



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Silver Spring, MD 20993

The Honorable Joseph R. Pitts  
Chairman  
Subcommittee on Health  
Committee on Energy and Commerce  
House of Representatives  
Washington, D.C. 20515-6115

NOV 12 2014

Dear Mr. Chairman:

Thank you for providing the Food and Drug Administration (FDA or the Agency) with the opportunity to testify at the November 15, 2013, hearing before the Subcommittee on Health, Committee on Energy and Commerce, entitled "Reviewing FDA's Implementation of FDASIA." This is a response for the record to questions posed by you and other Committee Members to Dr. Jeffrey E. Shuren in a letter we received on December 17, 2013. We are also responding to questions posed by you and Representative Capps at the hearing.

Please let us know if you have any further questions.

Sincerely,

A handwritten signature in black ink, appearing to read "Thomas A. Kraus", written over a horizontal line.

Thomas A. Kraus  
Associate Commissioner  
for Legislation

cc: The Honorable Frank Pallone, Jr.  
Ranking Member  
Subcommittee on Health  
Committee on Energy and Commerce

We have restated each Member's questions below in bold, followed by our responses.

**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.**

INTRODUCTION

Pursuant to the Performance Goals and Procedures<sup>1</sup> adopted under the 2012 Medical Device User Fee Amendments<sup>2</sup> (MDUFA III), FDA agreed to participate with the device industry in a comprehensive assessment of the process for the review of device applications (the Independent Assessment). This requirement is to conduct a comprehensive assessment by an independent consulting firm of FDA premarket review processes for medical devices and to identify opportunities for improvement that will significantly impact the review of device premarket applications.<sup>3</sup>

In Phase 1 of the Independent Assessment, FDA and the medical device industry participated in the comprehensive assessment of the process for the review of medical device submissions. The Agency analyzed the recommendations of the assessment and implemented selected actions and incorporated selected outcomes of the assessment into a Good Review Management Practices guidance document.

Primary objectives of Phase 1 of the Independent Assessment included:

- Identification of best practices and prioritization of process improvements for conducting predictable, efficient, and consistent premarket reviews that meet regulatory review standards;
- In-depth analyses of the elements of the review process, in order to identify best practices and opportunities for improvement, including root-cause analyses of selected significant factors;
- Assessment of resource allocation to premarket device reviews across FDA;
- Development of implementation plans for selected recommendations; and
- Development of metrics to ensure successful implementation of recommendations and demonstrate achievement of expected results.

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<sup>1</sup> This document is commonly referred to as the "MDUFA III Commitment Letter" and is available on FDA's public website at <http://www.fda.gov/downloads/medicaldevices/newsevents/workshopsconferences/ucm295454.pdf>.

<sup>2</sup> Title II of the Food and Drug Administration Safety and Innovation Act, Public Law 112-144 (126 Stat. 993) (July 9, 2012) is available at <http://www.gpo.gov/jdsys/pkg:PLAW-112publ144/pdf/PLAW-112publ144.pdf>.

<sup>3</sup> The contract for the Independent Assessment contemplates a three-year performance period, from March 31, 2013, through February 1, 2016. The performance period for Phase 1 is March 31, 2013–September 30, 2014, and the performance period for Phase 2 is October 1, 2014–February 29, 2016.

Phase 2 of the Independent Assessment required the contractor to evaluate the implementation of recommendations adopted under Phase 1 and publish a written assessment of FDA's implementation of those recommendations. This was published on June 11, 2014.

#### FDA INVOLVEMENT IN THE INDEPENDENT ASSESSMENT

Upon enactment of FDASIA<sup>4</sup> in July 2012, FDA established a Project Advisory Group (PAG), comprised of high-level policy staff, to advise the Independent Assessment process, which held its Kickoff Meeting on July 12, 2012. A Technical Advisory Group (TAG), comprised of technical-level subject matter experts, was also established. The first meeting of the Independent Assessment TAG was held on September 12, 2012. The TAG drafted an initial Statement of Work,<sup>5</sup> which was reviewed and approved by the PAG, and in December 2012, FDA published a notice in the *Federal Register*,<sup>6</sup> soliciting public comments on the draft Statement of Work for the Independent Assessment.

The Agency received comments<sup>7</sup> from the device industry and other interested stakeholders in response to the *Federal Register* notice. In addition, on January 29, 2013, the Agency spoke with industry representatives regarding the feedback received about the draft Statement of Work. FDA took those comments and input into account when finalizing the Statement of Work<sup>8</sup> for the Independent Assessment on March 25, 2013.

On April 19, 2013, FDA issued the Request for Proposal for the Independent Assessment.

On June 11, 2013, FDA awarded the task order for the Independent Assessment to Booz Allen Hamilton, Inc. (BAH). BAH fully meets the qualification requirements stated in the Commitment Letter and has a solid record of successfully completing this type of assessment for other FDA user fee programs. The period of performance for the contract for the Independent Assessment began on June 11, 2013.

On July 1, 2013, FDA and BAH held a kick-off meeting for the Independent Assessment at FDA's headquarters in Silver Spring, Maryland. At the kick-off meeting, BAH introduced its team to the FDA PAG and TAG and laid out its technical approach to the Assessment, including the project's objectives and schedule.

As specified in the Statement of Work, BAH developed a project work plan to accomplish the requirements of the Statement of Work. That work plan identifies the

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<sup>4</sup> MDUFA III was enacted as Title II of the Food and Drug Administration Safety and Innovation Act, or FDASIA.

<sup>5</sup> The draft Statement of Work (dated Dec. 14, 2012) is available on FDA's public website at <http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/overview/ndufaiii/ucm331516.pdf>.

<sup>6</sup> FDA, "Comprehensive Assessment of the Process for the Review of Device Submissions: Request for Comments," Docket No. FDA-2012-N-1202, 77 *Fed. Reg.* 75 173 (Dec. 19, 2012), available at <http://www.gpo.gov/fdsys/pkg/FR-2012-12-19/pdf/2012-30511.pdf>.

<sup>7</sup> Copies of the public comments that were submitted are available at regulations.gov at <http://www.regulations.gov/#!documentDetail;D-FDA-2012-N-1202-0001>.

<sup>8</sup> The scope and requirements of the Independent Assessment are described in detail within the final Statement of Work, which is available on FDA's public website at <http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/overview/ndufaiii/ucm376252.pdf>.

sources, methods, and metrics to be included in the analysis; specifies the schedule of deliverables, including FDA review time of draft materials; details the sources, methods, and metrics to be used; identifies the project personnel and organizational structure; and explains the procedures to be followed to ensure proper communications, reporting, and project management controls.

BAH delivered its draft work plan for the Independent Assessment to FDA on July 19, 2013. FDA provided feedback regarding the draft work plan at a meeting held in Silver Spring, Maryland, on July 25, 2012, and BAH's final work plan for the Independent Assessment was received by the Agency on August 2, 2013.

Since July 2012, FDA has provided quarterly updates to industry and interested stakeholders on the progress being made in the conduct of the Independent Assessment. These updates, which are publicly available on the Agency's website, are provided as part of FDA's commitment in MDUFA III to provide detailed quarterly reports on the Agency's progress toward meeting the goals described in the MDUFA III Commitment Letter.<sup>9</sup> After the contract was awarded, at the July 30, 2013, quarterly MDUFA III update meeting between FDA and industry representatives, BAH introduced its team and outlined its planned approach to the assessment.

The conduct of the Independent Assessment contemplates that FDA (and industry) will participate in the Independent Assessment process, and that FDA (and industry) will be consulted during the course of that process.<sup>10</sup>

Progress reports and updates from BAH's assessment team are ongoing. BAH delivers written progress and financial reports to the FDA Contracting Officer's Representative (COR)<sup>11</sup> on a monthly basis. In addition, BAH makes oral presentations to FDA's PAG and TAG on each major report or plan deliverable prior to delivery. These presentations are scheduled by the FDA COR, and BAH is responsible for drafting minutes for each such meeting. In addition, bi-weekly progress reports are provided by BAH to the FDA COR via e-mail and in person. As of November 15, 2013, nine bi-weekly status reports had been provided to the FDA COR, and seven in-person meetings had been held.

On November 15, 2013, BAH delivered to FDA a working draft document with the contractor's preliminary findings and high-priority recommendations for the Independent Assessment, including data collected and sources, to allow FDA to verify the accuracy of the data and assumptions. The final written report on BAH's high-priority recommendations was delivered to FDA on December 6, 2013, and FDA posted that

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<sup>9</sup> See, e.g., "MDUFA III Quarterly Performance Update: Independent Assessment of Medical Device Review Process – 4<sup>th</sup> Quarter FY 2013 Status" (Nov. 5, 2013), available at <http://www.fda.gov/medicaldevices/deviceregulationandguidance/overview/medicaldeviceuserfeeandmodernizationact/ndufma/ucm109210.htm>.

<sup>10</sup> The Commitment Letter specifically states that "FDA and the device industry will participate in a comprehensive assessment of the process for the review of device applications. The assessment will include consultation with both FDA and industry." The final Statement of Work for the Independent Assessment specifies that interviews by BAH personnel with FDA medical device review staff, as well as observation of meetings between FDA and industry, are to comprise part of the data and information-gathering process.

<sup>11</sup> The COR serves as the liaison between FDA and BAH.

report on the Agency’s public website on December 11, 2013. A copy of the report is available at

<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFAIII/UCM378202.pdf>.

## NEXT STEPS IN THE INDEPENDENT ASSESSMENT PROCESS

In May 2014, FDA issued the Agency’s Implementation Plan for the high-priority recommendations that were reported by BAH in December 2013. In June 2014, BAH issued its Final Report, which included the contractor’s complete findings and recommendations for Phase I of the Independent Assessment. Phase 1 of the Independent Assessment will conclude in December 2014, when FDA issues the Agency’s Implementation Plan for BAH’s final recommendations.

The Phase 2 Final Evaluation Report for the Independent Assessment is scheduled to be posted on the FDA public website by February 1, 2016.

### **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?**

Section 604 of FDASIA added section 510(n)(2) to the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 USC 360(n)(2)). This new provision requires the Secretary of Health and Human Services to submit to the House of Representatives’ Committee on Energy and Commerce (E&C Committee) and the Senate Committee on Health, Education, Labor, and Pensions (HELP Committee) a report on when a premarket notification under section 510(k) of the FD&C Act should be submitted for a modification or change to a legally marketed device (“Modifications Report”). On June 13, 2013, FDA held a full-day public meeting, “510(k) Device Modifications: Deciding When to Submit a 510(k) for a Change to an Existing Device.” At this meeting of more than 1,200 registrants, representatives from FDA and interested stakeholders discussed the Agency’s policy and the current regulations concerning when a modification made to a 510(k)-cleared device requires a new 510(k) submission. FDA carefully considered the discussion at the public meeting and comments submitted to the docket in drafting the Modifications Report. The statutory deadline for submission of the Modifications Report to the E&C and HELP Committees was January 9, 2014. The report was sent to Congress on February 25, 2014.

As directed by Congress, in section 618 of FDASIA, FDA, in consultation with the Federal Communications Commission (FCC) and the Office of the National Coordinator for Health Information Technology (ONC), is working toward publishing a report containing a proposed strategy and recommendations on an appropriate, risk-based regulatory framework for health information technology (Health IT) that promotes innovation, protects patient safety and avoids regulatory duplication (Health IT Report). In 2013, FDA, in collaboration with ONC and FCC, created a working group (the “FDASIA Workgroup”) of external stakeholders and experts under ONC’s Health IT

Policy Committee. FDA, ONC, and FCC intend to use the input from ONC’s Health IT Policy Committee, which adopted in full the FDASIA Workgroup’s recommendations, in the development of the Health IT Report. Although the Health IT Report was due to be posted on the websites of FDA, FCC and ONC by January 9, 2014, the three agencies needed additional time to allow for careful consideration of the FDASIA Workgroup’s recommendations adopted by ONC’s Health IT Policy Committee and other public input. This report was completed on April 1, 2014.

- 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?**

Section 608 of FDASIA changed the procedures for requiring premarket approval for preamendments Class III devices (“call for PMAs”) under section 515(b) of the FD&C Act, 21 U.S.C. § 360e(b), and for reclassifying devices under section 513(e) of the FD&C Act, 21 U.S.C. § 360c(e), from a rulemaking to an administrative order process, and added a requirement for review by a device classification panel (panel). Section 608 of FDASIA revised section 515(i) of the FD&C Act, 21 U.S.C. §360e(i), to reflect the new administrative order process; however, FDASIA did not otherwise change the process or add any additional steps to the FD&C Act. Congress did not comment during the enactment of FDASIA on FDA’s long-standing process for addressing the remaining types of preamendments Class III devices, for which there has not been a call for PMAs (by either calling for PMAs or reclassifying into Class I or II), other than to suggest that FDA act expeditiously to do so.<sup>12</sup>

Congress<sup>13</sup> and GAO<sup>14</sup> have urged FDA to address the issue of preamendments Class III devices,<sup>15</sup> for which there has not been a call for PMAs in an expeditious manner, and the

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<sup>12</sup> H. Rep. 112-495 (2012) at 28.

<sup>13</sup> See the legislative history of the Safe Medical Devices Act (SMDA) of 1990. The Senate report makes clear the need to require submission of PMAs as soon as possible for those devices that are to remain in Class III, stating “...it is of profound importance to the Committee that the revision of classifications and the regulations requiring PMAs be completed as quickly as possible” (S. Rept. 513, 101st Cong., 2d sess. 18 (1990)). In addition, the House of Representatives Report states that when formulating the schedules for requiring the submission of the PMAs, FDA should take into account its priorities and limited resources, together with the Committee’s intention that the evaluation of the process be expeditious (H. Rept. 808, 101st Cong., 2d sess. 26 (1990)).

<sup>14</sup> In January, 2009, the Government Accountability Office (GAO) issued a report, Government Accountability Office (GAO) (09-190), FDA Should Take Steps to Ensure that High-Risk Device Types are Approved through the Most Stringent Premarket Review Process. This report recommended that “FDA expeditiously take steps to issue regulations for Class III device types currently allowed to enter the market via the 510(k) process.” GAO further stated that “[t]hese steps should include issuing regulations to (1) reclassify each device type into Class I or Class II, or requiring it to remain in Class III, and (2) for those device types remaining in Class III, require approval for marketing through the PMA process.”

Agency has taken many actions in order to promptly and efficiently address this issue in a transparent and predictable manner. These actions include, among others, the publication of a notice in the *Federal Register*,<sup>16</sup> describing FDA’s strategy for implementation of the SMDA, P.L.101-629 (1994 strategy document) and the 515 Program Initiative (discussed below).

The process described in the 1994 strategy document was created to carry out Congress’ intent.<sup>17</sup> It established an efficient means to review the regulatory status of the remaining 117 preamendments Class III devices, for which FDA had not yet initiated any action to call for PMAs while providing ample opportunity for public participation, in accordance with applicable law and regulation. FDA made significant progress on addressing the preamendments Class III devices, for which there had not been a call for PMAs since publishing the 1994 strategy document; however, as of 2009, 26 preamendments Class III device types still had not been reclassified or had a call for PMAs. Therefore, in 2009, FDA implemented the 515 Program Initiative to further facilitate a transparent review of the remaining 26 preamendments Class III device types still requiring additional Agency action. FDA developed a five-step process for finalizing the classification of preamendments device types and publicized the process on the Agency’s 515 Program Initiative web page at

<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/ucm240310.htm> (515 initiative page). FDA also publicly tracks the status of the remaining device types that needed to be addressed on the 515 Project Status web page at

<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/ucm240318.htm> (515 status page).

Since late 2009, when FDA began the 515 Program Initiative, FDA has made substantial progress in reclassifying or calling for PMAs for the 26 remaining types of preamendments Class III devices. As of January 17, 2014, FDA has either issued a proposed or final order for 21 of the 26 remaining device types. In addition, FDA has issued two proposed rules that have yet to be reissued as proposed orders, as required by FDASIA.<sup>18</sup> Significantly, for 25 of the 26 device types, FDA has taken at least one of three major regulatory actions—proposed reclassification or called for PMAs; held a panel meeting; or issued a final reclassification or called for PMAs.

FDA continues to focus resources on expeditiously and transparently completing the process for the remaining device types that allows for multiple opportunities for public

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<sup>15</sup> A preamendments Class III device is a Class III device that was introduced or delivered for introduction into interstate commerce for commercial distribution prior to the passage of the Medical Device Amendments of 1976, or is of a type so introduced or delivered and is substantially equivalent to another device within that type (see section 515(b) of the FD&C Act, 21 U.S.C. § 360e(b)).

<sup>16</sup> 59 Fed. Reg. 23731 (May 6, 1994).

<sup>17</sup> See footnote 2.

<sup>18</sup> FDASIA required FDA to issue six proposed orders for device types, for which proposed rules for preamendments Class III devices had already been issued but not finalized. FDA has moved forward and has already re-proposed four of the six actions as proposed orders.

participation. The Agency has taken the following steps to ensure timely completion of this effort:

- The 515 initiative page and the 515 status page have been revised to capture the changes from FDASIA, and the 515 status page is updated each time an action is taken regarding one of the remaining device types (e.g., panel meetings, proposed orders, and final orders). Since FDASIA's enactment, FDA has issued proposed orders for 14 preamendments Class III device types, five of which have been finalized.
- On March 25, 2014, the Agency published the Medical Device Classification and Reclassification Procedures proposed rule, proposing changes to its reclassification process to conform to the new, streamlined procedures FDASIA required. FDA is also proposing to clarify the criteria for Class III (high-risk) devices. The proposed clarifications should promote transparency in our risk-based regulation and provide insight into the level of regulatory control necessary to address their risks. Clear regulations increase the predictability, transparency, and consistency of Agency actions. A general update to FDA's medical device classification regulation will increase certainty about how devices will be regulated, benefitting industry, device users, and FDA staff.
- Senior management within the Center for Devices and Radiological Health is regularly briefed on the status of the remaining preamendments Class III device types, for which there has not been a call for PMAs, so that they may guide and monitor the process.

In short, FDA is working diligently to complete the task it began in 2009. Upon completion, the 1994 strategy document will no longer be relevant. FDA does not believe diverting resources from this important task to make changes to the 1994 strategy document is currently warranted.

- 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?**

As discussed in the answer above, section 608 of FDASIA amended the procedures for a call for PMAs under section 515(b) of the FD&C Act, 21 U.S.C. § 360e(b), and reclassifying devices under section 513(e) of the FD&C Act, 21 U.S.C. § 360c(e), from rulemaking to an administrative order process and added a requirement for a panel review but did not otherwise change the process or add any additional steps to the FD&C Act or affect FDA's long-standing process for addressing preamendments Class III devices, for which there has not been a call for PMAs. FDASIA made similar changes to section 515(i) of the FD&C Act to be consistent with the administrative order process, but the process was not otherwise changed. Congress did not comment during the enactment of FDASIA on FDA's long-standing process for addressing the remaining preamendments Class III devices in this category, other than to suggest that FDA act expeditiously to do so.<sup>19</sup> FDA, therefore, implemented section 608 of FDASIA by adapting its long-standing process to the order process FDASIA mandated.

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<sup>19</sup> H. Rep. 112-495 (2012) at 28

As discussed above, after enactment of the SMDA, FDA published the 1994 strategy document<sup>20</sup> to describe the Agency’s strategy for implementing the provisions of the SMDA, addressing Class III preamendments devices, for which there had not been a call for PMAs. FDA stated in the 1994 strategy document that “the SMDA does not prevent FDA from proceeding immediately to rulemaking under section 515(b) of the [FD&C Act] on specific devices, in the interest of public health, independent of the procedure in section 515(i) of the [FD&C Act].”<sup>21</sup> The Agency also implemented the 515 Program Initiative in 2009. FDA lays out the five-step process for addressing the remaining preamendments Class III devices, for which there has not been a call for PMAs on the Agency’s 515 initiative page, and publicly tracks the status of the remaining device types in this category on the 515 status page.

As you note, devices within a preamendments Class III type may be cleared through the less-stringent 510(k) process, unless and until FDA calls for PMAs; if FDA reclassifies them into Class II they may continue to be cleared through the 510(k) process. FDA’s procedures for addressing the remaining preamendments Class III devices subject only to 510(k), including AEDs, is consistent with the FD&C Act and long-standing Agency practices, provides full and fair opportunity for interested persons, including manufacturers, patients, health care professionals, other members of the general public, and experts, to comment on a proposed reclassification or call for PMAs, and ensures that FDA may continue to expeditiously work to address all remaining preamendments Class III device types that are currently permitted to utilize the 510(k) process to enter the market. The process, as revised to be consistent with FDASIA, provides multiple opportunities for public input. For example for Automated External Defibrillators (AEDs):

**1995 515(i) Order:**<sup>22</sup> FDA published a 515(i) order in 1995 regarding certain preamendments Class III devices. The order required manufacturers of these devices to submit safety and effectiveness information to FDA. Included in this order were arrhythmia detectors and alarms. At the time, AEDs were considered part of the arrhythmia detectors and alarms device type because AEDs were found substantially equivalent to these devices. Prior to 2003, both AEDs and the arrhythmia detectors and alarms were Class III devices.

**2002 Proposed Rule:**<sup>23</sup> FDA issued a proposed rule in 2002 to reclassify arrhythmia detector and alarms from Class III to Class II with special controls. This action was taken in response to reclassification petitions requesting that arrhythmia detectors and alarms be reclassified. In this proposed rule, FDA announced that although the Agency was proposing to reclassify arrhythmia detectors and alarms to Class II, FDA was proposing to retain AEDs in Class III and establish a separate AED classification. The proposed

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<sup>20</sup> 59 Fed. Reg. 23731 (May 6, 1994). This strategy also is available on FDA’s website at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081251.htm>.

<sup>21</sup> 59 Fed. Reg. 23731, 23731.

<sup>22</sup> 60 Fed. Reg. 41984 (Aug. 14, 1995).

<sup>23</sup> 67 Fed. Reg. 76706 (Dec. 13, 2002).

rule also stated that FDA would address, at a later date, the possible reclassification of AEDs.

**2003 Final Rule:**<sup>24</sup> FDA issued a final rule that reclassified arrhythmia detector and alarms from Class III to Class II and established a separate classification regulation retaining AEDs in class III (see 21 CFR 870.5310). In addition, this final rule reiterated the comment made in the proposed rule about addressing, at a later date, the possible reclassification of AEDs. In the same *Federal Register* issue as this final rule, a Notice of Intent was published<sup>25</sup> requesting information concerning the safety and effectiveness of AEDs.

**2009 515(i) Order:**<sup>26</sup> FDA issued a 515(i) order in 2009 for certain preamendments Class III devices, including AEDs. This order required manufacturers to submit to FDA a summary of any information known or otherwise available to them, including adverse safety or effectiveness information. FDA considered the information received in response to the 515(i) order in determining whether to call for PMAs or to reclassify the devices that were the subject of the order, including AEDs.

**January 25, 2011 Panel Meeting:** FDA convened a meeting of the Circulatory System Devices Panel (the AED panel), which was open to the public. Interested persons were provided the opportunity to present data, information, or views, orally or in writing, on the issues pending before the AED panel.<sup>27</sup> A number of AED manufacturers had the opportunity to present their recommendation for reclassifying AEDs. FDA also presented its analysis of the proper classification for AEDs. The AED panel discussed and made recommendations on whether AEDs should remain Class III (subject to premarket approval) or be reclassified to Class II (subject to special controls and general controls including premarket notification). A significant majority of the AED panel recommended that AEDs remain in Class III and subject to PMA requirements. The AED panel reached this conclusion because insufficient information exists to determine that general and special controls would provide a reasonable assurance of safety and effectiveness and AEDs are lifesaving devices. Moreover, AEDs have a significant history of adverse events and recalls. This adverse event history indicates existing controls were not adequately mitigating the risks associated with AEDs and, therefore, are likely insufficient to provide a reasonable assurance of safety and effectiveness. The AED panel meeting transcript and other meeting materials are available to the public on FDA's website at

<http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/CirculatorySystemDevices>.

**March 2013 Proposed Order:**<sup>28</sup> In this proposed order, FDA announced its intention to call for PMAs for the AED device, including its accessories (i.e., pad electrodes,

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<sup>24</sup> 68 Fed Reg 61342 (Oct. 28, 2003).

<sup>25</sup> 68 Fed. Reg. 61446 (Oct. 28, 2003).

<sup>26</sup> 74 Fed. Reg. 16214 (Apr. 9, 2009).

<sup>27</sup> 75 Fed. Reg. 81282 (Dec. 27, 2010).

<sup>28</sup> 78 Fed. Reg. 17890 (Mar. 25, 2013).

batteries, and adapters). As required by section 515(b) of the FD&C Act, as amended by FDASIA, the proposed order provides its proposed findings regarding (1) the degree of risk of illness or injury designed to be eliminated or reduced by requiring that this device have premarket approval, and (2) the benefits to the public from use of the device. These findings are based on the reports and recommendations of the AED panel for the proper classification of these devices, along with information submitted in response to the 2009 515(i) order and any additional information that FDA obtained since convening the AED panel.

In accordance with section 515(b)(2)(D) of the FD&C Act, 21 U.S.C. 360e(b)(2)(D), FDA provided an opportunity in the proposed order for interested persons to submit a request for a change in classification of AEDs. FDA opened a docket for interested persons to submit comments or request a change in classification in response to the proposed order.

The comment period closed on June 24, 2013. FDA received more than 50 comments to the proposed order, including one request for a change in classification. FDA also engaged with AED manufacturers to discuss the proposed order. FDA will consider the request for a change in classification and all comments to the proposed order before issuing any final administrative 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?**

As stated above, FDASIA did not grant FDA new authority to call for PMAs and reclassify preamendments Class III devices. FDASIA simply amended the existing

authorities to replace the rulemaking process with an administrative order process and mandated review by a device classification panel. Section 515(b) of the FD&C Act, as amended by section 608 of FDASIA, sets out the following critical steps in the process to require premarket approval for a preamendments Class III device, stating that FDA may do so:

by administrative order following publication of a proposed order in the *Federal Register*, a meeting of a device classification panel described in section 513(b), and consideration of comments from all affected stakeholders . . .

This provision makes clear that issuance of a proposed order and a meeting of a device classification panel must precede issuance of a final administrative order, but does not prescribe the order of the panel meeting relative to issuance of the proposed order. Therefore, this provision provides the Agency with the flexibility to hold a panel meeting either before or after the issuance of a proposed order. Whether the panel meeting takes place before or after the proposed order, interested parties will have an opportunity to participate in accordance with FDA regulations and policies governing the panels.

The benefits in efficiency created when a proposed reclassification or call for PMAs reflects the input of FDA's expert panels may explain why the FD&C Act mandates that the panel meeting occur *before* issuance of the proposed classification regulation for initial classifications of devices.<sup>29</sup> Further, although the FD&C Act did not mandate a meeting of an advisory panel for reclassifying or calling for PMAs for devices prior to the enactment of FDASIA,<sup>30</sup> when FDA held panel meetings associated with such actions, the meetings would often occur before any proposal issued.

Convening a panel meeting prior to the issuance of a proposed order for a preamendments Class III device allows FDA to receive advice and recommendations from the panel on the appropriate regulatory action for the device (i.e., reclassification or call for PMAs) and also provides the public an opportunity to present its views on this topic prior to FDA formulating a proposal and utilizing the Agency's resources to issue a proposed order. In many cases, the interests of regulated industry and the general public may be best served by ensuring FDA receives expert input *before* issuing a proposed order. When the appropriate regulatory action for a preamendments Class III device is unclear, the opinions of FDA's expert panel members are an important part of the record that FDA relies upon in determining whether a preamendments Class III device should be reclassified or should be subject to premarket approval. When FDA issues a proposed order without the benefit of panel input, there is an increased likelihood of a conflict between the panel's recommendation and the proposed order and, therefore, a higher probability that FDA may reconsider its proposed order or even have to issue a new

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<sup>29</sup> See 513(d)(1) of the FD&C Act, 21 U.S.C. § 360c(d)(1).

<sup>30</sup> Former section 515(b) of the FD&C Act, however, required FDA to consult with the appropriate panel, if a request for reclassification was received within 15 days of issuance of a proposed rule calling for PMAs. Former section 513(e) of the FD&C Act provided for FDA, at its discretion, to secure a panel recommendation prior to the promulgation of a reclassification rule. Prior to FDASIA, when a panel meeting was discretionary, FDA oftentimes held a panel meeting prior to proposing reclassification for a device, for example, when the Agency determined that a recommendation from the panel would help inform whether proposing reclassification for the device was appropriate.

proposed order. Such an outcome would not only further delay completion of the final action (i.e., either reclassification or call for PMAs) for preamendments Class III devices and needlessly expend scarce FDA resources, but would create uncertainty for manufacturers and for the public.

For AEDs, FDA has followed its long-standing practice described above for preamendments Class III devices, for which there has not been a call for PMAs. The findings in the March 2013 proposed order are based on the reports and recommendations of the January 2011 AED panel for the proper classification of these devices, with information submitted in response to the 2009 515(i) order, and any additional information that FDA obtained since convening the AED panel. In accordance with section 515(b)(2)(D) of the FD&C Act, 21 U.S.C. 360e(b)(2)(D), FDA provided an opportunity in the proposed order for interested persons to submit a request for a change in classification of AEDs. FDA also opened a docket for interested persons to submit comments or request a change in classification in response to the proposed order. FDA will review and consider all comments made in response to the issuance of the proposed order, and will also consider the request for a change in classification that the Agency received before taking any further action.

#### **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 sequestered 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?**

As Commissioner Hamburg has said, an agency as important as FDA needs predictability, and cannot be run well if you don't know what budget you'll be given during the year, or if you do not know whether or not you can draw from certain resources. The administration has not taken a position on this bill. The sequester restricted access to an estimated \$79 million in user fees in FY 2013. Sponsors paid fees for specific commitments that were negotiated as part of the Prescription Drug User Fee Act (PDUFA), Medical Device User Fee Amendments (MDUFA), Generic Drug User

Fee Act (GDUFA), Biosimilar User Fee Act (BsUFA), Animal Drug User Fee Act (ADUFA), and Animal Generic Drug User Fee Act (AGDUFA) agreements, but FDA did not have access to the full FY 2013 amounts of the funds due to the sequestration. Sequestration impacts FDA's ability to meet these commitments, such as the program enhancements specified in the PDUFA V and MDUFA III commitment letters. This work must be done by FDA, not other FDA constituencies. Many of these enhancements will have long-term benefits for the public health. The delay of these enhancements resulting from the sequester will postpone these benefits. If sequestration is mitigated in FY 2014 and future years, FDA will have enhanced capacity to meet its commitments to industry and the public.

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

Previously, we estimated the overall sequestration of user fees to be \$85M. The estimate for sequestration as of September 30, 2013, is \$79M. Of that amount, \$54M is attributable to PDUFA, GDUFA, BsUFA, and MDUFA. The reason for the change in sequestration amounts is that actual collections were different from the estimates at the beginning of the year.

The FY 2013 sequestration and rescission reductions have harmed FDA's ability to protect the public and ensure the safety of America's food and medical products. FDA has been unable to hire to the appropriate staffing level for its workload. This reduced staffing level has:

- delayed FDA's ability to conduct regulatory review and issue regulations and guidance
- impaired FDA's ability to conduct inspections in a timely manner
- reduced FDA's capability to conduct relevant regulatory research.

Furthermore, due to the sequestration budget reductions, FDA has reduced staff training, impairing the Agency's ability to remain current on the most recent scientific and regulatory advances. A major reduction in travel also means FDA cannot as readily interact with key stakeholders and regulatory partners. Additionally, the development of reports, guidances, rules, and *Federal Register* notices to implement FDASIA provisions has been delayed.

Any further reductions to FDA's resources in FY 2014 will exacerbate the challenges FDA faced as a result of the FY 2013 sequestration.

**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?**

FDA did not have the additional resources needed to meet the new commitments made under PDUFA V that offered critical enhancements to communications with sponsors, new drug regulatory science, and more efficient and effective post-market safety oversight, beginning in FY 2013.

It is expected that all of the gains FDA has made in bringing PDUFA performance back to the 90 percent or greater goal performance are at risk, and FDA may no longer be able to meet critical performance goals for new drug review. This means potential delays in the availability of new drugs for patients and increased costs and adverse economic impacts on the U.S. pharmaceutical industry.

FDA's capacity to effectively launch the new user fee programs, GDUFA and BsUFA, has been reduced. These programs are designed to enable FDA to leverage user fee resources to provide many benefits to the public, including expediting the availability of high-quality, cost-effective generic drugs and biosimilars. FDA's ability to meet the performance goals negotiated with industry, including performance goals for expediting the review of generic drugs and biosimilars, is at risk. This may result in significantly delayed access to more affordable drug and biological products for patients.

FDA plans to meet key performance commitments negotiated under MDUFA III, such as improvements to premarket approval (PMA) goals and 510(k) goals. Sequestration made it challenging for FDA to meet MDUFA performance goals, but FDA minimized the impact of sequestration, where possible. FDA does not believe sequestration will impact MDUFA review times.

Any further reductions to FDA's resources in FY 2014 will exacerbate the challenges FDA faced as a result of the FY 2013 sequestration.

- 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?**

FDA has discussed this issue within the Administration and with Congressional staff. We are pleased that the FY 2014 appropriation restores \$124 million in budget authority

to FDA, lost due to the FY 2013 sequestration and rescission cuts. Section 747 of the FY 2014 appropriation also includes funding for the FY 2013 sequestered user fees.

- 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?**

FDA has discussed this issue within the Administration and with Congressional staff. We are pleased that the FY 2014 appropriation restores \$124 million in budget authority to FDA, lost due to the FY 2013 sequestration and rescission cuts. Section 747 of the FY 2014 appropriation also includes funding for the FY 2013 sequestered user fees.

- 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?**

FDA has discussed this issue within the Administration and with Congressional staff. We are pleased that the FY 2014 appropriation restores \$124 million in budget authority to FDA, lost due to the FY 2013 sequestration and rescission cuts. Section 747 of the FY 2014 appropriation also includes funding for the FY 2013 sequestered user fees.

#### **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 purposes are achieved through a chemical action within or on the body of a man?**

As you note, FDA issued the Draft Guidance on Classification of Products as Drugs and Devices & Additional Product Classification Issues<sup>31</sup> (Classification Guidance) and

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<sup>31</sup> Available at <http://www.fda.gov/RegulatoryInformation/Guidances/ucm258946.htm>.

related Draft Guidance on Interpretation of the Term “Chemical Action” in the Definition of Device under Section 201(h) of the FD&C Act<sup>32</sup> (Chemical Action Guidance) in 2011. These draft guidance documents concern classification of products as drugs and devices. The Agency is currently evaluating these draft guidance documents in light of the U.S. District Court for the District of Columbia’s September 2012 opinion in *Prevor v. Food and Drug Admin. (Prevor I)*, 895 F. Supp. 2d 90 (D.D.C. 2012), and opinion in *Prevor v. Food and Drug Admin. (Prevor II)*, Case No. 1:13-cv-01177-RMC (D.D.C. Sept. 9, 2014).

- 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?**

FDA strives to regulate similar products in a similar manner. FDA classifies products in accordance with the statutory definitions established by Congress. Differences in product composition or intended uses, or both, can affect product classification. Due to such factors, products that appear to be similar may, in fact, not be similar and, thus, have different classifications.

- 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?**

We agree that a device may have more than one primary intended purpose.

- 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?**

FDA follows its regulations at 21 CFR 10.115 in developing guidance documents. Accordingly, FDA agrees that when the Agency issues a draft guidance document setting forth “changes in interpretation or policy that are of more than a minor nature,” FDA should not implement that guidance document until it is finalized (see 21 CFR 10.115(c)(1)). However, FDA must implement its statutes and regulations, regardless of whether it chooses to issue guidance in an effort to provide greater detail and transparency to industry and other stakeholders.

The Agency is currently evaluating its “Classification” and “Chemical Action” draft guidance documents, in light of the U.S. District Court for the District of Columbia’s rulings in *Prevor I* and *Prevor II*. FDA follows its regulations at 21 CFR 10.115 in developing guidance documents.

- 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**

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<sup>32</sup> Available at <http://www.fda.gov/RegulatoryInformation/Guidances/ucm259059.htm>.

**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?**

The Agency is currently evaluating its “Classification” and “Chemical Action” draft guidance documents in light of the U.S. District Court for the District of Columbia’s rulings in *Prevor I* and *Prevor II*. We note that the product to which you refer—Diphoterine Skin Wash—is not a “portable body shower.” It is comprised of a pressurized canister that delivers a diphoterine solution onto the skin as an aerosolized mist. Its primary intended purpose is to help prevent or minimize accidental chemical burn injuries. The diphoterine solution is expected to react with harmful chemicals to neutralize them, draw chemicals from the interior to the exterior of the skin, and displace chemicals from the body. The device canister aids in delivery of the diphoterine solution by allowing its ready delivery onto the skin. FDA classified the product as a combination product, consisting of a drug constituent part (the diphoterine solution) and a device constituent part (the aerosol spray canister), with a drug primary mode of action to that the Center for Drug Evaluation and Research (CDER) was designated as the lead Center for premarket review and regulation of the product. The Agency is currently evaluating its classification of Prevor’s product in light of the U.S. District Court for the District of Columbia’s ruling *Prevor II*.

- 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?**

The Agency is currently evaluating its interpretation of the relevant statutory language in light of the U.S. District Court for the District of Columbia’s rulings in *Prevor I* and *Prevor II*.

- 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.**

Some products that are regulated as drugs in the United States are regulated as devices in other countries and vice versa. FDA classifies products in accordance with the statutory definitions in force in the United States. We seek to implement our regulatory programs for drugs and devices in a manner that is consistent with U.S. law and our mission to protect the public health, without imposing undue burden. We have developed regulatory programs to facilitate the development and availability of important products for U.S. patients. These include drug and device review programs. We remain committed to

pursuing efforts with foreign counterparts to pursue regulatory coherence to minimize regulatory burden consistent with U.S. law and the promotion and protection of the public health.

*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 entirety to the Committee upon its completion?**

The final written report on BAH's high-priority recommendations for the MDUFA III Independent Assessment was delivered to FDA on December 6, 2013, and was posted on the Agency's public website on December 11, 2013. A copy of the report is available at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFAIII/UCM378202.pdf>.

**The Honorable Lois Capps**

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

Section 615 of FDASIA explicitly requires expansion of active post-market risk identification and analysis to include and apply to medical devices.

In September 2012, FDA released an initial report, "Strengthening Our National System for Medical Device Postmarket Surveillance," which provided an overview of FDA's medical device post-market authorities and the current U.S. medical device post-market surveillance system, and also proposed four specific actions to strengthen the medical device post-market surveillance system in the United States. These actions include the expansion of the active surveillance approach of Sentinel to medical devices. This report can be found at

<http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM301924.pdf>. Following release of the report, FDA held a series of public meetings in September 2012, including one focused on Sentinel, and accepted comments via its website to garner stakeholder feedback.

The update to the report, issued in April 2013, incorporates the public input that FDA received and details the concrete steps that the Agency will complete to more efficiently

collect better and timely data, helping to identify safety issues more quickly. This update to the report can be found at

<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm301912.htm>.

Two implementation action items that the Agency identified include the establishment of a (1) National Medical Device Postmarket Surveillance Planning Board (Planning Board) and (2) National Medical Device Registry Task Force (Registry Task Force).

To facilitate establishment of the Planning Board, FDA's Center for Devices and Radiological Health (CDRH) awarded a cooperative agreement to the Brookings Institution to convene and manage the Planning Board.

To facilitate establishment of the Registry Task Force, CDRH awarded a cooperative agreement to Duke University to leverage the existing Medical Device Epidemiology Network (MDEpiNet) Public-Private Partnership via the MDEpiNet Partnership Coordinating Center at Duke University. The calls for nominations for the Planning Board and the Registry Task Force were issued on December 18, 2013, and nominations were accepted until January 17, 2014.

In addition, CDRH issued two five-year announcements for cooperative agreements to support building of public-private partnerships to implement the National Medical Device Postmarket Surveillance Plan through development of new data sources, epidemiology infrastructure, analysis methodologies, analysis tools, and registries. CDRH awarded cooperative agreements in September 2013, which will support the initial stages of development of the Registry Task Force through the MDEpiNet partnership coordination center at Duke University and will support convening the Planning Board through the Brookings Institution. Awards were also made to: (1) the Lahey Clinic for examination of Data Extraction and Longitudinal Trend Analysis (DELTA) software as a prospective active surveillance tool, (2) the University of Washington to develop the Dynamic Automated External Defibrillator (AED) Registry, and (3) Weill Cornell Medical College to develop an international consortium of cardiovascular registries. Each of these efforts involves substantial contribution from a broad array of external stakeholders in both the public and private sectors working toward common public health goals.