THE COMMITTEE ON ENERGY AND COMMERCE

INTERNAL MEMORANDUM

April 24, 2012

To: Energy and Commerce Committee Members

From: Majority Staff

Re: Subcommittee Markup

On Thursday, April 26, 2012, at 10:00 a.m. in room 2123 Rayburn House Office Building, the Subcommittee on Health will meet in open markup session to consider legislation to reauthorize user fee programs for prescription drugs and medical devices, establish user fee programs for generic drugs and biosimilars, and reform FDA programs.

I. BACKGROUND

The following provides background on the discussion draft:

Title I: Prescription Drug User Fee Act (PDUFA)

The first title would reauthorize the Prescription Drug User Fee Act (PDUFA). Under the PDUFA V agreement, the industry would pay approximately $713 million in FY 2013 (possibly more based on adjusters) and a higher amount in the remaining four years. As part of the PDUFA V agreement, the Food and Drug Administration (FDA) would commit to attaining certain performance goals regarding the review of priority and standard drug applications. It also would foster greater interaction between drug sponsors and FDA and more engagement with patients, including those with rare diseases.

Title II: Medical Device User Fee Act (MDUFA)

The second title would reauthorize the Medical Device User Fee Act (MDUFA). The new MDUFA agreement would provide for $595 million in user fees for Fiscal Years 2013-2017. Under its current user fee authority, FDA will collect $287 million from Fiscal Year 2008 to Fiscal Year 2012.

The user fee agreement also would include the following improvements: (1) FDA would have to report its total time for reviewing devices; (2) FDA's review process would include greater interaction between sponsors and the agency; and (3) an independent entity would review the device approval and clearance processes, and FDA would have to implement a corrective action plan to address deficiencies.

Title III: Generic Drug User Fee Act (GDUFA)

This title would authorize the new Generic Drug User Fee Act (GDUFA). The proposed generic drug user fee would provide additional resources for the review and regulation of generic drugs. Under GDUFA, the generic drug industry would pay approximately $1.5 billion over five years. The industry agreed to this fee in return for faster and more predictable review of generic drug applications and increased inspections of drug facilities.

Title IV: Biosimilars User Fee Act (BSUFA)

Title IV contains language that would authorize the new Biosimilars User Fee Act (BSUFA). This user fee would apply to products approved under the abbreviated approval pathway for biological products shown to be biosimilar to an FDA-licensed biological product. BSUFA would authorize the following four types of fees: application, product, establishment and biosimilar product development. The first three would be set equal to the PDUFA rate for each type of fee. The product development fee would be set at 10 percent of the PDUFA application fee.

Title V: Best Pharmaceuticals for Children Act (BPCA) and Pediatric Research Equity Act (PREA)

This title includes language from legislation offered by Mr. Rogers, Ms. Eshoo and Mr. Markey (H.R. 4274) that would permanently authorize the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA). BPCA and PREA foster the development of prescription drugs for children and safe use of drugs by children. BPCA was established in 1997. It provides FDA with the authority to grant a six-month marketing exclusivity period to a manufacturer of a drug in return for FDA-requested pediatric use studies and reports.

The Pediatric Research Equity Act (Section 505B of the FFDCA) requires a manufacturer of a drug or biologic who submits an application to market a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration to also submit a pediatric assessment.

Title VI: FDA Administrative Reforms

This title would improve FDA's guidance process and amend FDA's conflict of interest rules for individuals serving on advisory committees to ensure FDA has access to needed expertise.

Title VII: Medical Device Regulatory Reforms

Title VII would address issues related to medical devices including the following:

- Clarify the Investigational Device Exemption (IDE) process which enables the device to be used in a clinical study.

- Reaffirm the least burdensome provisions added during the Food and Drug Administration Modernization Act of 1997.

- Require FDA to provide the scientific or regulatory rationale for major decisions and establish an expedited approval appellate process for challenging those decisions.

- Clarify when a device manufacturer must notify FDA of a modification of its device.

- Streamline the de novo classification process, which is used for novel, innovative devices, by striking the requirement that a sponsor receive a Not Substantially Equivalent finding before entering the de novo process, thus making the process more efficient.

- Require FDA to enter into agreements with foreign countries on harmonizing inspections and common international labels of medical devices.

- Reauthorize the third party review and third party inspection programs.

- Extend the exemption on profit for devices that have been granted Humanitarian Device Exemptions to include certain devices intended for use in adults.

Title VIII: Drug Regulatory Reforms

This section includes a placeholder for provisions related to pharmaceutical supply chain and medical gas regulation. It also would provide new incentives for the development of antibiotics to address the public health threat of antibiotic resistance and improve access to the Accelerated Approval pathway, including for drugs that treat rare diseases.

Title IX: Drug Shortages

Title IX would do the following:

- Modify existing reporting requirements for manufacturers of drugs that are life-supporting, life-sustaining, and intended for use in the prevention of a debilitating disease or condition.

- Require FDA to maintain a drug shortage list and provide patients, providers and the public with such information in order to prevent, mitigate, and manage drug shortages on the ground.

- Require DEA to provide timely approvals or denials of increases in quotas of controlled substances in instances where such an increase could help address a drug shortage.

- Require FDA to expedite the approval of manufacturing changes that could help prevent or mitigate a drug shortage.

- Authorize the GAO to conduct a study to examine the causes of drug shortages and issue recommendations on how to prevent or alleviate a drug shortage. This provision will provide needed data on how the regulatory framework, manufacturing challenges, or other factors contribute to drug shortages, as well as recommendations to address such issues.

- Require FDA and DEA to report annually on their efforts on drugs shortages based on the metrics set forth by Congress.

II. CONCLUSION

Should you have any questions regarding the hearing, please contact Clay Alspach or Ryan Long at (202) 225-2927.