THE COMMITTEE ON ENERGY AND COMMERCE

INTERNAL MEMORANDUM

January 30, 2012

To: Energy and Commerce Committee Members

From: Majority Staff

Re: Hearing on "Reauthorization of PDUFA: What It Means for Jobs, Innovation and Patients"

On February 1, 2012, at 10:00 a.m. in 2123 Rayburn House Office Building, the Subcommittee on Health will hold a hearing entitled, "Reauthorization of PDUFA: What It Means for Jobs, Innovation, and Patients." At the hearing, the Subcommittee will examine issues pertaining to the reauthorization of the Prescription Drug User Fee Act (PDUFA). This hearing also will focus on the reauthorization of the Best Pharmaceuticals for Children Act (BPCA) and Pediatric Research Equity Act (PREA) and pharmaceutical supply chain issues. The following memorandum provides background on the hearing.

I. WITNESSES

Panel I

The Honorable Margaret A. Hamburg, M.D.
Commissioner
U.S. Food and Drug Administration

Panel II

Mr. Geno Germano
President and General Manager
Specialty Care and Oncology
Pfizer, Inc.

David L. Gollaher, Ph.D.
President and CEO
California Healthcare Institute

Mr. Richard F. Pops
Chairman and CEO
Alkermes
On behalf of
Biotechnology Industry Organization

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

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

Ms. Diane Edquist Dorman
Vice President, Public Policy
National Organization for Rare Disorders

Dr. Daniel A.C. Frattarelli, M.D, FAAP
Chair of Pediatrics, Oakwood Hospital and Medical Center
Chair, American Academy of Pediatrics, Committee on Drugs

II. **PDUFA**

Congress first authorized PDUFA in 1992 and last reauthorized the user fee in the Food and Drug Administration Amendments Act of 2007 (FDAAA). Under the user fee authority, FDA collects funds from drug sponsors to help expedite the human drug approval process. The funds collected come from the following three basic types of user fees: application review fees, establishment fees, and product fees.

Following the process prescribed by statute, FDA and industry negotiated an agreement regarding the size and scope of the user fee for FY 2013-2017. Under the proposed PDUFA V agreement, the industry would pay approximately $713 million in FY 2013 and higher amounts in the remaining four years. On January 13, 2012, FDA sent its final legislative recommendations on the agreement to the Committee as required by statute.[1]

In the past, these user fee reauthorizations have been viewed as opportunities to examine and improve the FDA regulatory process. This hearing presents a chance for Members to hear from FDA and other witnesses on the issues that the Committee should consider in reauthorizing PDUFA, including BPCA, PREA, and pharmaceutical supply chain issues.

[1] Additional information on the agreement can be found here:
http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm149212.htm

Best Pharmaceuticals for Children Act and Pediatric Research Equity Act[2]

BPCA and PREA foster the development of prescription drugs for children and safe use of drugs by children. First established in 1997, BPCA 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. The pediatric assessment shall include "data, gathered using appropriate formulations for each age group for which the assessment is required, that are adequate—(i) to assess the safety and effectiveness of the drug or the biological product for the claimed indications in all relevant pediatric subpopulations; and (ii) to support dosing and administration for each pediatric subpopulation for which the drug or the biological product is safe and effective."[3]

III. CONCLUSION

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

[2] The following CRS report contains additional information on BPCA and PREA: "FDA's Authority to Ensure That Drugs Prescribed to Children Are Safe and Effective," http://www.crs.gov/pages/Reports.aspx?PRODCODE=RL33986&Source=search

[3] Section 505B(a)(2) of the Federal Food, Drug, and Cosmetic Act.