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

February 28, 2017

TO: Members, Subcommittee on Health

FROM: Committee Majority Staff

RE: Hearing entitled "Examining FDA's Generic Drug and Biosimilar User Fee Programs"

I. INTRODUCTION

The Subcommittee on Health will hold a hearing on Thursday, March 2, 2017, at 10:00 a.m. in 2123 Rayburn House Office Building. The hearing is entitled "Examining FDA's Generic Drug and Biosimilar User Fee Programs." Both the Generic Drug User Fee Amendments of 2012 (GDUFA) and the Biosimilar User Fee Act of 2012 (BsUFA) expire 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 programs have been implemented to date and present recommendations pertaining to their reauthorization.

II. WITNESSES

Panel I

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

Panel II

- David Gaugh, Senior Vice President of Sciences and Regulatory Sciences, Association for Accessible Medicines;
- Bruce A. Leicher, Senior Vice President and General Counsel, Momenta Pharmaceuticals, Inc., Chair, The Biosimilars Council, a Division of the Association for Accessible Medicines;
- Juliana Reed, Vice President of Government Affairs, Coherus BioSciences, Immediate Past President, The Biosimilars Forum;
- Kay Holcombe, Senior Vice President of Science Policy, Biotechnology Industry Organization; and,
- Allan Coukell, Senior Director, Health Programs, The Pew Charitable Trusts.

III. BACKGROUND

Since 1992, pursuant to the Prescription Drug User Fee Act (PDUFA), Congress has authorized FDA to collect fees from regulated industry to supplement Congressional appropriations. Revenues generated from these fees have been used on specific activities related to the review and regulation of medical products. In exchange for industry agreeing to pay fees, FDA commits to meeting certain performance goals, such as completing product reviews 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 for other interested stakeholders, including patient and consumer groups, and provides opportunity for broader public comment.

Based in large part on the positive impact PDUFA had on expediting new drug product review times and improving related regulatory activities at FDA, medical device user fees were authorized in 2002 and the Medical Device User Fee Amendments (MDUFA) were reauthorized in 2007 and 2012, along with PDUFA. Reauthorization of PDUFA and MDUFA will be addressed at subsequent hearings. 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.

GDUFA

Due to growing concerns from a wide range of stakeholders about the time it was taking FDA to review generic drug applications (known as "abbreviated new drug applications" or "ANDAs") and the backlog of such applications pending at the agency, Congress passed the Generic Drug User Fee Amendments in 2012 (GDUFA I) as part of the Food and Drug Administration Safety and Innovation Act (FDASIA). GDUFA I was funded at a level of $299 million annually, adjusted each year for inflation and workload, based on the assumption that FDA would receive 750 ANDAs per year. Over the first four years of GDUFA I, FDA actually received, on average, approximately 1,000 ANDAs and is projected to spend about $430 million in the final year. To maintain current productivity and implement a number of negotiated improvements, including faster review cycles, FDA and industry are proposing user fees totaling $493.6 million annually adjusted each year for inflation and workload for Fiscal Years 2018-2022 (in what will now be known as GDUFA II).[1]

BSUFA

Pursuant to the Biologics Price Competition and Innovation Act (BCPIA) of 2009, Congress established a new regulatory authority for FDA to create an abbreviated approval pathway for biological products demonstrated to be "highly similar" to, or "interchangeable" with, a previously licensed biological product. As part of FDASIA, Congress passed the

[1] Additional information on the agreement can be found here: https://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM525234.pdf

Biosimilars User Fee Act of 2012 (BsUFA I) to authorize FDA to collect user fees from biosimilar product manufacturers. Unlike the well-established generic drug industry, the biosimilar industry is still in its nascent phase. Because no biosimilar products were marketed at the time BsUFA I was negotiated, it included fees to establish the program and enable FDA to meet with companies developing such products with the goal of submitting applications for approval. According to FDA, while the product development workload has increased substantially, the agency received and approved fewer applications than expected.[2] FDA estimates that the fees negotiated for BsUFA II will average approximately $45 million per year.[3]

H.R. 749, Lower Drug Costs Through Competition Act

The hearing will also provide an opportunity to discuss H.R. 749, the Lower Drug Costs Through Competition Act, introduced by Rep. Kurt Schrader (D-OR) and Rep. Gus Bilirakis (R-FL), which seeks to increase generic competition.

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.

[2] FDA approved the first biosimilar (for Neupogen) in March 2015 and has since approved an additional three biosimilars, the latest being in September 2016 (for Humira).
[3] Additional information on the agreement can be found here: https://www.fda.gov/downloads/ForIndustry/UserFees/BiosimilarUserFeeActBsUFA/UCM521121.pdf