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ONE HUNDRED THIRTEENTH CONGRESS

Congress of the United States

House of Representatives

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December 17, 2013

Dr. Jeffrey E. Shuren
Director
Center for Devices and Radiological Health
U.S. 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 Friday, November 15, 2013, to testify at the hearing entitled "Reviewing FDA's Implementation of FDASIA."

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.

Also attached are Member requests made during the hearing. The format of your responses to these requests should follow the same format as your responses to the additional questions for the record.

To facilitate the printing of the hearing record, please respond to these questions and requests by the close of business on Thursday, January 9, 2014. Your responses should be mailed to Sydne Harwick, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to **Sydne.Harwick@mail.house.gov**.

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

Sincerely,

Joseph R. Pitts
Chairman
Subcommittee on Health

cc: The Honorable Frank Pallone, Jr., Ranking Member, Subcommittee on Health

Attachments

Attachment 1—Additional Questions for the Record

The Honorable Joseph R. Pitts

1. Please describe how the FDA was involved in setting the parameters of the assessment between industry and the FDA that objectively assess the FDA's premarket review process. Please submit a detailed accounting of the agency's involvement with the contractor relating to the review and any recommendations or direction you provided.

2. In your testimony, you note that you are making significant progress in implementing FDASIA and meeting most due dates. Which due dates are you missing and when will they be completed?

3. The FDA appears to not have revised its 1994 strategy document on reviewing and finalizing the regulatory status of pre-amendment Class III devices based on the changes made in the law by FDASIA last year. Since FDASIA made significant changes in the sections of the law governing the processes by which the Agency goes about considering the revision of pre-amendment Class III devices, when does the Agency plan to revise this outdated document, and, in the meantime, what steps has the Agency taken to ensure that all of the new process requirements of FDASIA (especially sections 515(i) and 515(b)) are being met as pre-amendment Class III devices move through the revision/reclassification process?

4. As you know, in the Safe Medical Devices Act of 1990 Congress added a new subsection to Section 515 (i.e. Section 515(i)) to address the situation created by the failure of the Agency to resolve the classification issues associated with pre-amendment Class III devices. As you also know, these pre-amendment devices are devices about which FDA was uncertain how to classify when the classification system first began. However, most of these devices have been going to market through the 510(k) market notification process for decades. The purpose of this new subsection was to provide a clear path to revise the classification of this special category of devices either into Class I or Class II, or, if required, keep the device in Class III.

   A part of this Section 515(i) (i.e. Section (515(i)(3)) clearly states that when this process of revision is completed if the device is to remain in Class III "The Secretary shall…establish a schedule for the promulgation of a subsection (b) of this section…." Again, as you well know, this subsection (b) refers to a different subsection and establishes the basis for requiring a Pre-Market Approval (PMA).

   To resolve the final disposition of these pre-amendment Class III devices, especially if the FDA was proposing to regulate them as Class III devices, Congress authorized a two-step process:

   > Step 1 – (or Section 515(i)) - Revise the classification of the device to either a Class I or Class II, or decide that it must be regulated as a Class III device, and if it is to be a Class III device, then
   >
   > Step 2 – (or Section 515(b)) – Require that the device have an approval of an application for a pre-market approval.

   I have three questions that pertain to the Agency's Proposed Order for Automatic External Defibrillators (AEDs) issued on March 25, 2013:

   a. Has the Agency ever issued a Proposed Order as required by Section 515(i)(2)? If no, why not? If yes, please provide.

b. Has the Agency ever issued the "schedule for the promulgation of a subsection (b) of this section…" as required by Section 515(i)(3)? If no, why not? If yes, please provide.

c. On what legal basis does the Agency justify conflating into one step the Congressionally mandated two-step process involved in the Section 515(i) and 515(b) requirements (or perhaps just omitting the Section 515(i)(2) and (3) requirements altogether and going straight to the Section 515(b) requirements) as it appears to have done in the March 25th Proposed Order?

5. The only legislative history for what became FDASIA Section 608 is language that was drafted and adopted by this Committee. As you know, in the original House version of the bill, no changes were made to the reclassification provisions in Sections 515(i) and 515(b). As a result, this legislative history is relevant only to the original pre-FDASIA reclassification process. Given the absence of a legislative history pertaining to the changes in this section of the law ultimately passed by Congress, the actual legislative language itself controls.

   FDASIA states that an order requiring PMA cannot become final until three events occur in the following order, as listed in Section 608: a proposed order, a panel, and a response to comments on the order. In the case of AEDs, based on the Agency's March 25, 2013 proposed order, the Agency appears to take the position that it can remove the panel from this sequence, and that Congress did not intend the sequence that is explicitly listed in the statutory language. Specifically, the FDA appears to rely on a panel meeting that occurred over 18 months before the enactment of FDASIA. Given the fact that in FDASIA Congress granted the Agency a new authority to revise and reclassify pre-amendment devices based on a final order rather than rulemaking, and that the only guidance on this new language is what exists in the statute itself, on what basis does the Agency believe it has the authority to ignore the sequence listed in the statute?

The Honorable Leonard Lance

1. As you may be aware, I have authored legislation, the FDA Safety Over Sequestration (FDA SOS) Act, which would protect the FDA user fees from the threat of sequester, should Congress face a similar budget situation as we did earlier this year. This legislation is supported by many of my colleagues on this committee on both sides of the aisle and it is our hope that it be considered and passed soon in order to maintain predictability in the review process, as well as incentive to continue to engage in these agreements.

   OMB unfortunately interpreted sequestration to apply equally to both FDA appropriations and industry user fees. As a result, more than $80 million in private user fee funding is being sequestrated in an agency account where they cannot be spent or put to any practical purpose. The FDA Safety Over Sequestration (FDA SOS) Act would clarify that industry user fees cannot be sequestered. From the perspective of a senior FDA manager, what impacts is the sequestration of user fees having on FDA operations, regulatory science, and product evaluation? Would you support passage of the FDA SOS bill?

2. Briefly, how are Agency operations impacted by sequestration? As a result, how are you absorbing these cuts?

3. How has sequestration affected product review times, if at all? Are certain products/review divisions/therapeutic areas more or less impacted than others?

How has sequestration, including of industry-paid user fees, impacted the Agency's ability to implement FDASIA in terms of the new responsibilities it is required to undertake with respect to promoting innovation, stakeholder engagement, and drug supply chain integrity?

4. It seems that the decision to sequester the PDUFA user fees violates the intent of the statute that the industry's user fees should only be used for the review of new medicines. Has the agency discussed any strategy to release the sequestered fees through the FY2014 fiscal process or otherwise?

   Have you talked to either the House or Senate Appropriations Committees about finding a mechanism to release the fees? Has FDA requested that HHS or OMB release the fees? When and who took part in these discussions?

   Has FDA questioned OMB's analysis that PDUFA user fees are subject to sequester or any other use than for FDA's human drug review program? If so, when did FDA have these discussions and with whom?

5. FDA continues to be unable to access approximately $83 million in sequestered user fees for FY2013. The loss of these fees has meant that the implementation of key aspects of FDASIA have been delayed including the hiring of any new scientific and medical personnel to advance crucial regulatory science priorities. Undoubtedly, this is bad for patients, bad for science and bad for public health.

   Given the gravity of the impact losing these fees has had on the agency's ability to fulfill its public health mission, shouldn't a mechanism to release them be among the Agency's top priorities for anomalies in any end of year fiscal package? Has the agency communicated with the Hill about such an anomaly? If so, to whom and when?

6. Budget and Appropriations leaders have indicated that giving "flexibility" to agencies in how sequester cuts are implemented is a top priority for the end of year fiscal package. What kind of authority would FDA need for there to be a real impact on how effectively the agency is able to mitigate the impact of the sequester, including user fee programs? Have you communicated this to Budget and Appropriations negotiators by providing them with language or engaging in any conversations at all?

The Honorable Gus Bilirakis

1. I am concerned about FDA's actions regarding combination products. Given that there are numerous products classified as devices that have some chemical action within or on the body of man, would you agree that the draft guidance, "Classification of Products as Drugs and Devices & Additional Product Classification Issues," reflects a substantial policy change by requiring a product to be classified as a drug if any of its intended purposed are achieved through a chemical action within or on the body of a man?

2. Would you agree that similar products should be regulated in the same manner and that the substantial policy change could have an impact on new products being regulated similarly to products on the market prior to issuance of the draft guidance?

3. The plain language of the Act indicates that a device may have more than one primary purpose. The 2011 FDA draft guidance appears to arbitrarily depart from this plain language. What is the rationale for doing so?

4. This draft guidance has not been finalized but appears to have been implemented by FDA. Would you agree that a draft guidance document should not be implemented until finalized?

5. The FDA recently applied its revised interpretation of the Federal Food, Drug and Cosmetic Act in the 2011 draft guidance to classify a portable body shower as a drug rather than a medical device. The U.S. District Court for the District of Columbia found that the FDA designation of the product as a drug was based on a "doubly grandiose" interpretation of the phrase "primary intended purpose." When and how will FDA revise the 2011 draft guidance to reflect the ruling?

6. In response to the ruling, FDA created a new "meaningful contribution" standard for determining if a product is a device. Please explain how FDA developed its "meaningful contribution" test, and what criteria FDA will apply in determining whether that test is met. How is it that FDA can reinterpret statute at will against court directions?

7. Would you agree that requiring companies to comply with U.S. drug regulations, when they are required to comply with medical devices regulations in all other countries for the identical product, places an unreasonable burden on the companies and could prevent introduction of important products to U.S. patients? That is apparently the case with the portable body shower.

Attachment 2—Member Requests for the Record

During the hearing, Members asked you to provide additional information for the record and you indicated that you would provide that information. For your convenience, descriptions of the requested information based on the relevant excerpts from the hearing transcript regarding these requests are provided below.

The Honorable Joseph R. Pitts

1. Under MDUFA III, industry and the FDA agreed to have an independent two-phase assessment and program evaluation to objectively assess the FDA's premarket review process. Would you please submit a compiled list of recommendations in its entirely to the Committee upon its completion?

The Honorable Lois Capps

1. Will you please give me an update on where the agency is with Sentinel?