PRV) whereby applicants were receiving a valuable PRV for products that had been approved in other countries prior to the creation of the program by requiring an applicant for a Tropical Disease PRV to conduct one or more new clinical investigations (other than bio-availability studies) in order to receive the PRV. Finally, the Government Accountability Office (GAO) is directed to study the rate of first-cycle approvals and tentative approvals for generic drugs over the past five years to determine best practices. This amendment was adopted by a voice vote during health subcommittee consideration.

[1] U.S. Food and Drug Administration, *Implementation of the Generic Drug User Fee Amendments of 2012 (GDUFA) - House Testimony* (Feb. 4, 2016) (https://www.fda.gov/NewsEvents/Testimony/ucm485057.htm).