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ONE HUNDRED FIFTEENTH CONGRESS

Congress of the United States

House of Representatives

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April 27, 2017

Dr. Jeffrey E. Shuren
Director
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Shuren:

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 Gus Bilirakis

1. Why I have a question related to the topic of 3rd party repair of medical devices. Based on the information obtained by the FDA in the open docket and insight gathered at the public forum, do you see a need for FDA intervention to protect patients? Why or why not? If so, can you provide the Committee with insight around specific problem areas and next steps to address the areas of concern?

2. The Administration has imposed a "regulatory freeze" across the federal agencies, including the FDA. How does the freeze potentially impact the FDA's ability to move to next steps to mitigate patient risks associated with these patient safety and third party repair? With critical patient safety issues at play, can you offer any insight into the timeline of where the FDA is on this issue and what steps the Agency is now contemplating to address this issue?

The Honorable Richard Hudson

North Carolina is home to a vibrant life sciences industry and a large number of device companies. A priority for me is ensuring these companies have access to the most efficient review process possible. I understand that the MDUFA IV agreement continues the independent assessment process that was begun under MDUFA III, where an outside management consultant was brought in to evaluate the device review process.

1. Did you find that independent assessment process helpful?

2. Can you explain how it will be continued under this new MDUFA agreement?

The Honorable Michael C. Burgess

1. The overwhelming majority of medical device manufacturers are small, innovative companies that may only have one product on the market, if any, at a time. Can you talk about how FDA works with these types of companies to ensure a smooth submission and review process? How are small businesses accounted for in this proposed agreement?

The Honorable Frank Pallone, Jr.

National Evaluation System for health Technologies (NEST)

The National Evaluation System for health Technologies, or NEST, is a nongovernment system run by external stakeholders that will utilize real world data collected during clinical care that can be used in the pre-market review of medical devices, as well as post-market reporting and safety monitoring. I understand that the standing up of NEST has been a priority for the agency.

Q1: How will a robust NEST help with pre-market medical device reviews, as well as post-market safety monitoring of medical devices?

Q2: I understand that funding for NEST under MDUFA IV is limited to pre-market activities. Given the potential for NEST to help with post-market surveillance, why did MDUFA IV limit funding for NEST to pre-market activities?

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 that the agency intends to tailor the program.

Q1: Please describe further how the Third Party Review program was intended to work, as well as any issues FDA has identified with how the program is working currently.

Q2: How will MDUFA IV help to address the issues identified by the agency and ensure that the Third Party Review program is reviewing devices appropriately?

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: Can you please discuss further how the pre-submission process has been working in the MDUFA Program, and the steps MDUFA IV will take to further improve the pre-submission process?

The Honorable Anna Eshoo

FDA Pediatric Device Consortia Program

1) Please describe some of the successes of the Pediatric Device Consortia program.

2) Can you describe how the Pediatric Device Consortia program has helped to support the development of pediatric medical devices?

3) How has the consortia leveraged FDA's funding with other sources of funding to support pediatric medical device projects?

Pediatric Device Extrapolation

1) To what extent are device companies using the pediatric extrapolation guidance to support the appropriate labeling of devices for use in children?

2) Can you provide examples of how FDA's pediatric device extrapolation guidance has been used to approve pediatric labeling of medical devices?

3) How does the FDA currently inform companies that they can use pediatric device extrapolation?

Lack of Progress on Pre-Market Application Labeling for Children

1) In recent years, less than 5% of pre-market application (PMA) devices have been approved for use in children under the age of 16. What improvements can be made to the FDA's approval process so that the agency is approving more PMAs labeled for children under the age of 16?

2) What is the FDA doing to ensure that device technologies approved for adults and that could be beneficial in children are being studied and labeled for use in children, regardless of whether it is for the same disease or condition?

Humanitarian Use Devices

The Federal Food, Drug and Cosmetic Act requires to seek the approval of a local institutional review board (IRB) prior to using a humanitarian use device (HUD). HUDs are devices intended to benefit patients by treating or diagnosing a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year.

IRBs exist to review research, so this requirement seems to imply that HUDs are experimental devices that are not approved for marketing. This could negatively impact securing payment from insurers for HUDs, which thousands of patients rely on to treat rare disease and conditions.
1) Are HUDs experimental devices that are not approved for marketing? If they are not, are there other entities, other than IRBs, that are better suited to ensuring the safe use of HUDs?

The Honorable G. K. Butterfield

1. Do you believe NEST can address clinical trial enrollment efficiencies and can it be helpful in enabling greater diversity in clinical trials? How will PDUFA VI help with the development and approval of rare disease treatments?

2. Does the agreement also include funding to protect patient information used for real-world evidence?

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

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

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

6. I understand that hearing loss is not simple, where one description fits everyone's medical issue. You can have problems with the middle ear or in the inner ear or the hearing nerve or even a combination of the two. There are different treatment strategies for each. Then there's the issue of diagnosing the severity of the hearing loss in each ear, and it can be different in each ear. That's a lot of self-diagnosis to expect from consumers. What data exists to demonstrate that patients can (1) distinguish between conductive, sensorineural, and mixed hearing loss and (2) calibrate the severity of their hearing impairment so that they can self-treat with a hearing aid?

7. Primary care physicians are on the front lines of patient care, treating the whole patient over time, and referring to other providers when needed. They see the impact of hearing loss, and have recommended hearing loss screening be included in routine patient exams. The American Academy of Family Physicians practice recommendations also specifically state that older patients with likely hearing loss should be referred for audiometric testing. A recent study comparing professionally fitted hearing aids with pre-programmed out-of-the-box devices had each patient undergo the standard-of-care audiometric testing. It appears that pursuing this very broad category of OTC devices is designed to eliminate that step even when hearing loss is interfering with an individual's ability to hear and participate in conversations. I am concerned that eliminating all testing looks a bit like an experiment. If there isn't current scientific evidence that warrants ignoring recommendations of clinicians, what plans are in place to ensure the data supports the broad OTC category before it's implemented?

8. When you look at the various hearing loss severity scales, there is a 50 decibel range from the beginning of the "mild" category to the ceiling of the "moderate" category. Just 20 decibels separates this range from normal hearing on one end and profound hearing loss on the other. That means that these OTC devices, even with output limits, will have the potential to do damage. What studies have been or are being done to determine the safeguards these devices will require for safety?