THE COMMITTEE ON ENERGY AND COMMERCE

MEMORANDUM

May 3, 2013

To: Health Subcommittee

From: Energy and Commerce Committee Majority Staff

Re: Subcommittee Markup, May 7-8, 2013

On Tuesday, May 7, 2013, at 4:00 p.m. in 2123 Rayburn House Office Building, the Subcommittee on Health will meet in an open markup session for opening statements on H.R. 1407, the Animal Drug User Fee Amendments Act of 2013, and H.R. ___, a bill to amend the Federal Food, Drug, and Cosmetic Act with respect to the pharmaceutical distribution supply chain, and for other purposes. The Subcommittee will reconvene on Wednesday, May 8, at 9:00 a.m. in 2123 Rayburn House Office Building in open markup session on the legislation. It is expected that an Amendment in the Nature of a Substitute to H.R. 1407 will be considered.

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. 1407

H.R. 1407 was introduced by Rep. Shimkus on April 9, 2013. The Subcommittee on Health held a legislative hearing on April 9, 2013, entitled "Reauthorization of Animal Drug User Fee Act (ADUFA) and Animal Generic Drug User Fee Act (AGDUFA)."[1] The Amendment in the Nature of a Substitute (AINS) would reauthorize both ADUFA and AGDUFA through Fiscal Year 2018. Below is background on the bill.

Title I - ADUFA

Title I of the AINS would reauthorize ADUFA. In 2003, Congress first enacted ADUFA 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

[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.

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 - AGDUFA

Title II of the bill would reauthorize AGDUFA. The language of this title derives from H.R. 1408, which was introduced by Rep. Gardner on April 9, 2013; this bill wasalso the subject of the legislative hearing on April 9.

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 the agency to eliminate 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 ADUFA, 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 $7,328,00 in Fiscal Year 2014 ($6,478,000 plus $850,000 for one-time information technology funding), $6,944,00 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]

II. H.R. ___, a bill to amend the Federal Food, Drug, and Cosmetic Act with respect to the pharmaceutical distribution supply chain, and for other purposes

The bill 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 FDA and stakeholders to better move to

[2] For more information, please see the following: http://www.fda.gov/forindustry/userfees/animaldruguserfeeactadufa/default.htm.

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

unit-level traceability. The Subcommittee on Health held a hearing on the legislation on April 25, 2013. Below is a summary of the bill.[4]

SECTION-BY-SECTION

SECTION 1: SHORT TITLE

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 chain only transact with registered or licensed entities. Finally, the section would require manufacturers to serialize prescription drugs at the unit level. These changes would begin on January 1, 2015, and phase in rapidly.

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.

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.

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.

SECTION 6 – PENALTIES – This section would establish penalties for violations of the requirements of the bill to ensure bad actors are held accountable.

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.

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

SECTION 8 – ELECTRONIC LABELING REQUIREMENT – This section would allow prescription drug labeling to be provided by electronic means.

III. CONCLUSION

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