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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

Mr. Patrick Daly
President and CEO
Cohera Medical
227 Fayetteville Street
Suite 900
Raleigh, NC 27601

Dear Mr. Daly:

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

Attachment — Additional Questions for the Record

The Honorable Richard Hudson

1. Mr. Daly, first thank you being here. It's an honor to have a North Carolina company representing the device industry on this panel. The medical device community is made up of both large manufacturers and small ones like yours. The MDUFA agreement includes improvements to total time review goals. Can you comment on these total time goals and what they mean for companies like yours?

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: How did FDA and industry determine the number of additional employees that would be needed to help implement MDUFA IV recommendations?

Q2: Why is the hiring of an additional 217 employees at the Center for Devices and Radiological Health (CDRH) important to the implementation of MDUFA IV?

Support for MDUFA IV

Current statute outlines a detailed process for the reauthorization of the Medical Device User Fee Amendments. FDA is charged to not only negotiate with industry to develop recommendations, but also to solicit public input and hold public meetings, and consult periodically with Congress and patient and consumer groups, among others. The recommendations that are the result of this process must also be available publicly for a period of public comment, and ultimately are required by statute to be transmitted to Congress by January 15, 2017. The process that led to the ultimate transmittal of the MDUFA IV recommendations kicked off over a year and a half ago in September 2015.

Q1: Will you discuss further industry's role in the reauthorization of MDUFA, and in particular, the timeline for these activities?

Q2: As you know, the statute requires that the recommendations be transmitted to Congress no later than January 15, 2017, a deadline that FDA has already met. Does the statute allow FDA to transmit recommendations for the reauthorization of MDUFA at an alternative date?

Q3: MDUFA IV expires on September 30, 2017. What would be the impact to your company, and the member companies at AdvaMed if Congress does not pass the reauthorization of MDUFA before September 30th?

Q4: Do you support the MDUFA IV recommendations as transmitted to Congress?

Timeline for Review

Prior to the establishment of MDUFA, the medical device program was suffering from a lag in medical device review timelines, a lack of expertise among FDA personnel, and insufficient resources to maintain the program. MDUFA was first enacted in 2002 and has since worked to address these issues. One area MDUFA has had clear success in is reducing the total time to decision for medical device applications. The average total time to a decision on a pre-market approval (PMA) in 2015 has been reduced by 35 percent or 150 days over six years, and the average total time to decision for a 510(k) in 2015 has been reduced by 11 percent over five years.

Q1: The MDUFA IV agreement includes additional improvements on the total review time goals. Can you discuss further the improvements made in MDUFA IV and what they mean for companies like yours?

Pre-Submission Communication

Timely and meaningful communication between FDA and sponsors is critical to ensuring that both parties have a clear understanding of the standards and expectations for review, as well as the actions needed to receive timely approval of their device application. I understand that both FDA and industry agree that meaningful communication pre-submission can help to improve the efficiency of the device review process.

Q1: How has the pre-submission process been working from your perspective, and what steps will MDUFA IV take to further improve the pre-submission process?

The Honorable G. K. Butterfield

1. Can you discuss the current process for FDA inspections of medical device manufacturers?

2. Does FDA provide any sort of advance warning to manufacturers before inspections occur?

3. Does FDA inspect all manufacturers with the same level of regularity and in the same manner?

4. Does the MDUFA 4 agreement address any of the concerns the industry has related to inspections?

5. What can be done to bring more predictability and transparency into the process?