U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY AND COMMERCE

March 20, 2017

TO: Members, Subcommittee on Health

FROM: Committee Majority Staff

RE: Hearing entitled "Examining FDA's Prescription Drug User Fee Program"

I. INTRODUCTION

The Subcommittee on Health will hold a hearing on Wednesday, March 22, 2017, at 10:15 a.m. in 2322 Rayburn House Office Building. The hearing is entitled "Examining FDA's Prescription Drug User Fee Program." The Prescription Drug User Fee Act (PDUFA), as reauthorized by the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA), expires in September 2017 and must be reauthorized for the Fiscal Years 2018 to 2022. The Food and Drug Administration (FDA) and interested stakeholders will provide testimony on how the program has been implemented to date and present recommendations pertaining to its reauthorization.

II. WITNESSES

Panel I

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

Panel II

- Jeff Allen, President and CEO, Friends of Cancer Research;
- Kay Holcombe, Senior Vice President of Science Policy, Biotechnology Industry Organization; and,
- Anne Pritchett, Vice President of Policy and Research, Pharmaceutical Research and Manufacturers of America.

III. BACKGROUND

Since 1992, PDUFA has authorized FDA to collect user fees from biopharmaceutical manufacturers to supplement Congressional appropriations. Revenues generated from these fees have been used on specific activities related to the review and regulation of new drug products. In exchange for industry agreeing to pay fees, FDA commits to meeting certain performance goals, such as reviewing applications within specified timeframes. FDA's ability to collect such fees must be reauthorized every five years following a process laid out in statute that involves

negotiations between the agency and regulated industry and recommendations provided to Congress. The reauthorization process allows for input from other interested stakeholders, including patient and consumer groups, and provides opportunity for broader public comment. Each five-year reauthorization sets a total amount of fee revenue for the first year and provides a formula for annual adjustments to that total based on inflation and workload changes.

This will be the sixth reauthorization of PDUFA. The proposed agreement (PDUFA VI)[1], which was transmitted to Congress prior to the statutory deadline, builds upon process improvements enacted pursuant to FDASIA, including enhanced support for the Breakthrough Therapy Program. Further, it would aid in the implementation of several key provisions in the 21st Century Cures Act and further streamline the development and review of innovative new drugs for patients. FDA estimates that the fees negotiated in PDUFA VI will average approximately $1 billion per year.

IV. STAFF CONTACTS

If you have any questions regarding this hearing, please contact Carly McWilliams or John Stone of the Committee staff at (202) 225-2927.

[1] Additional information on the agreement can be found here: https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf.