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ONE HUNDRED FIFTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

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April 27, 2017

Ms. Cynthia Bens
Vice President of Public Policy
Alliance for Aging Research
1700 K Street, N.W.
Suite 740
Washington, DC 20006

Dear Ms. Bens:

Thank you for appearing before the Subcommittee on Health on March 28, 2017, to testify at the hearing entitled "Examining FDA's Medical Device User Fee Program."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on May 11, 2017. Your responses should be mailed to Jay Gulshen, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to jay.gulshen@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Michael C. Burgess, M.D.
Chairman
Subcommittee on Health

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health

Attachment — Additional Questions for the Record

The Honorable Frank Pallone, Jr.

Hiring Freeze and MDUFA

User fees under MDUFA also assist FDA in hiring and retaining the staff necessary to support the activities associated with the review of medical device applications. Under MDUFA IV, FDA has agreed to hire up to 217 employees by fiscal year 2022.

Q1: FDA has consistently had issues recruiting and retaining personnel in part due to the long hiring process, but largely due to the agency's inability to compete with the salaries of the private sector. While 21st Century Cures worked to address this issue, I am concerned that the federal hiring freeze proposed by this Administration endangers the ability for success. Can you discuss further what impact a federal hiring freeze could have on FDA and the medical device review process?

Trump Budget

I have grave concerns with the recent budget announcement from the Administration. In his proposal, the President proposes doubling user fees for medical product review to $2 billion, while simultaneously cutting the agency's budget authority. As you know, not all of FDA's critical public health responsibilities are funded with user fee dollars.

Q1: Will you please discuss further the types of public health activities at FDA that could be scaled back or negatively impacted by this proposal?

Third Party Review

Under current law, FDA accredits external third parties to conduct reviews of certain low and moderate risk devices if desired by the device developer. The goal of this program was to allow FDA to prioritize its resources for higher-risk and complex device reviews, and to improve the review of low and moderate risk devices.

MDUFA IV outlines a number of steps the agency will take to improve the Third Party Review Program, including increased training for third parties, issuing guidance for accreditation criteria, and eliminating routine re-review. The commitment letter also notes the agency intends to tailor the program.

Q1: Does the Alliance for Aging Research support the use of third parties in the medical device review process? If yes, please explain why. If no, please explain why.

Q2: How do you think MDUFA IV will help to ensure that the Third Party Review program is reviewing devices appropriately?

The Honorable G. K. Butterfield

1. What do you envision the pilot project for real-world evidence looking like? How will real world evidence help to combat health disparities?

2. How do you envision CDRH using patient input to inform clinical study design and how can that benefit your constituency?

3. How do you intend to share patient preference information with the FDA? How can smaller patient advocacy organizations also participate?

4. How do you see NEST helping to increase enrollment efficiencies and do you believe it will be helpful in enabling greater diversity in clinical trials?

5. You mention that currently on 40 percent of de novo requests are reviewed on time. MDUFA 4 sets the goal of reviewing 70 percent of de novo requests by 2020. What type of impact could that have on your constituency?