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

March 24, 2017

TO: Members, Subcommittee on Health

FROM: Committee Majority Staff

RE: Hearing entitled "Examining FDA's Medical Device User Fee Program"

I. INTRODUCTION

The Subcommittee on Health will hold a hearing on Tuesday, March 28, 2017, at 10:15 a.m. in 2123 Rayburn House Office Building. The hearing is entitled "Examining FDA's Medical Device User Fee Program." The Medical Device User Fee Amendments (MDUFA), 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

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

Panel II

- Cynthia Bens, Vice President of Public Policy, Alliance for Aging Research;
- Robert Kieval, Founder and Chief Development Officer, CVRx;
- Patrick Daly, President & CEO, Cohera Medical; and
- Diane Wurzburger, Executive, Regulatory Affairs U.S. & Canada, Global Strategic Policy & Programs, GE Healthcare.

III. BACKGROUND

Since 2002, MDUFA has authorized FDA to collect user fees from medical device manufacturers to supplement Congressional appropriations. Revenues generated from these fees have been used on specific activities related to the review and regulation of medical devices. In exchange for industry agreeing to pay fees, FDA commits to meeting certain performance goals,

such as reviewing submissions 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.

The proposed agreement (MDUFA IV),[1] which was transmitted to Congress prior to the statutory deadline, builds upon process improvements enacted pursuant to FDASIA. Further, it would aid in the implementation of several key provisions in the 21st Century Cures Act and streamline the development and review of innovative medical devices for patients. FDA estimates that the fees negotiated in MDUFA IV will average approximately $200 million 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/MedicalDeviceUserFee/UCM535548.pdf.