THE COMMITTEE ON ENERGY AND COMMERCE

MEMORANDUM

May 10, 2013

To: Energy and Commerce Committe

From: Majority Staff

Re: Markup of H.R. 271, Resolving Environmental and Grid Reliability Conflicts Act of 2013; H.R. 1407, Animal Drug User Fee Amendments of 2013, as amended by the Subcommittee on Health; and H.R. 1919, Safeguarding America's Pharmaceuticals Act 2013

The Committee on Energy and Commerce will meet in open markup session on Tuesday, May 14, 2013, at 4:00 p.m. in 2123 Rayburn House Office Building for opening statements on H.R. 271, Resolving Environmental and Grid Reliability Conflicts Act of 2013; H.R. 1407, Animal Drug User Fee Amendments of 2013, as amended by the Subcommittee on Health; and H.R. 1919, Safeguarding America's Pharmaceuticals Act 2013. The Committee will reconvene on Wednesday, May 15, at 10:00 a.m. in 2123 Rayburn House Office Building in open markup session on the legislation. A summary of the legislation to be considered is below.

In keeping with Chairman Upton'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.

I. H.R. 271, RESOLVING ENVIRONMENTAL AND GRID RELIABILITY CONFLICTS ACT OF 2013

H.R. 271, the Resolving Environmental and Grid Reliability Conflicts Act of 2013, was introduced on January 15, 2013, by Representatives Olson (R-TX), Doyle (D-PA), Terry (R-NE), Green (D-TX), and Kinzinger (R-IL). Identical legislation – H.R. 4273 – was passed by the House of Representatives in the 112th Congress.

The bill includes the following provisions:

A. SECTION 1: SHORT TITLE

Provides the short title of "Resolving Environmental and Grid Reliability Conflicts Act of 2013."

B. SECTION 2: AMENDMENTS TO THE FEDERAL POWER ACT

Section 2(a) amends section 202(c) of the Federal Power Act (16 U.S.C. 824a(c)) to direct the Department of Energy (DOE), in issuing an order pursuant to section 202(c) that may result in a conflict with a requirement of any Federal, State, or local environmental law or regulation, to ensure that the order limits the generation, delivery, or transmission of electricity to only those hours necessary to meet the emergency and serve the public interest. DOE also must ensure the order, to the maximum extent practicable, is consistent with any applicable Federal, State, or local laws or regulations and minimizes any adverse environmental impacts that may result from such order.

Section 2(a) further amends section 202(c) to provide that if a party takes an action that is necessary to comply with a section 202(c) order and such action results in noncompliance with any Federal, State, or local environmental law or regulation, then such action shall not be considered a violation of such environmental law. Nor would the action subject the party to any requirement, civil or criminal liability, or a citizen suit under such environmental law.

Section 2(a) further amends section 202(c) to require that an order issued pursuant to section 202(c) that may result in a conflict with an environmental law or regulation shall expire not later than 90 days after issuance. DOE may renew or reissue such an order for subsequent periods, not to exceed 90 days, as DOE determines necessary to meet the emergency and serve the public interest. In renewing or reissuing the order, DOE must consult with the primary Federal agency with expertise in the environmental interest protected by a potentially conflicting environmental law. DOE must include in the renewed or reissued order conditions determined by such primary Federal agency to be necessary to minimize any adverse environmental impacts that may result from such renewed or reissued order to the maximum extent practicable. DOE has discretion to exclude such a condition from the renewed or reissued order if it determines the condition would prevent the order from adequately addressing the emergency.

Section 2(b) amends section 202(d) of the Federal Power Act (16 U.S.C. 824a(d)) to clarify that section 202(d) is applicable to municipalities, and not solely to "persons" as defined under section 3 of the Federal Power Act (16 U.S.C. 796).

Should you have any questions regarding H.R. 271, please contact Patrick Currier or Tom Hassenboehler at (202) 225-2927.

II. H.R. 1407, ANIMAL DRUG USER FEE AMENDMENTS OF 2013, AS AMENDED BY THE SUBCOMMITTEE ON HEALTH

H.R. 1407 was introduced by Rep. Shimkus on April 9, 2013. The Subcommittee on Health held a legislative hearing on H.R. 1407 on April 9, 2013, entitled "Reauthorization of Animal Drug User Fee Act (ADUFA) and Animal Generic Drug User Fee Act (AGDUFA)."[1] At the Subcommittee markup on May 8, 2013, the Subcommittee approved an amendment in the nature of a substitute (AINS) to H.R. 1407. The AINS combined the text of H.R. 1407 and H.R. 1408, Animal Generic Drug User Fee Amendment of 2013, which was introduced by Rep. Gardner on April 9, 2013, and also considered during the Subcommittee on Health's hearing on April 9, 2013. H.R. 1407, as amended, would reauthorize both ADUFA and AGDUFA through Fiscal Year 2018. The bill was approved by the Subcommittee on Health, as amended, by a voice vote. Below is summary of the bill.

TITLE I: ANIMAL DRUG USER FEE AMENDMENTS

Title I of the AINS would reauthorize ADUFA. In 2003, Congress first enacted ADUFA (ADUFA I) to help improve the Food and Drug Administration (FDA) review of new animal drugs. The program was modeled on the Prescription Drug User Fee Program for human drugs, and it was authorized for five years. Under the user fee authority of ADUFA I, FDA collected funds to help expedite the new animal drug approval process, reduce the application backlog, and improve communications with drug sponsors. In 2008, because of the success of the program, Congress reauthorized ADUFA for five years (ADUFA II). Unless Congress reauthorizes these user fees, FDA cannot collect them after September 30, 2013.

Following the process prescribed by statute, FDA and industry negotiated an agreement regarding the size and scope of the user fees for Fiscal Years 2014-2018. In February 2013, FDA sent its final legislative recommendations on the agreement to the Committee. Under the proposed ADUFA III agreement, industry would pay approximately $23,600,000 in Fiscal Year 2014 ($21,600,000 plus $2,000,000 for one-time information technology funding), and similar amounts in the remaining four years based on inflation adjusters. The fee would be paid through application fees (20 percent of the total), product fees (27 percent of the total), sponsor fees (27 percent of the total), and establishment fees (26 percent of the total).[2]

TITLE II: ANIMAL GENERIC DRUG USER FEE AMENDMENTS

Title II of the bill would reauthorize AGDUFA.

In 2008, Congress authorized the AGDUFA program for five years in order to improve the review of abbreviated new animal drug applications. AGDUFA I enabled FDA to eliminate

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[1] For additional information on the ADUFA reauthorization legislative hearing, please see the following, http://energycommerce.house.gov/hearing/reauthorization-animal-drug-user-fees-adufa-and-agdufa .
[2] For more information, please see the following: http://www.fda.gov/forindustry/userfees/animaldruguserfeeactadufa/default.htm.

its application backlog and reduce review times. FDA cannot collect these user fees after September 30, 2013, unless they are reauthorized by Congress.

Similar to the ADUFA reauthorization process, FDA and industry negotiated an agreement regarding the size and scope of AGDUFA for Fiscal Years 2014-2018, and FDA sent its final legislative recommendations on the AGDUFA agreement to the Committee in February 2013. Under the proposed AGDUFA agreement, the industry would pay $7,328,000 in Fiscal Year 2014 ($6,478,000 plus $850,000 for one-time information technology funding), $6,944,000 in Fiscal Year 2015, $7,429,000 in Fiscal Year 2016, $7,936,000 in Fiscal Year 2017, and $8,467,000 in Fiscal Year 2018. These fees would be paid through application fees (25 percent of total), product fees (37.5 percent of total), and sponsor fees (37.5 percent of the total).[3]

Should you have any questions regarding H.R. 1407, please contact Paul Edattel, Carly McWilliams, or Clay Alspach at (202) 225-2927.

III. H.R. 1919, SAFEGUARDING AMERICA'S PHARMACEUTICALS ACT 2013

H.R. 1919 would enhance the security of the pharmaceutical distribution supply chain for America's patients while preventing duplicative Federal and State requirements. It also would establish a collaborative, transparent process between the Food and Drug Administration (FDA) and stakeholders to ensure a reasonable, practical transition to unit-level traceability. The Subcommittee on Health held a hearing on the legislation on April 25, 2013. On May 8, 2013, the Subcommittee on Health approved a discussion draft of the legislation by a voice vote. On May 9, 2013, Rep. Latta introduced H.R. 1919, which is substantially similar to the discussion draft approved by the Subcommittee. Below is a summary of the bill.[4]

A. SECTION 1: SHORT TITLE

Provides the short title of "Safeguarding America's Pharmaceuticals Act 2013."

B. SECTION 2: PHARMACEUTICAL DISTRIBUTION SUPPLY CHAIN

This section would increase the security of the supply chain by establishing lot-level tracing requirements for manufacturers, wholesale distributors, pharmacies, and repackagers based on changes in ownership. It also would require the members of the supply chain, including third-party logistics providers, to undertake verification and notification activities regarding suspect or illegitimate products. Further, it would require that members of the supply

[3] For additional information, please see the following: http://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/default.htm.

[4] For additional information on the legislative hearing, please see the following: http://energycommerce.house.gov/hearing/securing-our-nations-prescription-drug-supply-chain.

chain only transact with registered or licensed entities. Finally, the section would require manufacturers to serialize prescription drugs at the unit level.

C. SECTION 3: ENHANCED DRUG DISTRIBUTION SECURITY

This section would require FDA to establish pilot projects and hold biannual public meetings in order to foster collaboration with stakeholders regarding moving to unit-level traceability. The section also would require that the Government Accountability Office (GAO) and FDA submit reports to Congress on those same subjects. As part of the FDA report, FDA would include the findings of a study by a third-party entity on small dispensers' ability to conduct interoperable tracing at the unit level. Finally, it would require FDA to issue a proposed regulation on unit-level traceabilty in 2027.

D. SECTION 4: NATIONAL STANDARDS FOR WHOLESALE DISTRIBUTORS

This section would establish national standards for wholesale distributors, while continuing State licensing of wholesale distributors and State fee collection.

E. SECTION 5: NATIONAL LICENSURE STANDARDS FOR THIRD-PARTY LOGISTICS PROVIDERS

This section would establish third-party logistics provider licensure standards and allow FDA to charge a user fee. It would not prevent a State from licensing third-party logistics providers in accordance with the section.

F. SECTION 6: PENALTIES

This section would establish penalties for violations of the requirements of the bill to ensure bad actors are held accountable.

G. SECTION 7: UNIFORM NATIONAL POLICY

This section would preempt, upon enactment, State laws on tracing drugs through the distribution system. It also would preempt State laws regarding standards for wholesale drug distributors and third party logistics providers. This preemption would not affect the authority of States to collect fees from wholesale drug distributors or third-party logistics providers.

H. SECTION 8: ELECTRONIC LABELING REQUIREMENT

This section would allow prescription drug labeling to be provided by electronic means.

Should you have any questions regarding H.R. 1919, please contact Paul Edattel, Carly McWilliams, or Clay Alspach at (202) 225-2927.