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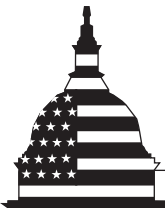
Testimony
Before the Special Committee on Aging,
U.S. Senate

For Release on Delivery
Expected at 2:00 p.m. EDT
Wednesday, April 13, 2011

MEDICAL DEVICES

**FDA's Premarket Review
and Postmarket Safety
Efforts**

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Why GAO Did This Study

The Food and Drug Administration (FDA) is responsible for overseeing medical devices sold in the United States. In general, new devices are subject to FDA review via either the 510(k) premarket notification process, which determines if a device is substantially equivalent to another legally marketed device, or the more stringent premarket approval (PMA) process, which requires the manufacturer to supply evidence providing reasonable assurance that the device is safe and effective. FDA also has broad responsibilities for postmarket surveillance of devices, including oversight of recalls. A recall involves the correction or removal of a product from the market and is an important remedial action that can mitigate the risks associated with a defective or unsafe medical device. In recent years, GAO has identified a wide variety of concerns related to FDA's ability to fulfill its mission of protecting the public health and added FDA's oversight of medical products, including devices, to its list of high-risk areas.

This statement provides an update on FDA's actions in response to a recommendation made in GAO's report, *Medical Devices: FDA Should Take Steps to Ensure That High-Risk Device Types Are Approved through the Most Stringent Premarket Review Process* ([GAO-09-190](#), January 15, 2009). It also contains preliminary information on FDA's oversight of medical device recalls. Because of the preliminary nature of this work, GAO is not making recommendations at this time.

View [GAO-11-556T](#) or key components. For more information, contact Marcia Crosse at (202) 512-7114 or crossem@gao.gov.

April 13, 2011

MEDICAL DEVICES

FDA's Premarket Review and Postmarket Safety Efforts

What GAO Found

FDA has begun to take steps to address GAO's 2009 recommendation about high-risk devices that are allowed to enter the U.S. market through the less stringent 510(k) process, but progress has been limited. High-risk devices include those which are implantable or life sustaining. In 2009, GAO recommended that FDA expeditiously take steps to issue regulations for the device types classified as high risk that are currently allowed to enter the market via the 510(k) process. Since then, FDA has set strategic goals to address these device types, but has issued a final rule regarding the classification of only one device type. As of April 1, 2011, FDA's action on the 26 remaining types of high-risk devices was incomplete. Thus, these types of devices—such as automated external defibrillators and implantable hip joints—can still enter the U.S. market through the less stringent 510(k) process. GAO found that, since its report was issued in January 2009, FDA has cleared at least 67 510(k) submissions that fall within these high-risk device types. FDA has taken some additional steps to enhance premarket device safety since GAO's 2009 report was issued—for example, it commissioned the Institute of Medicine to conduct an independent review of the premarket review process—but it is too early to tell whether any forthcoming changes will enhance public health.

GAO's preliminary analysis shows that, from 2005 through 2009, firms initiated 3,510 voluntary medical device recalls, an average of just over 700 per year. Although FDA maintains extensive information on each recall, it has not been routinely analyzing recall data that would allow it to explain trends in recalls over time, thus missing an opportunity to proactively identify and address the risks presented by unsafe devices. GAO's preliminary work also identified several gaps in the medical device recall process that limited recalling firms' and FDA's abilities to ensure that the highest-risk recalls were being implemented in an effective and timely manner. GAO found that firms frequently were unable to correct or remove all devices subject to the highest-risk recalls. GAO's preliminary findings indicate that FDA lacks clear guidance for overseeing recalls which has led to inconsistencies in FDA's assessments of whether individual recalls were implemented effectively. Consequently, FDA officials examining similar situations sometimes reached opposite conclusions regarding whether recalls were effective. In addition, FDA had not established thresholds for assessing whether firms effectively completed recalls by correcting or removing a sufficient number of recalled devices. Further, GAO determined that FDA's decisions to terminate completed recalls—that is assess whether firms had taken sufficient actions to prevent a reoccurrence of the problems that led to the recalls—were frequently not made within its prescribed time frames. Finally, GAO found that FDA did not document its justification for terminating recalls. Taken together, GAO's preliminary work suggests that the combined effect of these gaps may increase the risk that unsafe medical devices could remain on the market.

Chairman Kohl, Ranking Member Corker, and Members of the Committee:

I am pleased to be here today as you examine issues related to medical device safety. Americans depend on the Food and Drug Administration (FDA) to ensure that medical products sold in the United States are safe and effective. FDA's responsibilities begin before a new device is brought to market and continue after its clearance or approval. Among other things, FDA reviews thousands of submissions for new devices filed each year to decide whether they should be allowed to be marketed in the United States. FDA is also responsible for oversight of thousands of devices already on the market.

In general, unless exempt by regulation, new devices are subject to FDA premarket review via either the 510(k) premarket notification process, to determine whether a new device is substantially equivalent to another legally marketed device, or the more stringent premarket approval (PMA) process, which requires the manufacturer to supply evidence providing reasonable assurance that the device is safe and effective. In addition to its premarket duties, FDA also has broad responsibilities for postmarket surveillance of thousands of devices already on the market, including overseeing recalls. A recall involves the correction or removal of a product from the market and is an important remedial action that can mitigate the risk of serious health consequences associated with a defective or unsafe medical device.

Over the last several years we have identified a wide variety of concerns related to FDA's ability to fulfill its mission of protecting the public health, including weaknesses in FDA's premarket review and postmarket surveillance activities related to medical devices.¹ As a result, FDA's oversight of medical products was added to our list of high-risk areas in 2009 and was also included on our 2011 update of this list.²

¹See "Related GAO Products" at the end of this testimony.

²We regularly report on government operations that we identify as high risk, due to their greater vulnerabilities to fraud, waste, abuse, mismanagement, or the need for transformation to address economy, efficiency, or effectiveness challenges. See GAO, *High-Risk Series: An Update*, [GAO-09-271](#) (Washington, D.C.: Jan. 2009); and GAO, *High-Risk Series: An Update*, [GAO-11-278](#) (Washington, D.C.: Feb. 2011).

In January 2009, we reported on concerns with FDA's premarket review of medical devices.³ Specifically, we found that a significant number of high-risk devices—including device types that FDA has identified as implantable; life sustaining; or posing a significant risk to the health, safety, or welfare of a patient—were cleared for the U.S. market through FDA's less stringent 510(k) review process. We recommended that FDA expeditiously take steps to ensure that high-risk device types are approved through the agency's more rigorous PMA review process. More recently, we have turned our attention to postmarket surveillance and are currently conducting work assessing FDA's oversight of medical device recalls.

My remarks today will focus on concerns that we previously raised regarding the 510(k) process and will include an update on the steps FDA has taken in response to the recommendation contained in our January 2009 report. I will also share our preliminary findings from our ongoing work related to FDA's oversight of the medical device recall process.

For this statement, we interviewed FDA officials and reviewed pertinent statutes, regulations, *Federal Register* notices, and other documents. To determine the steps FDA has taken in response to our 2009 recommendation, we analyzed information from FDA databases⁴ and obtained information on actions taken from FDA's Web site and FDA officials. For our ongoing work on medical device recalls, we obtained information from FDA's Recall Enterprise System on all voluntary recalls initiated and reported to FDA from January 1, 2005, through December 31,

³See GAO, *Medical Devices: FDA Should Take Steps to Ensure That High-Risk Device Types Are Approved through the Most Stringent Premarket Review Process*, [GAO-09-190](#) (Washington, D.C.: Jan. 15, 2009).

⁴We analyzed information from FDA's product code classification database to identify class III device types that can be cleared for the U.S. market through the 510(k) process and analyzed information from that database as well as FDA's premarket notification 510(k) database to identify traditional and abbreviated 510(k) submissions for class III devices that FDA cleared for the U.S. market since we issued our report on January 15, 2009. Our analysis did not include certain types of device submissions, for example, special 510(k) submissions, which are requests for clearance of minor modifications to devices that have already been cleared through the 510(k) process. Because related devices can be "bundled" together in a single submission, one submission may include one or more devices.

2009.⁵ We then used this information to determine, among other things, the number of recalls initiated per year; the number of recalls by recall risk levels; and status of the recalls. In addition, we examined FDA's oversight of 53, or 40 percent, of all high-risk recalls that were initiated from January 1, 2005, through December 31, 2009. For each of these 53 recalls, we obtained and reviewed the case files which documented firms' and FDA's actions. We reviewed key documents such as information from the firms on the causes of the recalls, the firms' actions to prevent reoccurrence of similar problems, the recall notifications firms sent out to customers, and FDA's correspondence with firms. As part of our review, we reviewed whether firms and FDA followed FDA's procedures for implementing and overseeing the recalls. We determined that the data we used for our report were sufficiently reliable for our purposes. We received technical comments on a draft of this statement from FDA, which we incorporated as appropriate.

We conducted our work related to FDA's premarket review of medical devices and our update of that work in accordance with generally accepted government auditing standards.⁶ Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives. We are also conducting our work on FDA's oversight of medical device recalls in accordance with generally accepted government auditing standards.⁷ Because of the preliminary nature of this work, we are not making recommendations on FDA's recall process at this time.

⁵While FDA has authority to order a mandatory recall, it did not exercise this authority during the period we reviewed. See 21 U.S.C. § 360h(e), 21 C.F.R. pt. 810 (2010). Also, our information does not include devices that a firm may have voluntarily taken off the market for other, less serious, reasons. For example, a market withdrawal is a firm's correction or removal of a distributed device that involves no violation or a minor violation of the laws FDA administers and for which FDA would not initiate legal action. 21 C.F.R. § 806.2(h) (2010).

⁶We conducted the work for our 2009 report, [GAO-09-190](#), from March 2008 to January 2009. We conducted the work to update FDA actions taken in response to that report's recommendation from January 2011 to April 2011.

⁷We began conducting this work in January 2010 and our work is ongoing.

Background

FDA classifies each device type into one of three classes based on the level of risk it poses and the controls necessary to reasonably ensure its safety and effectiveness.⁸ Examples of types of devices in each class include the following:

- class I: tongue depressors, elastic bandages, reading glasses, and forceps;
- class II: electrocardiographs, powered bone drills, and mercury thermometers; and
- class III: pacemakers and replacement heart valves.

Premarket Review of Medical Devices

Before medical devices may be legally marketed in the United States, they are generally subject to one of two types of FDA premarket review, unless exempt by FDA regulations.⁹ These reviews are:

- **Premarket approval or PMA process:** The manufacturer must submit evidence, typically including clinical data, providing reasonable assurance that the new device is safe and effective. The PMA process is the most stringent type of premarket review. A successful submission results in FDA's approval to market the device.
- **Premarket notification or 510(k) process:** Premarket notification is commonly called "510(k)" in reference to section 510(k) of the Federal Food, Drug, and Cosmetic Act, where the notification requirement is listed. The manufacturer must demonstrate to FDA that the new device is

⁸FDA's classification of device types is codified in parts 862 through 892 of title 21 of the Code of Federal Regulations (2010). Class I devices are those for which compliance with general controls, such as good manufacturing practices specified in FDA's quality system regulation, is sufficient to provide reasonable assurance of their safety and effectiveness. Class II devices are subject to general controls and may also be subject to special controls, such as postmarket surveillance. Class III devices are those (1) for which insufficient information exists to determine whether general and special controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device and (2) that support or sustain human life or are of substantial importance in preventing impairment of human health, or that present a potential unreasonable risk of illness or injury. See 21 U.S.C. § 360c.

⁹A small percentage of devices enter the market by other means, such as through the humanitarian device exemption process that allows market entry, without adherence to certain requirements, for devices benefiting patients with rare diseases or conditions. See 21 U.S.C. § 360j(m), 21 C.F.R. pt. 814, subpart H (2010). In addition, many other less risky types of class I and II devices are also exempt from FDA's premarket review.

substantially equivalent to a device already legally on the market that does not require a PMA.¹⁰ For most 510(k) submissions, clinical data are not required and substantial equivalence will normally be determined based on comparative descriptions of intended device uses and technological characteristics, and may include performance data. A successful submission results in FDA's clearance to market the device.

In general, class I and II device types subject to premarket review are required to obtain FDA clearance through the 510(k) process, and class III device types are required to obtain FDA approval through the more rigorous PMA process. With the enactment of the Medical Device Amendments of 1976, Congress imposed requirements under which all class III devices would be approved through the PMA process before being marketed in the United States.¹¹ However, certain types of class III devices that were in commercial distribution in the United States before May 28, 1976,¹² (called preamendment device types) and those determined to be substantially equivalent to them may be cleared through the less stringent 510(k) process until FDA publishes regulations requiring them to go through the PMA process or reclassifies them into a lower class.¹³ Between 1976 and 1990, FDA issued regulations requiring some class III device types to go through the PMA process, but many class III device types continued to be reviewed through the 510(k) process. The Safe Medical Devices Act of 1990 required FDA (1) to re-examine the preamendment class III device types for which PMAs were not yet required to determine if they should be reclassified to class I or II or remain in class III and (2) to establish a schedule to promulgate regulations requiring those

¹⁰*Substantial equivalence or substantially equivalent* means that the device has the same intended use as another legally marketed device and the same technological characteristics, or that the device has different technological characteristics and information submitted to FDA demonstrates that the device is as safe and effective as the legally marketed device and does not raise different questions of safety or effectiveness. 21 U.S.C. § 360c(i)(1)(A).

¹¹See Pub. L. No. 94-295, § 2, 90 Stat. 539, 552-59 (codified at 21 U.S.C. § 360e).

¹²May 28, 1976, is the date of enactment of the Medical Device Amendments of 1976, which established the three device classes.

¹³FDA may, by regulation, change the classification of a device from class III to (1) class II if it determines that special controls would provide reasonable assurance of the safety and effectiveness of the device and that general controls alone would not provide reasonable assurance of the safety and effectiveness of the device or (2) class I if FDA determines that general controls alone would provide reasonable assurance of the safety and effectiveness of the device. 21 U.S.C. § 360c(e).

preamendment device types that remain in class III to obtain FDA approval through the PMA process.¹⁴ Accordingly, all class III devices are eventually to be reviewed through the PMA process.

In our January 2009 report, we found that although Congress envisioned that all class III devices would be approved through the more stringent PMA process, the agency's actions to make this the case were incomplete. We found that in fiscal years 2003 through 2007, FDA continued to clear submissions for class III devices through the less stringent 510(k) process—clearing 228 over the 5-year period. We recommended that FDA expeditiously take steps to issue regulations for each class III device type allowed to enter the market through the 510(k) process, including 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. FDA agreed with our recommendation when we issued our report, but did not specify time frames in which it would take action.

Postmarket Oversight of Voluntary Medical Device Recalls

Overseeing recalls is an important element of FDA's postmarket responsibilities. FDA defines a recall as a firm's removal or correction of a marketed product that FDA (1) considers to be in violation of the laws it administers, and (2) against which the agency would initiate legal actions.¹⁵ Nearly all medical device recalls are voluntarily initiated by a recalling firm, usually the manufacturer of the device. To initiate a voluntary recall, a firm notifies those who have received, purchased, or used the device. The firm may be asked to provide FDA with information such as the reason for the correction or removal of the device, an assessment of the health hazard associated with the device, and the volume of product in distribution and proposed strategy for conducting the recall.¹⁶ The strategy should contain details on the firm's plan for ensuring that its customers and device users correct or remove the device

¹⁴Pub. L. No. 101-629, § 4(b), 104 Stat. 4511, 4515-17 (codified at 21 U.S.C. § 360e(i)).

¹⁵21 C.F.R. § 7.3(g) (2010). A removal is the physical removal of a device from its point of use to some other location for repair, modification, adjustment, relabeling, destruction, or inspection. A correction may involve these actions without the physical removal of a device from its point of use. See 21 C.F.R. 806.2(d), (i) (2010).

¹⁶The firm will contact one of FDA's district offices depending upon the location from which it chooses to manage the recall. This district will have primary responsibility for monitoring the recall. Each district has a recall coordinator, who, among other duties, processes medical device recalls and monitors the progress of the firm's actions.

according to the firm's instructions. FDA's role is generally to oversee a firm's management of a recall. As part of its oversight, FDA reviews and recommends changes to the recall strategy and assigns one of three recall classifications—class I, II, or III—to indicate the relative degree of health hazard posed by the product being recalled. For a class I recall, FDA has determined that there is a reasonable probability that use of, or exposure to, the product could cause serious adverse health consequences or death. Class II recalls are those for which FDA has determined that the use of, or exposure to, the product could cause temporary or medically reversible adverse health consequences or that the probability of serious adverse health consequences is remote. For class III recalls, FDA has determined that use of, or exposure to, a device is not likely to cause adverse health consequences. FDA advises the recalling firm of the assigned recall classification; and posts information about the recall in its weekly enforcement report.

It is important to note that FDA's device and recall classification schemes carry opposite designations. The potential degree of health risk associated with device classes is designated from class III (high) to class I (low), while the potential risk associated with recall classes is designated from class I (high) to class III (low).

FDA also monitors the progress of a recall and verifies whether the recalling firm has effectively implemented the recall strategy. FDA requests that a recalling firm periodically provide the monitoring district with status reports that provide updates on the progress of recalls. FDA district staff also conduct audit checks to confirm that the recalling firm has properly corrected or removed devices from the market, in accordance with the recall strategy. Once the firm believes it has completed the recall—that is, done everything as outlined in the recall strategy—it should submit a recall termination request to the monitoring district office. As part of the termination decision, FDA should assess whether the firm has taken sufficient corrective actions to prevent a reoccurrence of the problem that led to the recall. For class I recalls, FDA district staff review a firm's request, and if they agree, send a recall termination request to headquarters. For class II and III recalls, FDA district staff make the final termination decision. According to FDA's procedures, FDA should terminate a recall within 3 months after the firm completes the recall.

FDA Has Taken Some Actions in Response to Our Recommendation to Strengthen the Premarket Review Process, but Concerns About the 510(k) Process Remain

FDA has begun to take steps to address our 2009 recommendation about class III devices that are still allowed to enter the U.S. market through the less stringent 510(k) process, but progress has been limited. Concerns persist about the effectiveness of the 510(k) process in general, including its ability to provide adequate assurance that devices are safe and effective. In 2009, we recommended that FDA expeditiously take steps to address class III device types allowed to enter the market via the 510(k) process by issuing regulations requiring submission of PMAs or reclassifying them to a lower class. Since our report was issued, the agency has set strategic goals to address this matter, but has issued a final rule regarding the classification of only one device type.¹⁷ As of April 1, 2011, 26 additional class III device types could still enter the U.S. market through the less stringent 510(k) process.

FDA has been taking steps to address the 26 class III device types—including automated external defibrillators and implantable hip joints—that can still enter the U.S. market through the 510(k) process. Specifically, FDA is following a 5-step process to require PMAs or to reclassify them to a lower device class. As shown in table 1, as of April 1, 2011, FDA was at step 2—assessing the risk and benefits—for 21 device types.¹⁸ FDA was at step 4—receiving and reviewing comments provided on proposed rules—for 5 other device types, but had not yet issued final rules requiring PMAs or reclassifying any of them.¹⁹

¹⁷See 74 *Fed. Reg.* 42773. (Aug. 25, 2009).

¹⁸On April 9, 2009, FDA published a notice in the *Federal Register* requiring manufacturers of 25 of the 26 device types to submit summary information, including adverse safety or effectiveness information, to determine whether to require PMAs or to reclassify the device types. 74 *Fed. Reg.* 16214.

¹⁹FDA published a proposed rule on August 25, 2010, that, if finalized, would retain class III designation and require PMAs for four device types. 75 *Fed. Reg.* 52294. FDA published a proposed rule, regarding classification, for another device type on April 6, 2006. 71 *Fed. Reg.* 17390.

Table 1: Status of FDA Action for 26 Class III Device Types that Can Be Cleared through the 510(k) Process, as of April 1, 2011

Step in FDA process	Number of device types at this step in the process
Step 1: FDA collects existing information, which includes publishing a <i>Federal Register</i> notice to solicit information, and may include holding an FDA advisory panel meeting	0
Step 2: FDA assesses the risks and benefits	21
Step 3: FDA proposes classification into class I, II, or III, which is announced as a proposed rule in a <i>Federal Register</i> notice	0
Step 4: FDA receives and reviews comments provided	5
Step 5: FDA finalizes classification into class I, II, or III, which is announced as a final rule in a <i>Federal Register</i> notice ^a	0

Source: GAO analysis of FDA information.

Note: This table presents the FDA 5-step process and status from the FDA Web site <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHTransparency/ucm240318.htm>, accessed April 1, 2011.

^aFor device types retained in class III, FDA will call for PMA applications and sponsors of devices previously cleared through the 510(k) process will need to submit PMA applications in order to continue to market their devices (with a grace period to permit possible transition to obtaining PMA approval).

While FDA has taken essential initial steps toward implementing our recommendation, until the agency issues final regulations either reclassifying or requiring PMAs for class III device types that currently can be cleared through the less stringent 510(k) process, its actions remain incomplete. Thus, these 26 device types can still enter the U.S. market through the less stringent premarket review process. Since we issued our report in January 2009, FDA cleared at least 67 individual submissions that fall within 12 of these class III device types through the 510(k) process.²⁰

Subsequent to the issuance of our 2009 report and in response to numerous concerns over the effectiveness of the 510(k) process, including its ability to provide adequate assurance that devices are safe and effective, FDA announced it would take additional actions to enhance

²⁰Our analysis did not include special 510(k) submissions, which are requests for clearance of minor modifications to devices that have already been cleared through the 510(k) process.

premarket device safety. In 2009, FDA reported that it would conduct its own comprehensive internal assessment of the premarket medical device approval process and commissioned the Institute of Medicine to conduct an independent review to assess whether the 510(k) process sufficiently protects patients and promotes public health. The Institute of Medicine is expected to issue its report in mid-2011.

Shortcomings in FDA's Oversight of the Highest-Risk Medical Device Recalls Increase the Risk That Unsafe Devices Continue to Be Used

Our preliminary findings suggest that shortcomings in FDA's oversight of the medical device recall process may limit the agency's ability to ensure that the highest-risk recalls are being implemented in an effective and timely manner. These shortcomings span the entire range of the agency's oversight activities—from the lack of a broad-based program to systematically assess trends in recalls, to inconsistencies in the way FDA ensures the effective completion of individual recalls.

FDA Has Not Routinely Used Recall Data to Aid Its Oversight of the Recall Process

Although FDA's recall data system contains numerous data elements that would allow for analyses of recall data, our preliminary findings suggest that FDA is not using this system to effectively monitor and manage its recall program. This system contains information on, for example, the status of each recall (e.g., ongoing or terminated); the reason for the recall; the specific device being recalled; the recall classification level assigned based on FDA's assessment of risk; the dates the recalls were initiated, classified, and terminated; and the medical specialty—area of use—for each device subject to recall (e.g., cardiovascular or orthopedic). However, FDA has not routinely used these recall data as a surveillance tool or for examining broad trends of medical device recalls.²¹ Instead of using this information to conduct systemic analyses of the recall program, which would be consistent with the agency's strategic goal of improving the quality and safety of manufactured products in the supply chain, FDA has primarily been using data from its recall system for processing individual recalls.

²¹We previously reported on the importance of establishing and using metrics as a management tool. See, for example, GAO, *Food and Drug Administration: Opportunities Exist to Better Address Management Challenges*, [GAO-10-279](#) (Washington, D.C.: Feb. 19, 2010).

Our preliminary analysis showed that between January 1, 2005, and December 31, 2009, firms initiated 3,510 device recalls. Only a small percentage of these recalls—about 4 percent—were classified by FDA as class I recalls—those that pose a reasonable probability that the use of, or exposure to, these products will cause serious adverse health consequences or death. The vast majority—nearly 83 percent—were classified by FDA as class II recalls, meaning use of, or exposure to, these devices may cause temporary or medically reversible adverse health consequences or that the probability of serious adverse health consequences is remote; and about 14 percent were classified as class III recalls, which pose the lowest risk.

Based on our preliminary analysis, we provided key summaries to FDA officials and asked them to comment on trends that we observed. Officials indicated that they have not fully analyzed these data and could not explain trends without extensive research of individual case files. For example, they could not explain why the majority of recalls are class II, why class I recalls more than doubled between 2008 and 2009, or why many recalls had been ongoing for 5 years. Officials also could not provide definitive answers when we asked them to comment on other related topics, such as:

- trends in the number of recalls over time;
- variation in the numbers of recalls by recall classification levels;
- types of devices and medical specialties of devices accounting for most recalls; and
- length of time needed to complete or terminate recalls.

Although FDA has not been routinely analyzing recall data to assess the effectiveness of the recall process, officials indicated that they have used these data to support compliance and subsequent enforcement actions. For example, officials indicated that they use recall data to help identify which firms the agency should inspect for assessing compliance with laws and regulations.

FDA Inconsistently Assessed the Effectiveness of Recalls

Our preliminary analysis revealed inconsistencies in FDA's assessments of the effectiveness of recalls. A key tool to making these assessments are FDA's "audit checks" in which investigators from FDA's district offices contact a percentage of customers or device users affected by the recall to determine whether they received the recall notice and followed the recalling firm's instructions for removing or correcting the device. However, we identified numerous inconsistencies in the way FDA's investigators implemented these audit checks, resulting in conflicting determinations about whether recalls were effectively conducted.

Our analysis of 2,196 audit check forms associated with the class I recalls we reviewed found a variety of inconsistencies in how the audit checks were implemented and documented for nearly 90 percent of these recalls.²² For each of these recalls we found inconsistencies in how different investigators determined whether a recall was effective or ineffective when conducting their audit checks of recalls. We also identified inconsistencies in the level of detail provided in the audit check report and the level of effort undertaken by different investigators. These recalls covered a wide range of devices, including implantable pumps and automated external defibrillators. For example, when conducting audit checks, some investigators concluded that recalls were effective, despite noting problems (such as device users not following the firm's instructions), while other investigators concluded under similar circumstances that recalls were ineffective. In other recalls, some investigators noted actions they took when they discovered problems, such as providing the device users with a copy of the recall notice or instructing them on actions to take in order to implement a recall. In contrast, other investigators did not indicate whether they made any attempt to help the user implement the recall.

FDA officials at both headquarters and the district offices we contacted acknowledged that there are no detailed instructions or requirements for conducting audit checks and that there can be inconsistencies in the process. They also agreed that this may be an area where enhanced guidance is needed.

²²FDA's regulatory procedures note that audit checks should be conducted for all class I recalls. FDA conducted audit checks for 45 of the 53 class I recalls (85 percent) we reviewed. In six of the eight cases in which FDA did not conduct audit checks, the recall file contained written documentation explaining why audit checks were not conducted.

FDA Lacks Specific Criteria to Determine Whether Firms Have Taken Adequate Steps to Correct or Remove Recalled Devices

One of the gaps in FDA's recall process suggested by our preliminary work is that FDA lacks specific criteria for making decisions about whether recalling firms have effectively completed their recalls by taking adequate steps to correct or remove recalled devices. Our preliminary review of FDA's recall procedures found that the procedures do not contain any specific criteria or general guidelines governing the extent to which firms should be correcting or removing various types of devices—such as a benchmark recall rate—before a recall should be considered completed. FDA officials indicated they consider a recall complete when a firm has completed actions outlined in its recall strategy. In particular, they evaluate whether firms completed their assigned level of effectiveness checks, and have corrected or removed recalled devices in “an acceptable manner.” However, FDA officials said that they do not have specific criteria or thresholds concerning the proportion of various types of devices that firms should be able to correct or remove.

Our preliminary review shows that firms are not always able to correct or remove all unsafe medical devices from the market. Of the 53 class I recalls we reviewed, we found 10 were ongoing, 14 were completed—meaning that FDA district office officials concluded that the firm had fulfilled its responsibilities for correcting or removing the devices—and 29 were terminated—meaning that FDA headquarters determined that recalling firms had taken sufficient corrective actions to prevent reoccurrence of the problems that led to the recalls.²³ Of the 43 recalls in our sample that were either completed or terminated, we found that for 20, or 47 percent of these recalls, firms were able to correct or remove all products. However, we found that in the other 23 recalls, or 53 percent, firms were unable to correct or remove all products. These recalls ranged widely, in both volume of devices subject to recall and the types of devices being recalled. Some recalls involved hundreds of thousands of disposable products, while others involved a small number of life-sustaining implantable devices. Recalling firms were often unable to correct or remove all devices. This was because firms either could not locate some of the customers or device users, or these customers or device users could not locate the devices subject to recall. In other cases, devices could not be corrected or removed because they were sold at retail outlets (such as glucose test strips) to individuals who may not have known about the

²³We obtained the current status of these recalls through our reviews of the recall files and discussions with FDA district office officials. These discussions took place between December 2010 and February 2011.

recall. For example, in a recall of tracheal tubes included in certain pediatric medical kits, 1,400 tubes had been distributed but only 200 were returned to the recalling firm. The firm said that the rest had likely been used.

FDA's Recall Termination Process Is Compromised by Weak Procedures and May Result in Recalled Medical Devices Remaining on the Market

Our preliminary findings also suggest another gap in the recall process—insufficient documentation justifying FDA's termination decisions. Without such documentation, we were unable to assess the extent to which FDA's termination process appropriately evaluated recalling firms' corrective actions. Although FDA requests that firms submit corrective and preventive action plans for review and approval before a recall can be terminated, we found little documentation regarding how FDA assessed whether such plans were sufficient when it terminated recalls. When we asked to review documentation justifying the decisions for the 29 terminated recalls in our sample, FDA officials indicated that they do not maintain extensive documentation justifying the basis for their termination decisions. They told us that creating documentation to support concurrence with the termination recommendation is not part of past or current termination procedures. This approach is inconsistent with internal control standards for the federal government, which indicate "that all transactions and other significant events need to be clearly documented," and stress the importance of "the creation and maintenance of related records which provide evidence of execution of these activities as well as appropriate documentation."²⁴

Also, we found that FDA termination decisions were frequently not made in a timely manner—within 3 months of the completion of the recall—increasing the risk that unsafe or defective devices remained available for use. Of the 53 recalls in our sample, 29 were terminated—meaning FDA headquarters agreed with an FDA district office that the firm did not need to take additional actions to prevent reoccurrence of problems that led to the recall. For 72 percent of the terminated recalls, FDA did not make its termination decision within 3 months of the recall's completion, as called for in FDA's regulatory procedures. Overall, termination decisions took on average 180 business days from the completion date, though they ranged from 10 days to 800 days after that date.

²⁴See GAO, *Standards for Internal Control in the Federal Government*, GAO-AIMD-00-21.3.1 (Washington, D.C.: Nov.1999).

We found at least one instance where FDA's failure to make a timely termination assessment allowed for a potentially unsafe product to be re-introduced into the market and used for surgical procedures. In this case, based on adverse event reports that screws in its spinal fixation system were becoming loose post-operatively, the firm decided to recall the device in December 2005. The firm implemented its recall, and removed all devices. The firm indicated that it developed a corrective action plan for the screw problem, and relaunched the device in April 2006. It then requested termination from FDA in May 2006. FDA followed up on this request by leaving three voice mail messages with the firm and received no response. The agency sent out a request for information a year later, in May 2007. In June 2007, the company again indicated that the recall was complete, and requested termination. In September 2007, FDA conducted an inspection of the company's manufacturing facility, and found that while the recall was complete, the corrective action was not adequate. Over the course of the next 2 years, the firm worked with FDA to get revisions to the device approved, but eventually agreed to a second recall for the revised device. This recall was initiated in May 2009. We identified five reports of adverse events related to continuing problems with the implanted device that were filed with FDA subsequent to the firm's relaunch of the device in April 2006. These reports were filed from December 2006 through March 2007, and revealed that in all cases, patients required surgical intervention to correct or remove the device.

While FDA's recent actions to try to improve the premarket approval process are positive steps—such as commissioning the Institute of Medicine to conduct an independent review of the process—it remains to be seen whether these actions will help ensure that medical devices marketed in the United States receive appropriate premarket review. In addition, gaps in FDA's postmarket surveillance shows that unsafe and ineffective devices may continue to be used, despite being recalled. The agency faces a challenging balancing act. While it is important to allow devices on the market to treat patients who need them, it is also essential that FDA take necessary steps to provide a reasonable assurance that those medical devices that do enter the market are safe and effective. Likewise, it is vital that the agency's postmarket safety efforts are both vigorous and timely.

Chairman Kohl and Ranking Member Corker, this completes my prepared statement. I would be happy to respond to any questions you or the other members of the committee may have at this time.

Contacts and Acknowledgments

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