



THE COMMITTEE ON ENERGY AND COMMERCE

INTERNAL MEMORANDUM

April 16, 2012

To: Energy and Commerce Committee Members

From: Majority Staff

Re: "FDA User Fees 2012: How Innovation Helps Patients and Jobs"

On Wednesday, April 18, 2012, at 10:15 a.m. in 2123 Rayburn House Office Building, the Subcommittee on Health will hold a hearing entitled "FDA User Fees 2012: How Innovation Helps Patients and Jobs." The following provides background on the hearing.

I. WITNESSES

Panel I

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Jeffrey E. Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
U.S. Food and Drug Administration

Panel II

David E. Wheadon, M.D.
Senior Vice President, Scientific and Regulatory Affairs
Pharmaceutical Research and Manufacturers of America

Sara Radcliffe
Executive Vice President, Health
Biotechnology Industry Organization

David Gaugh, R.Ph.
Vice President, Regulatory Sciences
Generic Pharmaceutical Association

Joseph A. Levitt, J.D.
Partner
Hogan Lovells US LLP
on behalf of Advanced Medical Technology Association

Allan Coukell
Director of Medical Programs, Pew Health Group
The Pew Charitable Trusts

II. 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 FDCA) 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

Title VI includes language from legislation related to advisory committee conflicts of interest, FDA's mission statement, guidance documents and cosmetics.

Title VII: Medical Device Regulatory Reforms

Title VII includes provisions from legislation related to medical devices. This legislation would reform certain premarket and post-market processes.

Title VIII: Drug Regulatory Reforms

Title VIII includes the provisions on the following topics: pharmaceutical supply chain; medical gas; antibiotic incentives; and accelerated approval.

Title IX: Drug Shortages

This title contains provisions to address the current drug shortage crisis. These provisions would end regulatory delays and improve existing programs to help alleviate drug shortages.

The provisions also would authorize a root cause analysis of the problem to inform the Committee on whether further Congressional action is needed.

III. CONCLUSION

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