

June 2011

# MEDICAL DEVICES

## FDA Should Enhance Its Oversight of Recalls



G A O

Accountability \* Integrity \* Reliability

## Why GAO Did This Study

Recalls are an important tool to mitigate serious health consequences associated with defective or unsafe medical devices. Typically, a recall is voluntarily initiated by the firm that manufactured the device. The Food and Drug Administration (FDA), an agency within the Department of Health and Human Services (HHS), oversees implementation of the recall. FDA classifies recalls based on health risks of using the recalled device—class I recalls present the highest risk (including death), followed by class II and class III. FDA also determines whether a firm has effectively implemented a recall, and when a recall can be terminated. This report identifies (1) the numbers and characteristics of medical device recalls and FDA's use of this information to aid its oversight, and (2) the extent to which the process ensures the effective implementation and termination of the highest-risk recalls. GAO interviewed FDA officials and examined information on medical device recalls initiated and reported from 2005 through 2009, and reviewed FDA's documentation for a sample of 53 (40 percent) of class I recalls initiated during this period.

## What GAO Recommends

To aid its oversight of the medical device recall process, FDA should routinely assess information on device recalls, develop enhanced procedures and criteria for assessing the effectiveness of recalls, and document the agency's basis for terminating individual recalls. HHS agreed with GAO's recommendations.

View [GAO-11-468](#) or key components. For more information, contact Marcia Crosse at (202) 512-7114 or [crossem@gao.gov](mailto:crossem@gao.gov).

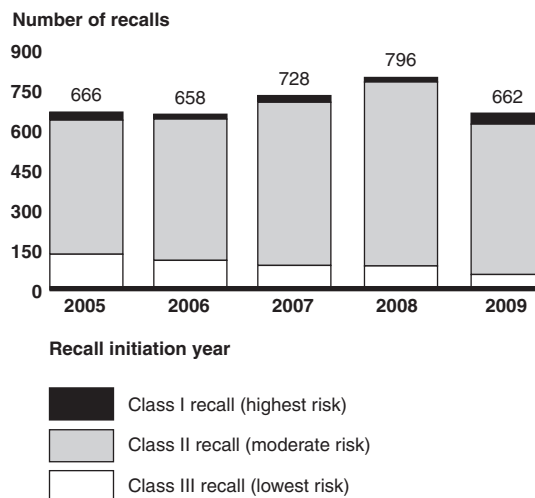
# MEDICAL DEVICES

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## What GAO Found

From 2005 through 2009, firms initiated 3,510 medical device recalls, an average of just over 700 per year. FDA classified the vast majority—nearly 83 percent—as class II, meaning use of these recalled devices carried a moderate health risk, or that the probability of serious adverse health consequences was remote. Just over 40 percent of the recalls involved cardiovascular, radiological, or orthopedic devices. FDA has used recall data to monitor individual recalls and target firms for inspections. However, it has not routinely analyzed recall data to determine whether there are systemic problems underlying trends in device recalls. Thus, FDA is missing an opportunity to use recall data to proactively identify and address the risks presented by unsafe devices.

**Number of Medical Device Recalls Initiated from 2005 through 2009**



Source: GAO analysis of FDA data.

Several gaps in the medical device recall process limited firms' and FDA's abilities to ensure that the highest-risk recalls were implemented in an effective and timely manner. For many high-risk recalls, firms faced challenges, such as locating specific devices or device users, and thus could not correct or remove all devices. FDA's procedures for overseeing recalls are unclear. As a result, FDA officials examining similar situations sometimes reached opposite conclusions on whether recalls were effective. FDA had also not established criteria, based on the nature or type of devices, for assessing whether firms corrected or removed a sufficient number of recalled devices. Additionally, FDA's decisions to terminate completed recalls—that is, assess whether firms had taken sufficient actions to prevent a recurrence of the problems that led to the recalls—were frequently not made within its prescribed time frames. Finally, FDA did not document its justification for terminating recalls. If unaddressed by FDA, the combined effect of these gaps may increase the risk that unsafe medical devices could remain on the market.

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# Contents

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|               |  |          |
|---------------|--|----------|
| <b>Letter</b> |  | <b>1</b> |
|               | Background   | 5        |
|               | Firms Initiated Several Thousand Medical Device Recalls, but FDA Has Not Routinely Analyzed This Information to Aid Its Oversight of Recalls | 14       |
|               | Gaps in the Medical Device Recall Process Limit the Effective Implementation and Termination of the Highest-Risk Recalls                     | 24       |
|               | Conclusions  | 35       |
|               | Recommendations for Executive Action   | 36       |
|               | Agency Comments  | 37       |

---

|                   |  |           |
|-------------------|--|-----------|
| <b>Appendix I</b> | <b>Tools to Help Identify Recalled Devices and Planned Initiatives for Assisting with Device Recalls</b> | <b>38</b> |
|-------------------|--|-----------|

---

|                    |  |           |
|--------------------|--|-----------|
| <b>Appendix II</b> | <b>Class I Medical Device Recalls from Our Sample for Which Firms Were Unable to Correct or Remove All Devices</b> | <b>46</b> |
|--------------------|--|-----------|

---

|                     |  |           |
|---------------------|--|-----------|
| <b>Appendix III</b> | <b>Comments from the Department of Health and Human Services</b> | <b>48</b> |
|---------------------|--|-----------|

---

|                    |  |           |
|--------------------|--|-----------|
| <b>Appendix IV</b> | <b>GAO Contact and Staff Acknowledgments</b> | <b>51</b> |
|--------------------|--|-----------|

---

|               |  |    |
|---------------|--|----|
| <b>Tables</b> |  |    |
|               | Table 1: Comparison of FDA Medical Device Classification and Recall Classification Levels, by Risk                   | 10 |
|               | Table 2: Number and Percentage of Medical Device Recalls Initiated from 2005 through 2009, by Medical Specialty Area | 16 |
|               | Table 3: Number and Percentage of Medical Device Recalls Initiated During 2008 and 2009, by Root Cause               | 17 |

---

|   |    |
|---|----|
| Table 4: Number, Percentage, and Timeliness of Correction or Removal Reports Submitted for a Sample of Class I Medical Device Recalls Initiated from 2005 through 2009, by FDA District | 25 |
| Table 5: Examples of Available Recall Alert Services  | 39 |
| Table 6: Class I Medical Device Recalls for Which Firms Were Unable to Correct or Remove All Devices  | 46 |

---

## Figures

|   |    |
|---|----|
| Figure 1: The Voluntary Medical Device Recall Process Followed by FDA, Firms, Customers, and Device Users   | 13 |
| Figure 2: Number of Medical Device Recalls Initiated from 2005 through 2009   | 15 |
| Figure 3: Status of Medical Device Recalls Initiated from 2005 through 2009   | 19 |
| Figure 4: Average Time from Initiation to Termination for Medical Device Recalls Initiated from 2005 through 2009   | 20 |
| Figure 5: Percentage of Medical Device Recalls Terminated More Than 90 Days after Completion Date, for Recalls Initiated in Calendar Years 2005 through 2009                      | 21 |
| Figure 6: Percentage of Our Sample of Class I Medical Device Recalls Initiated from 2005 through 2009 for Which Recall-Related Inspections Were Conducted, by FDA District Office | 26 |
| Figure 7: Status of Our Sample of 53 Class I Medical Device Recalls Initiated from 2005 through 2009  | 28 |
| Figure 8: Example of a Potential Unique Device Identification Label   | 41 |
| Figure 9: Timeline of Events for the Development of the Unique Device Identification Initiative   | 44 |

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## Abbreviations

|       |   |
|-------|---|
| CDRH  | Center for Devices and Radiological Health          |
| FDA   | Food and Drug Administration                        |
| FDAAA | Food and Drug Administration Amendments Act of 2007 |
| HHS   | Department of Health and Human Services             |
| ORA   | Office of Regulatory Affairs                        |
| PMA   | premarket approval                                  |
| RES   | Recall Enterprise System                            |
| UDI   | unique device identification                        |

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**United States Government Accountability Office**  
Washington, DC 20548

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June 14, 2011

The Honorable Charles E. Grassley  
Ranking Member  
Committee on the Judiciary  
United States Senate

The Honorable Herb Kohl  
Chairman  
Special Committee on Aging  
United States Senate

Each day, millions of individual medical devices produced by thousands of manufacturing establishments in the United States and overseas are used in hospitals, physicians' offices, and other health care settings to diagnose, treat, or prevent illness. For example, in 2007 medical devices were involved in 45 million inpatient procedures. Also, there were approximately 117 million visits to hospital emergency departments, 89 million hospital outpatient visits, and 994 million visits to physicians' offices, which likely all involved the use of one or more medical devices. Medical devices include those that present little risk—such as tongue depressors and elastic bandages—and those that are used specifically to sustain or support life—such as pacemakers and artificial heart valves. Medical devices are an integral part of patient care. If one proves to be defective or unsafe once it is in widespread use, the ramifications can be severe, potentially resulting in permanent injuries or deaths to patients or providers using the device.

A recall is an important remedial action that can mitigate the risk of serious health consequences associated with a defective or unsafe medical device. Generally, the firm that manufactured the device voluntarily initiates a recall after it has discovered a problem based on its assessment of complaints or reports of safety issues it has received. The Food and Drug Administration (FDA), an agency within the Department of Health and Human Services (HHS), is responsible for ensuring that medical products sold in the United States are safe and effective. In some cases, FDA identifies a problem with a device based on its own oversight, such as an inspection of an establishment where a device is manufactured. In response, the firm may voluntarily initiate a recall. Additionally, FDA has

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the authority to require that the firm initiate a device recall when there is a serious risk to public health and the firm has not done so.<sup>1</sup>

FDA's role in the voluntary recall process is generally to oversee a firm's management of a recall, which includes monitoring the progress of the recall. FDA has issued guidance to aid firms in conducting such recalls and has also established internal procedures to govern its oversight of the recall process.<sup>2</sup> In addition, FDA assigns each recall a classification level—high, moderate, or low—based on its assessment of the degree of risk that is posed by the continued use of the device. An effective and timely recall depends on actions taken by the firm manufacturing the device, companies distributing the device, users of the device—such as hospitals, physicians, and patients—and FDA. Recalling firms are responsible for alerting FDA, their distributors, and users of the device about the recall. The recalling firm provides instructions on steps to be taken to fix the device or advises parties to discontinue its use. These parties must follow the firm's instructions in order to effectively implement the recall.

Despite efforts by recalling firms, FDA, and others, there have been reported incidents where individuals were seriously injured or died due to continued use of defective devices that had been recalled. You expressed concern with the effectiveness of the medical device recall process and asked us to follow up on our 1998 report on FDA's oversight of medical device recalls.<sup>3</sup> Our preliminary findings were included in an April 2011 hearing on the reform of the medical device approval process before the Senate Special Committee on Aging.<sup>4</sup> This report identifies (1) the numbers and characteristics of medical device recalls initiated from January 1, 2005, through December 31, 2009, and the extent to which FDA uses this information to aid in its oversight of recalls, and (2) the extent to

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<sup>1</sup>21 U.S.C. § 360h(e), 21 C.F.R. pt. 810 (2010). The steps that FDA follows for such mandatory recalls are separate and distinct from those followed during a voluntary recall. The steps that FDA follows during voluntary recalls are described at subpart C, part 7, of title 21 of the Code of Federal Regulations.

<sup>2</sup>For purposes of this report, we use the term guidance to refer to FDA's advice or recommendations to recalling firms managing voluntary recalls and the term procedures to refer to FDA's instructions to agency staff overseeing these recalls.

<sup>3</sup>GAO, *Medical Devices: FDA Can Improve Oversight of Tracking and Recall Systems*, [GAO/HEHS-98-211](#) (Washington, D.C.: Sept. 24, 1998).

<sup>4</sup>GAO, *Medical Devices: FDA's Premarket Review and Postmarket Safety Efforts*, [GAO-11-556T](#) (Washington, D.C.: Apr. 13, 2011).

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which the medical device recall process ensures the effective implementation and termination of those classified as high-risk recalls.

To identify the numbers and characteristics of voluntary medical device recalls, we obtained information on all such recalls initiated and reported to FDA from January 1, 2005, through December 31, 2009.<sup>5</sup> This information consisted of the most recent 5-year period of available data at the time we did our work. The source of this information was FDA's Recall Enterprise System (RES), the agency's central repository of recall information. FDA provided key information on each recall, including FDA's unique recall event number;<sup>6</sup> the status of the recall at the time FDA provided us with this information (e.g., ongoing or terminated);<sup>7</sup> the reason for the recall; the specific device being recalled; the recall classification level assigned based on FDA's assessment of risk; 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). We also obtained information identifying which of FDA's 19 district offices located throughout the United States were responsible for the day-to-day monitoring of the recalls. We then used this information to determine, among other things, the number of recalls initiated per year; the number of recalls by recall classification levels, the average length of time from initiation to termination for recalls that were terminated, and the number and percentage of recalls by medical specialty of the device being recalled.

To assess the reliability of the information FDA provided, we reviewed FDA's user guide for RES and interviewed officials responsible for

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<sup>5</sup>While 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). A stock recovery is a firm's correction or removal of a device that has not been marketed or that has not left the direct control of the manufacturer. 21 C.F.R. § 806.2(l) (2010). FDA does not consider market withdrawals and stock recoveries to be recalls.

<sup>6</sup>FDA tracks recalls by both the recall event, that is, the actual process of implementing a recall, and the products being recalled. A single recall event could involve multiple products (e.g., different sizes and models of the same device). We use the term recall in the report to refer to recall events.

<sup>7</sup>The status of the recalls is as of April 16, 2010, the date FDA provided us with the extract from RES.



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entering and reviewing the information in RES. Additionally, for a sample of recalls, we compared information from RES on the status and key dates to the source documents contained in FDA's recall files. We determined the data were sufficiently reliable for the purpose of our review. However, there are some limitations to our analyses. The data FDA provided may not include all recalls that firms actually initiated over this period. This is because FDA is dependent on firms self-reporting most recalls. In addition, FDA did not consistently enter certain data elements into RES over the 5-year period. For example, in certain cases the dates recalls were terminated were missing, and in many cases the root cause, or problem creating the need for the recall, was entered inconsistently. Therefore, we could not conduct certain analyses for all recalls initiated over the study period.

In addition to identifying information about the numbers and characteristics of recalls, we identified the extent to which FDA uses recall information to aid its oversight of recalls. To accomplish this, we interviewed officials from FDA's Office of Regulatory Affairs (ORA), which develops FDA-wide policy on compliance and enforcement matters and also has primary responsibility for RES, the day-to-day monitoring of individual recalls, and conducting inspections of firms. We also interviewed officials from FDA's Center for Devices and Radiological Health (CDRH), which regulates medical devices marketed in the United States and is responsible for classifying recalls and assessing the adequacy of a firm's actions to correct problems leading to the most serious recalls. In addition, we interviewed representatives from two device manufacturer associations and several device manufacturers to obtain their views about the recall process.

To identify the extent to which the medical device recall process ensures the effective implementation and termination of the highest-risk device recalls, we reviewed key documentation related to the recalling firms' management and FDA's oversight of a sample of the highest-risk recalls. We identified 131 recalls initiated over the 5-year period to which FDA assigned its highest-risk classification—recalls for which FDA determined that there was a reasonable probability that the use of or exposure to the devices would cause serious adverse health consequence or death. Of these 131, we selected a sample of 53 recalls for in-depth review by identifying the four FDA district offices that had the largest number of available recall files to review. These 53 recalls represented all such recalls during the 5-year period that were managed by these four offices and for which there were files available for our review. For these 53 recalls, we obtained from FDA and reviewed the recall case files that were maintained

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by district offices. These files contained key documents such as information from the firms on the causes of the recalls, the firms' actions to prevent recurrence of similar problems, the recall notifications firms sent out to customers, FDA's correspondence with firms, and documentation from RES. As part of our review, we identified actions recalling firms took to adhere to FDA's guidance and regulatory requirements, and the extent to which the firms were able to recall all of the affected devices. We also identified whether FDA followed its own procedures for overseeing and terminating the recalls and whether FDA's recall process was in conformance with internal control standards for the federal government.<sup>8</sup> For example, we reviewed the case files to determine whether or not FDA conducted recall audit checks in which FDA would contact a percentage of parties affected by the recall to determine whether they received the recall notice and followed the firms' instructions for removing or correcting the device. This included a review of over 2,000 audits check forms FDA completed for the 53 recalls we reviewed. Between December 2010 and February 2011 we discussed the recalls with officials from the responsible FDA district office, and determined the current status of the recalls.

We conducted this performance audit from January 2010 to June 2011, in accordance with generally accepted government auditing standards. 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.

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## Background

FDA is responsible for ensuring that medical products—including medical devices—sold in the United States provide reasonable assurance of safety and effectiveness and do not pose a threat to public health. FDA's oversight responsibilities for medical devices begin before a product is brought to market and continue after a product is available for sale. Its premarket responsibilities include reviewing thousands of submissions for new devices filed each year to decide whether they should be allowed to be marketed in the United States. Its postmarket responsibilities include monitoring the safety of thousands of medical devices already on the

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<sup>8</sup>See GAO, *Standards for Internal Control in the Federal Government*, [GAO/AIMD-00-21.3.1](#) (Washington, D.C.: Nov. 1999).

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market and identifying, analyzing, and acting on potential risks the devices may pose to the public. This monitoring includes overseeing recalls of medical devices.

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## FDA's Classification and Approval or Clearance of Medical Devices

FDA classifies each device type into one of three classes—class I, II, or III—based on the level of risk it poses and the controls necessary to provide reasonable assurance of its safety and effectiveness. According to FDA, the risk the type of device poses to the user is a major factor in the class it is assigned: class I includes devices with the lowest risk, and class III includes devices with the highest risk. 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.

In general, unless exempt under FDA regulations, medical devices are subject to one of two types of FDA premarket review before they may be legally marketed in the United States.<sup>9</sup> These reviews are as follows.

- **Premarket approval (PMA):** 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 (510(k)):** 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. Under this review, the manufacturer must demonstrate to FDA that the new device is

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<sup>9</sup> A 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.

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substantially equivalent to a device already legally on the market.<sup>10</sup> For most 510(k) submissions, clinical data are not required and substantial equivalence will normally be determined based on comparative descriptions of a device's intended use and technological characteristics, and may include performance data.<sup>11</sup> A successful submission results in FDA's clearance to market the device.

Most class I device types and some class II devices are exempt from FDA's premarket review. In general, those that are not exempt, but which are substantially equivalent to a legally marketed class I or class II device, are subject to premarket review through the 510(k) process. Class III device types are generally required to obtain FDA approval through the more stringent PMA process.<sup>12</sup>

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## The Voluntary Medical Device Recall Process

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 action.<sup>13</sup> Nearly all medical device recalls are voluntarily initiated by a firm, usually the manufacturer of the device. The recall process generally consists of a series of steps that we have categorized into broad phases—initiating and

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<sup>10</sup>*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).

<sup>11</sup>According to FDA, performance testing results should be submitted if there are important descriptive differences between the device and other devices of the same type or if the descriptive characteristics for the new device are not precise enough to ensure comparability. In these instances, the most appropriate bench testing, animal testing, or both to address the performance issue should be provided, and summary information on the testing should generally suffice.

<sup>12</sup>From 2003 through 2007, 79 percent of the riskiest medical devices (class III devices) were approved through the PMA process. As we reported in 2009, FDA has cleared some class III devices through the 510(k) process, rather than approving the devices through the more stringent PMA process. See 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).

<sup>13</sup>21 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. 21 C.F.R. § 806.2(d, i) (2010).

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classifying the recall, conducting and overseeing the recall, and completing and terminating the recall. While the recalling firm has primary responsibility for ensuring that the recalled devices are corrected or removed, FDA and other stakeholders each have responsibilities which they are supposed to undertake in order to effectively implement the various phases of a recall. FDA's role is generally to oversee a firm's management of recalls. It conducts its responsibilities as part of its postmarket surveillance. FDA staff from ORA—which is the lead office for all FDA field activities, including the agency's district offices—and CDRH are involved in overseeing recalls. Other stakeholders, including the firm's customers—such as distributors—and device users—such as hospitals or patients—are expected to correct or remove the recalled device according to the recalling firm's instructions.<sup>14</sup> A given recall may require the cooperation of thousands of different stakeholders depending on how many entities received, purchased, or used the device.

The following sections generally describe the voluntary recall process that FDA, as well as recalling firms, their customers, and device users, are expected to follow according to FDA's regulations, procedures, and guidance.

## Initiating and Classifying the Recall

During this phase of a device recall, a firm initiates a recall, while FDA classifies the recall based on health risks presented by use of the device. As part of this phase, a firm develops a strategy for implementing the recall, and FDA reviews and suggests changes to the strategy. In most cases, a firm arrives at the decision to initiate a recall after discovering a problem with a device, or a series of similar devices.<sup>15</sup> The firm may then contact an FDA district office or immediately begin implementing a recall.<sup>16</sup> A firm may initiate a recall—that is notify stakeholders such as distributors and device users about the recall—prior to contacting the

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<sup>14</sup>Stakeholders such as distributors and device users, and anyone else who received, purchased, or used the product being recalled are referred to as "consignees." 21 C.F.R. §§ 7.3(n), 806.2(c) (2010). In this report, we generally refer to these entities as customers and device users.

<sup>15</sup>A given recall may involve a single device or multiple devices. For example, a recall may include different sizes of the same device, or a device made up of multiple components (i.e., screws, bolts, tubes).

<sup>16</sup>The 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.

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FDA district office. However, according to federal regulations, a firm must provide FDA with a report of correction or removal within 10 working days of initiating a recall of a product that involves or may involve a risk to health.<sup>17</sup> As part of its report, the firm is to provide FDA with key information such as the reason the device is being recalled, the brand name and model of the device, the lot or serial numbers of the device, the number of devices subject to correction or removal, and contact information for its customers and device users who received, used, or purchased the device. According to FDA's guidance, the recalling firm is also asked to develop a recall strategy that takes into account its assessment of the health hazard associated with the device. The strategy should contain details on the firm's plan for ensuring that its customers and device users correct or remove the device according to the firm's instructions, and the need for public warnings about the device. As part of its oversight, FDA will review the strategy, and may suggest that the firm make changes to its approach for conducting the recall.

Once the district office is notified about the recall, it should create a record in RES, notify CDRH, and obtain and evaluate information CDRH needs to make its classification decision. The district office monitoring the recall will provide any information it receives from the firm, including the correction and removal report, to CDRH so it can begin the process of classifying the recall. For some recalls, the district office may need to conduct a recall inspection at the establishment where the device is manufactured in order to obtain additional information needed to classify the recall. According to FDA's procedures, when a recall appears to involve significant health risks, an inspection should be conducted to determine, among other things, the root causes of the problem and if the firm is implementing appropriate corrective action. The inspection may be performed by the FDA district office monitoring the recall or other district offices, such as those located near the firm's manufacturing establishment.

To classify the recall, CDRH is to conduct its own health risk assessment of the device being recalled. Based on this assessment, CDRH classifies the recall to indicate the relative degree of health hazard presented by use of the device. According to CDRH's procedures, the classification decision should be completed within 31 calendar days from the time it received the

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<sup>17</sup>21 C.F.R. § 806.10(a), (b) (2010). Reports are not required for recalls involving problematic devices that do not pose a health risk.

information from the district office.<sup>18</sup> Recalls are classified into one of three categories:

- class I—reasonable probability that the use of, or exposure to, a device will cause serious adverse health consequences or death. These are the most serious recalls.
- class II—use of or exposure to a device may cause temporary or medically reversible adverse health consequences, or the probability of serious adverse health consequences is remote.
- class III—use of, or exposure to, a device is not likely to cause adverse health consequences.<sup>19</sup>

Table 1 compares FDA’s classification of medical devices and recalls according to risk. 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).

**Table 1: Comparison of FDA Medical Device Classification and Recall Classification Levels, by Risk**

| Risk     | Device classification | Recall classification |
|----------|-----------------------|-----------------------|
| High     | III                   | I                     |
| Moderate | II                    | II                    |
| Low      | I                     | III                   |

Source: GAO analysis of FDA classification information.

Once the recall is classified, FDA is to notify the firm, in writing, of the assigned recall classification. This classification letter should also include instructions about the extent to which the firm should conduct effectiveness checks—that is, contacting customers and device users to determine whether the recall notification was received and acted upon appropriately. In general, for class I recalls, FDA recommends that firms

<sup>18</sup>FDA officials indicated that although this time frame was in effect at the time of our review, they have recently adjusted classification time frames, which now range from 26 to 40 days depending on the nature of the recall.

<sup>19</sup>See 21 C.F.R. § 7.3(m) (2010).

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## Conducting and Overseeing the Recall

conduct effectiveness checks with 100 percent of customers and device users affected by the recall. For class II recalls, FDA recommends effectiveness checks with 10 percent of such customers and device users, and 2 percent for class III recalls.

During this phase, the firm and recall stakeholders are supposed to implement the recall as outlined in the approved recall strategy, and FDA is responsible for monitoring the progress made. Once a recall is under way, the firm is to conduct effectiveness checks to ensure that those stakeholders affected by the recall have received notification about the recall and have taken appropriate action, such as returning defective devices, or taking actions to correct the known defects. (See app. I for information on tools to help customers and medical device users identify recalled devices and an FDA initiative intended to better track devices through the use of unique identifiers.) Additionally, at the request of the FDA district office responsible for monitoring the recall, the firm is expected to provide status reports on the progress of the recall. These reports should include information on how many customers and device users have received the recall notification and followed the firm's instructions, and how many still need to respond to the recall notice. The FDA district office reviews the reports, and, using RES, assigns the recall a status of ongoing if the reports indicate the recall is still under way.

During the recall, FDA district offices independently assess the effectiveness of the recall by conducting audit checks.<sup>20</sup> According to the agency's procedures, for each check, investigative staff from one or more of FDA's district offices will contact individual distributors or device users. These audit checks are generally conducted in person or by telephone, to confirm that the distributor or device user (1) received notification from the firm about the recall and (2) properly corrected or removed the recalled devices in accordance with the firm's recall strategy. The FDA district office responsible for monitoring the recall assigns the audit checks to one or more of the district offices, depending upon the location of the firm's customers and the device users. According to FDA procedures, the district office monitoring the recall should assign audit checks within 10 days of the recalling firm's initiation of the recall. The audit checks should be completed by FDA investigators, if possible, within

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<sup>20</sup> Audit checks, which generally cover from 2 to 10 percent of the total number of distributors and device users, are typically conducted by FDA on class I and class II recalls. Audit checks are generally not conducted on class III recalls. Audit checks are separate from effectiveness checks, which are conducted by the recalling firm.



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## Completing and Terminating the Recall

10 days of assignment. If an investigator determines that the firm and the distributor or device user followed the recall strategy, the investigator's audit check should conclude that the recall was effective. If not, the investigator's audit check should conclude that the recall was ineffective. The result of the audit check is documented on a standardized FDA form, and each form is provided to the district office that made the audit check assignment.

Once the firm believes it has completed the recall—i.e., done everything as outlined in the recall strategy—it needs to submit a final recall status report/recall termination request to the FDA district office monitoring the recall.<sup>21</sup> Regardless of the class of the recall, if the district office agrees that the firm has completed the recall, it is to change the status of the recall in RES to completed. If it disagrees, it generally requests the firm to take additional actions, such as re-contacting customers and device users. The FDA district office bases its assessment of whether the recall has been effectively completed by reviewing the firm's status reports and results of the audit checks. In addition, according to FDA procedures, the final monitoring step the district office may take is to conduct a limited postrecall inspection to verify that the recall has been completed. During this inspection, investigators should witness destruction or reconditioning of the recalled product, if applicable.

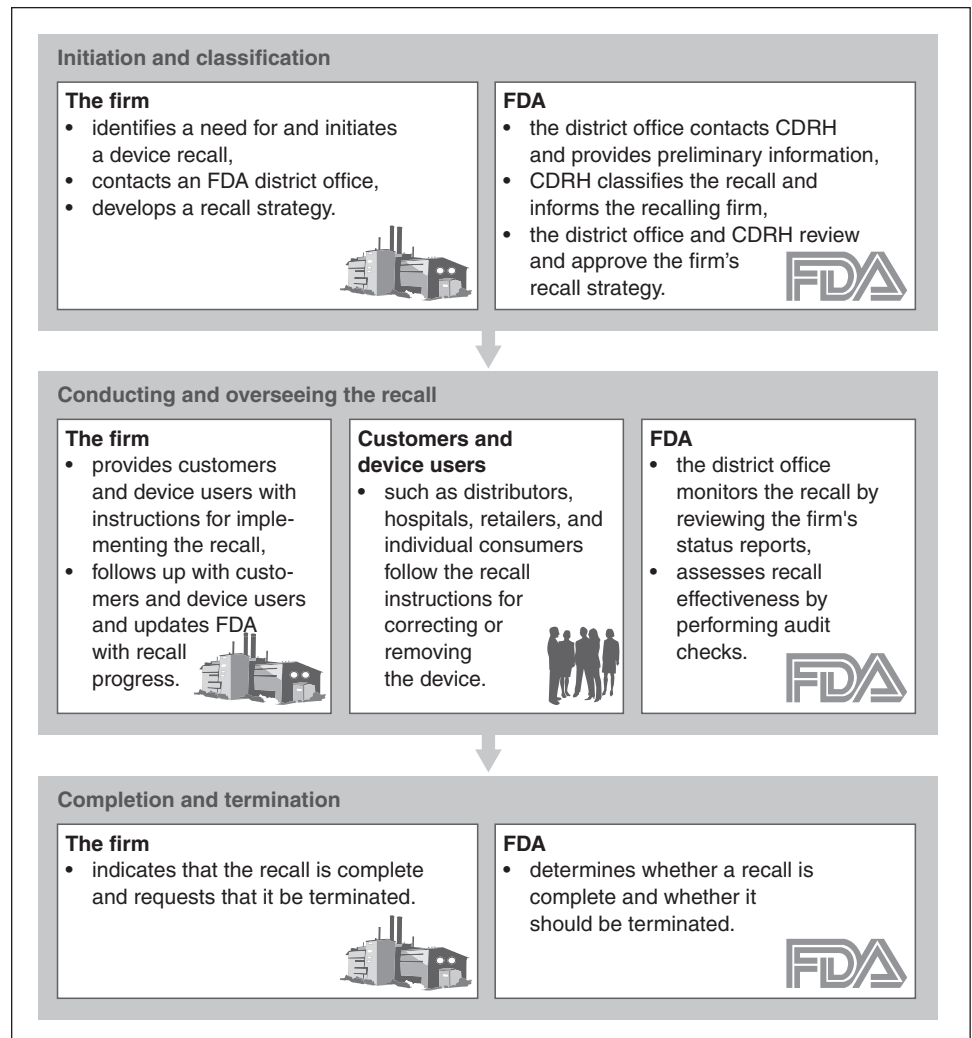
Once the district office considers a recall completed, FDA assesses whether it can terminate a recall. As part of its assessment, FDA may review a corrective and preventive action plan submitted by the recalling firm that describes the firm's actions to prevent a recurrence of the problem that led to the recall. Thus, this phase of the recall process is important because it provides FDA with the opportunity to determine whether the firm has taken sufficient corrective and preventive actions. The agency's procedures state that if a firm's corrective and preventive actions are adequate, FDA staff should terminate a recall within 3 months of completion. When terminating a class I recall, the district office sends a recall termination recommendation to CDRH. CDRH reviews the recalling firm's corrective and preventive action plan, and effectiveness and audit check results, and makes the decision on whether to terminate the recall. The district office does not need CDRH approval to terminate class II and

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<sup>21</sup> A firm's completion of a recall does not necessarily indicate that it corrected or removed 100 percent of the recalled devices, but rather that it made reasonable efforts to contact those affected by the recall and obtained as many devices as possible.

III recalls. If corrective actions are determined sufficient, the recall status in RES is changed from completed to terminated. When FDA terminates a recall, the district office will close the recall file and notify the firm, in writing, that it can cease recall activity. Figure 1 displays the general process from initiating to terminating a recall.

**Figure 1: The Voluntary Medical Device Recall Process Followed by FDA, Firms, Customers, and Device Users**



Source: GAO analysis of FDA information.

Note: According to FDA officials, the various phases of the recall process may not necessarily occur sequentially, and individual actions may be occurring simultaneously in different phases of the process for specific recalls.

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## Firms Initiated Several Thousand Medical Device Recalls, but FDA Has Not Routinely Analyzed This Information to Aid Its Oversight of Recalls

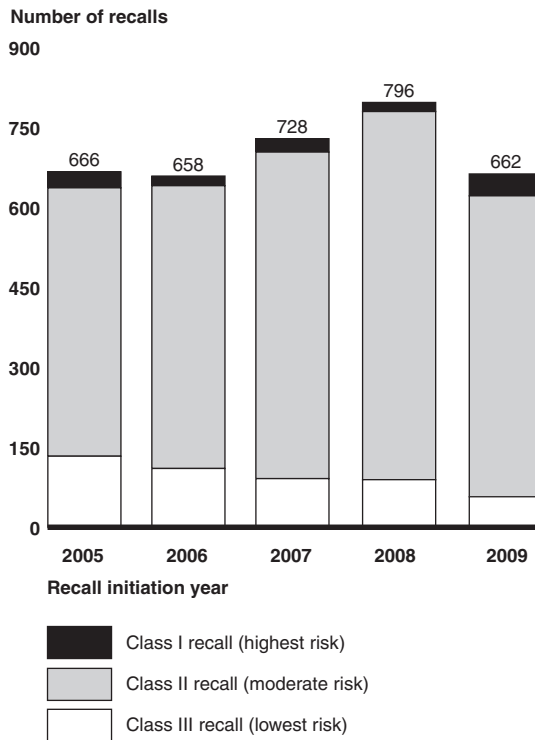
From 2005 through 2009, firms initiated 3,510 medical device recalls. Most of these were for medical devices in five areas of use or medical specialty areas. On average, the recall process took just over 420 days from initiation to termination, with class I recalls (the highest-risk recalls) averaging nearly 520 days. FDA has not routinely analyzed information about recalls to aid its oversight of the recall process, and thus could not explain trends in recalls over this time period.

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## Several Thousand Device Recalls Were Initiated; Most Were Class II and Involved Cardiovascular and Radiological Devices

Between January 1, 2005, and December 31, 2009, firms initiated 3,510 device recalls, an average of just over 700 per year. The annual volume fluctuated over this period, and ranged from a low of 658 in 2006 to a high of 796 in 2008. FDA classified the vast majority of all recalls—nearly 83 percent—as class II, meaning use of these devices may cause temporary adverse health consequences (moderate risk). FDA classified 14 percent as class III, meaning use of the device is not likely to cause any adverse consequences (lowest risk); and 4 percent were classified as class I (highest risk), because FDA determined that there was a reasonable probability that the use of or exposure to a violative product would cause serious adverse health consequences or death (see fig. 2). The number of class I recalls initiated between 2005 and 2009 ranged from 17 to 41. For example, in 2007, 25 class I recalls were initiated; in 2008, 17 were initiated; and in 2009, 41 were initiated. In comparison, the number of class II recalls generally increased each year and consistently exceeded 500 annually.

**Figure 2: Number of Medical Device Recalls Initiated from 2005 through 2009**



Source: GAO analysis of FDA data.

Our analysis found that approximately 60 percent of recalls during this period were for devices from five areas of use or medical specialty areas—cardiovascular, radiological, orthopedic, general hospital and personal use, and diagnostic chemistry.<sup>22</sup> According to FDA, these medical specialties are among those with the greatest number of devices on the market and four of the five specialties—cardiovascular, radiological, orthopedic, and general hospital—account for the greatest number of devices cleared or approved for marketing each year. The remaining recalls were for devices in 19 other areas (such as general and plastic surgery and neurological devices); no other specialty accounted for more than 8 percent of recalls (see table 2).

<sup>22</sup>General hospital and personal use devices include bandages, examination gowns, infusion pumps, and stretchers. Diagnostic chemistry devices include test systems, such as those for blood glucose.

**Table 2: Number and Percentage of Medical Device Recalls Initiated from 2005 through 2009, by Medical Specialty Area**

| Medical specialty area                         | Total number of recalls | Percentage of all recalls | Number of class I recalls <sup>a</sup> | Percentage of class I recalls |
|--|-------------------------|---------------------------|--|-------------------------------|
| Cardiovascular                                 | 532                     | 15                        | 40                                     | 31                            |
| Radiological                                   | 484                     | 14                        | 2                                      | 2                             |
| Orthopedic                                     | 410                     | 12                        | 4                                      | 3                             |
| General hospital and personal use <sup>b</sup> | 388                     | 11                        | 31                                     | 24                            |
| Diagnostic chemistry <sup>c</sup>              | 315                     | 9                         | 16                                     | 12                            |
| Other specialty areas                          | 1,381                   | 39                        | 38                                     | 29                            |
| <b>Total</b>                                   | <b>3,510</b>            | <b>100</b>                | <b>131</b>                             | <b>100</b>                    |

Source: GAO analysis of FDA data.

Note: Percentages do not add to 100 percent due to rounding.

<sup>a</sup>Class I recalls involve a reasonable probability that the use of, or exposure to, a device will cause serious adverse health consequences or death.

<sup>b</sup>General hospital and personal use devices include bandages, examination gowns, and stretchers.

<sup>c</sup>Diagnostic chemistry devices include test systems, such as those for measuring blood glucose.

As table 2 shows, for class I recalls, the greatest numbers were for devices from the cardiovascular medical specialty. In addition, the table shows that devices from the general hospital and personal use and diagnostic chemistry medical specialties accounted for a substantial number of class I recalls. Among class I recalls, we found that the largest number for cardiovascular devices involved automatic external defibrillators. The largest number of recalls for general hospital and personal use devices involved infusion pumps, including implantable programmable pumps.

RES also contains information on the root cause of recalls, that is, the problem creating a need for the recall. On average, in 2008 and 2009 (the only years for which FDA tracked these data in RES) the greatest numbers of recalls were caused by problems with manufacturing processes. FDA refers to this root cause as process control—developing, conducting, controlling, and monitoring production processes to ensure that a device conforms to its specifications. Other leading causes were device design and software design. The two most common causes of class I recalls were the same as for all classes—process control and device design—but the third cause was component design or selection (see table 3). In general, FDA officials indicated they do not believe that there is a relationship between root cause and recall class. However, FDA officials indicated that some root causes of recalls are more likely to affect certain types of

devices. For example, they stated that the root cause “incorrect or missing expiration date” is typically related to devices that involve sterilization.

**Table 3: Number and Percentage of Medical Device Recalls Initiated During 2008 and 2009, by Root Cause**

| <b>FDA assigned root cause<sup>a</sup></b> | <b>Total number of recalls</b> | <b>Percentage of all recalls</b> | <b>Number of class I recalls<sup>b</sup></b> | <b>Percentage of class I recalls</b> |
|--|--------------------------------|----------------------------------|--|--------------------------------------|
| Process control <sup>c</sup>               | 233                            | 16                               | 17   | 29                                   |
| Device design                              | 201                            | 14                               | 12   | 21                                   |
| Software design                            | 181                            | 12                               | 1  | 2                                    |
| Component design/selection                 | 59                             | 4                                | 7  | 12                                   |
| Additional root causes <sup>d</sup>        | 782                            | 53                               | 21   | 36                                   |
| <b>Total</b>                               | <b>1,456</b>                   | <b>100</b>                       | <b>58</b>                                    | <b>100</b>                           |

Source: GAO analysis of FDA data.

<sup>a</sup>The root cause is the problem creating a need for the recall.

<sup>b</sup>Class I recalls involve a reasonable probability that the use of, or exposure to, a device will cause serious adverse health consequences or death.

<sup>c</sup>Process control entails developing, conducting, controlling, and monitoring production processes to ensure that a device conforms to its specifications.

<sup>d</sup>Other root causes include false or misleading labeling, mistaken use of materials or components, or employee error.

Among all classes of recalls, we found that a higher proportion of recalls were for devices which were cleared for market through the 510(k) process as compared to other FDA review processes. This reflects the fact that the overwhelming majority of devices—99 percent, according to FDA—enter the market through this review process. Our analysis of RES data for 2,773 recalls<sup>23</sup> found that 87 percent of recalls involved a device cleared through the 510(k) process, nearly 8 percent involved a device approved through the more stringent PMA or PMA supplement process, and nearly 6 percent involved devices that were cleared through the 510(k)

<sup>23</sup>Information on mode of market entry—PMA, 510(k), or exempt—was missing for 737 (21 percent) of the 3,510 recalls. Our analysis is therefore based on the available data related to 2,773 recalls.

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process and approved through the PMA process, or that were exempt from FDA review.<sup>24</sup>

We found similar trends for 101 class I recalls.<sup>25</sup> We found that 74 of the recalls (73 percent) were for devices cleared through the 510(k) process, 22 percent were for PMA- approved devices, and the remaining 5 percent involved devices that were cleared through the 510(k) process and approved through the PMA process, or that were exempt from FDA review.<sup>26</sup> Compared to all recall classes, a higher percentage of class I recalls involved devices cleared through the PMA process (22 percent compared with 8 percent for all classes of recalls combined), which likely reflects the high risk of these devices.

Additionally, we found that 14 of those 74 class I recalls involving devices that were cleared through the 510(k) process were for devices that FDA designated as high-risk devices—class III devices. We further found that all 14 recalls involved cardiovascular devices, including 12 for automatic external defibrillators.

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## FDA Has Terminated Most Medical Device Recalls, with the Recall Process Taking over 500 Days for the Highest-Risk Recalls

At the time of our review, the 3,510 medical device recalls initiated from 2005 through 2009 were in various stages of the recall process. Approximately 60 percent—2,050—of all recalls initiated in this period had been terminated by FDA as of April 16, 2010, the date we received data from FDA. Firms had completed another 5 percent and were awaiting

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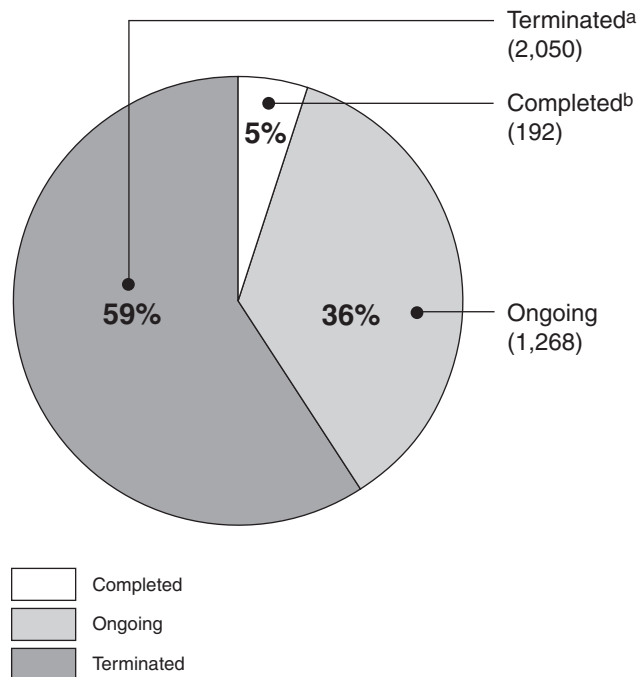
<sup>24</sup>This includes recalls involving multiple devices (such as kits containing a pump and a catheter) some of which were cleared through the 510(k) process, and others approved through the PMA process. It also includes devices that are exempt from FDA review, such as most class I devices.

<sup>25</sup>Information on mode of market entry—PMA, 510(k), or exempt—was missing for 30 (23 percent) of the 131 class I recalls that occurred during calendar years 2005 through 2009. Therefore, our above analysis is based on the available data related to 101 recalls.

<sup>26</sup>Two separate studies also analyzed class I recalls from 2005 to 2009 and found similar statistics as ours. See D. Zukerman, Paul Brown, Steven Nissen, *Medical Device Recalls and the FDA Approval Process*. *Archives of Internal Medicine* (Feb. 14, 2011) and related testimony at U.S. House of Representatives, Energy and Commerce Subcommittee on Health Hearing on “Impact of Medical Device Regulation on Jobs and Patients” (Feb. 17, 2011). See also R. Hall, *Using Recall Data to Assess the 510(k) Process*. *Presentation at Institutes of Medicine Meeting* (July 28, 2010) and related testimony at U.S. House of Representatives, Energy and Commerce Subcommittee on Health, Hearing on “Impact of Medical Device Regulation on Jobs and Patients” (Feb. 17, 2011).

FDA's review and decision on termination. The remaining 36 percent were ongoing (see fig. 3).

**Figure 3: Status of Medical Device Recalls Initiated from 2005 through 2009**



Source: GAO analysis of FDA data.

Note: Status as of April 16, 2010.

<sup>a</sup>Terminated—FDA headquarters determined that firms' corrective actions taken were sufficient to prevent a recurrence of the problems that led to the recall.

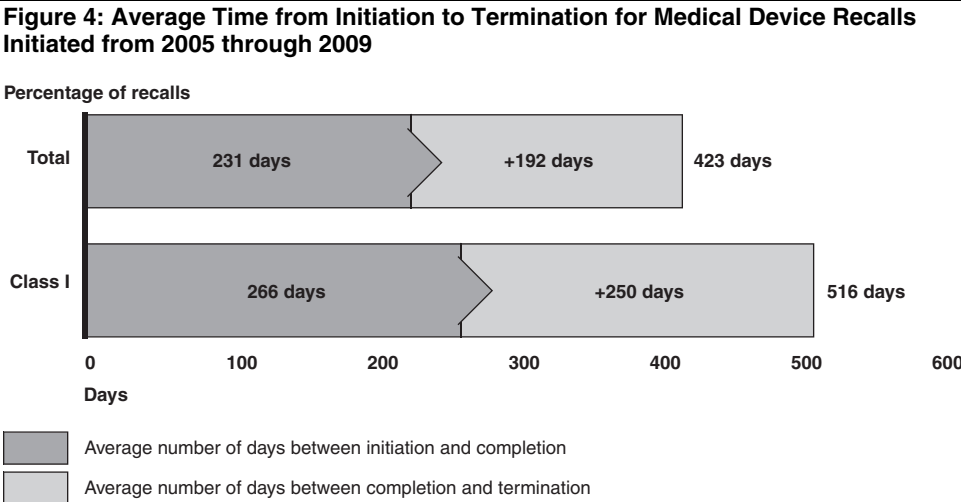
<sup>b</sup>Completed—An FDA district office concluded that the firm had essentially fulfilled their responsibilities for correcting or removing the devices.

We found that for recalls that had been terminated, the time between the firm's initiation and FDA's termination of a recall varied by class.<sup>27</sup> On average, over 420 days passed between initiation of a recall and FDA's termination. Among all classes of recalls, class I recalls took the longest—on average 516 days, while on average class II recalls took 436 days and

<sup>27</sup>Of the 2,050 medical device recalls that had been terminated, 22 were missing valid termination dates and hence were not included in our analysis.



class III took 352 days.<sup>28</sup> The amount of time needed to conduct and terminate recalls was split roughly evenly between the portions of the process that are primarily the recalling firms' responsibilities—conducting the recall itself—and the portions that are primarily FDA's responsibility—oversight of the recall (see fig. 4).



Source: GAO analysis of FDA data.

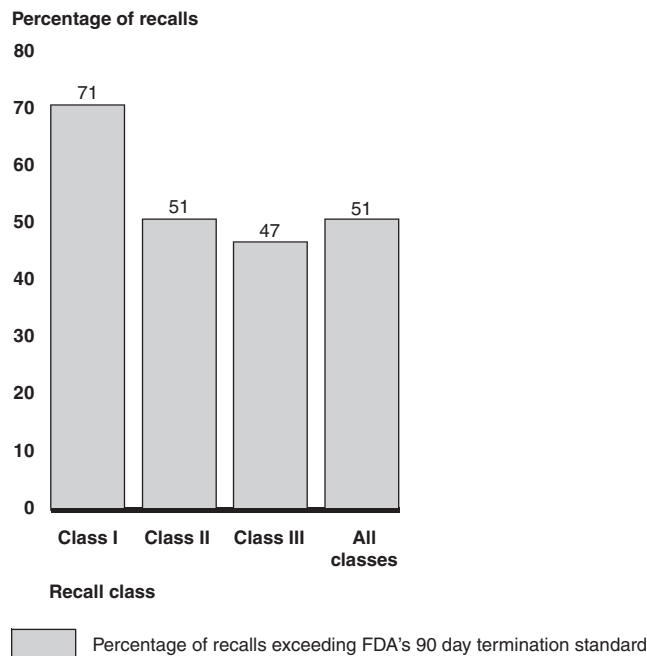
Note: Termination dates were available for 2,028 of the 2,050 recalls that were terminated during this period.

FDA frequently did not meet its 3 month time frame for terminating completed recalls. It did not meet this time frame for more than half of all recalls and over 70 percent of class I recalls (see fig. 5). On average, FDA took 192 days to terminate a recall after it determined a recall was completed, more than twice the time specified in its procedures. For class I recalls, the average was 250 days. FDA could not specifically identify reasons that explained why it took this amount of time to make termination decisions. The agency did indicate that termination time frames are affected by both FDA's ability to address recalling firms' termination requests, as well as firms' ability to provide adequate information in support of the termination decision. This information may include a sufficient corrective and preventive action plan to prevent a recurrence of the problem which led to the recall. These data indicate that

<sup>28</sup> According to FDA, in some cases a firm initiates a recall without contacting FDA, thus the agency may not learn about the recall until a much later date.

the timeliness of recall termination decisions appears to have deteriorated since our 1998 report.<sup>29</sup>

**Figure 5: Percentage of Medical Device Recalls Terminated More Than 90 Days after Completion Date, for Recalls Initiated in Calendar Years 2005 through 2009**



Source: GAO analysis of FDA data.

Note: Completion and termination dates were available for 1,992 of the 2,050 recalls that were terminated. A recall is considered complete when FDA agrees that the recalling firm has sufficiently completed all recall-related activities. A recall is terminated when FDA determines that in addition to completing the recall, the recalling firm has taken adequate corrective measures to prevent a recurrence of issues which led to the recall.

At the time of our review, 36 percent—1,268 recalls—were ongoing. Of these, most had been initiated in the past few years; however, some have been ongoing since 2005, the beginning of our review period. Of those recalls that were ongoing, most were initiated in 2008 and 2009; however, 456 (36 percent) had been ongoing for at least 2 years, including 86 that had been ongoing for nearly 5 years.

<sup>29</sup>We previously reported that FDA failed to meet its 90-day termination guideline in 33 percent of the 36 recalls we reviewed. See [GAO/HEHS-98-211](#).

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## FDA Has Not Routinely Analyzed Data to Identify Systemic Problems Underlying Device Recalls

Although RES contains numerous data elements that would allow for analyses of recall data, FDA is not effectively using these data to identify whether there are systemic problems underlying recalls.<sup>30</sup> Instead of using RES to conduct systemic analyses of recalls, which would be consistent with one of the agency's strategic goals—improving the quality and safety of manufactured products in the supply chain—FDA has used RES primarily for processing and tracking the progress of individual recalls.

Agency officials have not been using RES as a management tool to conduct broad surveillance of recalls and related issues. Neither the district offices we contacted nor CDRH officials prepared routine reports that would enable officials to identify areas of potential concern in the recall process, such as recalls that have been ongoing for an extended period, or whether specific manufacturing or design problems are causing increases in recalls or the types of devices being recalled. In fact, FDA officials appeared to be unaware of RES's capability to generate summary data. When we requested data from RES, FDA staff were unable to extract these data themselves, and initially indicated that it would be impossible to obtain data from RES. After 2 months, FDA officials concluded that through a special arrangement with a contractor they could obtain the RES data and meet our request.

After we completed our analysis of the RES data, 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. They indicated that at most, they could offer speculation about some of the trends we observed. 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:

- common causes of recalls;
- trends in the number of recalls over time;

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<sup>30</sup>We 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).

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

Although FDA has not been routinely analyzing recall data to identify whether there are systemic problems affecting recalls, officials indicated they have used these data to help direct their inspection resources, and to support compliance and enforcement actions. First, FDA officials indicated they use recall information as one of many elements to assess the relative risks that device manufacturers present, and thus which firms the agency should inspect in a given year. For example, the officials said that recall data is one of several elements that feed into a predictive model that determines the likelihood that firms are out of compliance with applicable laws or regulations, and therefore in need of inspection. Second, they told us they have plans to use recall information as the basis for developing a directed inspection plan. As part of this project, officials would use recall information to identify those firms that generate a large number of recalls, and target them for inspection. Officials indicated that these inspections would focus on specific areas—such as a particular manufacturing process. This effort is still in the planning phase, and officials have not yet established criteria, such as what constitutes a large number of recalls, for determining which firms to select. The officials also indicated that progress may be slow because they do not have sufficient resources available to devote to this effort.<sup>31</sup>

Although FDA has not regularly been using data to identify systemic problems, we found one example of FDA using recall data to detect and address safety issues with a particular type of device. In December 2010, FDA held a conference on a variety of issues related to automatic external defibrillators, including the safety of these devices. During this conference

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<sup>31</sup>We previously reported that FDA faced challenges fulfilling and managing its growing medical product oversight responsibilities and should develop complete estimates of its resource needs. See GAO, *Food and Drug Administration: FDA Faces Challenges Meeting Its Growing Medical Product Responsibilities and Should Develop Complete Estimates of Its Resource Needs*, [GAO-09-581](#) (Washington, D.C.: June 19, 2009).

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it presented historical recall data to help demonstrate the need for a specific focus on safety improvements for this type of device.<sup>32</sup>

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## Gaps in the Medical Device Recall Process Limit the Effective Implementation and Termination of the Highest-Risk Recalls

Gaps in the medical device recall process limit firms' and FDA's ability to ensure that the highest-risk recalls are implemented effectively and terminated in a timely manner. We found that both FDA and recalling firms generally upheld their respective responsibilities in the course of initiating and classifying recalls. However, FDA did not always follow its own procedures and some procedures are unclear. FDA did not consistently inspect the manufacturing establishments of recalling firms as outlined in the agency's procedures. FDA has also not established criteria, such as thresholds, based on the nature of devices, for assessing whether firms effectively completed recalls by correcting or removing a sufficient number of recalled devices. Further, we found that firms face challenges, such as locating specific devices or users of devices, and often could not correct or remove all devices. We also found that audit checks, a key mechanism for FDA's oversight of firms' conduct of recalls, are limited in scope. In addition, because of a lack of clarity in FDA's audit check procedures, they have been implemented inconsistently by FDA's district offices. Finally, FDA frequently failed to make recall termination decisions in a timely manner, and kept no documentation to justify its termination decisions.

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## Firms and FDA Have Generally Implemented Recalls Appropriately in the Initiation and Classification Phases, but FDA Has Failed to Consistently Conduct Recall-Related Inspections

In our review of a sample of the highest-risk device recalls initiated from January 1, 2005, through December 31, 2009, we found that once firms initiated recalls, they generally provided FDA with a correction or removal report in a timely manner—within FDA's 10-day time frame. In 51 of the 53 recalls (96 percent), firms submitted a correction or removal report to FDA. For 43 of these 51 recalls, firms submitted the report within 10 working days of initiating the recall. For 6 of the remaining 8 recalls, the correction and removal report was submitted within 21 business days; the reports for the other 2 recalls were submitted 62 business days and 227 business days after the recall was initiated, respectively. Table 4 shows the proportion of recalls, by district, where firms submitted these reports and whether they were submitted within 10 working days.

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<sup>32</sup>Statement of Dr. William Maisel, CDRH Deputy Director for Science, at FDA Public Workshop on External Defibrillators (Washington, D.C.: Dec. 15-16, 2010).

**Table 4: Number, Percentage, and Timeliness of Correction or Removal Reports Submitted for a Sample of Class I Medical Device Recalls Initiated from 2005 through 2009, by FDA District**

| District office | Number of recalls | Number of correction or removal reports submitted | Percentage of correction or removal reports submitted | Number of correction or removal reports submitted within 10 working days | Percentage of correction or removal reports submitted within 10 working days |
|-----------------|-------------------|---|---|--|--|
| Detroit         | 9                 | 9   | 100   | 8  | 89   |
| Los Angeles     | 15                | 14  | 93  | 9  | 64   |
| Minneapolis     | 16                | 16  | 100   | 15   | 94   |
| New England     | 13                | 12  | 92  | 11   | 92   |
| <b>Total</b>    | <b>53</b>         | <b>51</b>   | <b>96</b>   | <b>43</b>  | <b>84</b>  |

Source: GAO analysis of FDA medical device recall files.

Although our analysis indicates that firms generally provided these reports after initiating the recalls, FDA officials cautioned that this does not mean firms fully complied with the regulatory reporting requirements. They indicated that in some cases, firms' initial correction or removal reports lack some of the information needed and extra time was required for firms to provide additional information. To help address this, officials indicated that in November 2010 they began a recall process improvement project. As part of this initiative, CDRH plans to develop Web-based training modules for industry clarifying the information that needs to be provided when reporting corrections and removals to FDA.<sup>33</sup>

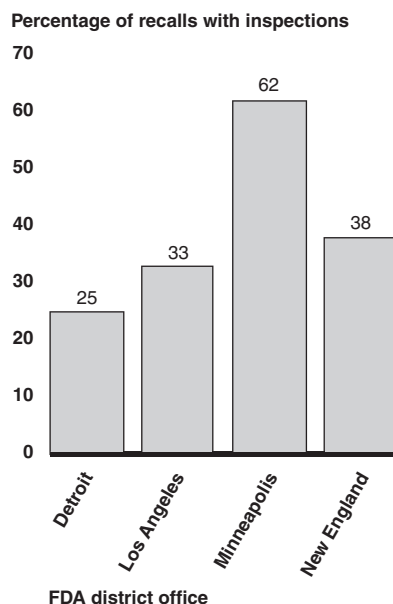
FDA infrequently—in less than one-half of the recalls—conducted an establishment inspection upon learning of a recall. According to FDA's procedures, upon learning of a potential class I recall, district offices should conduct establishment inspections to obtain further information about the recall. We found that FDA conducted such recall-related inspections for 20 of the 53 class I recalls we reviewed.<sup>34</sup> The frequency of

<sup>33</sup> According to FDA, this initiative also includes plans to develop strategies for improving CDRH's processes for classifying recalls and notifying the public about recalls.

<sup>34</sup> For 4 of the 53 recalls we reviewed, FDA identified the problem that led to the recalls through postmarket establishment inspections, unrelated to recalls. Thus, FDA did not need to conduct initial recall inspections.

inspections varied across the four district offices monitoring the recalls. Three of these offices (Detroit, Los Angeles, and New England) conducted recall-related establishment inspections upon the initiation of a recall between 25 percent and 38 percent of the time, while the Minneapolis district office conducted them in 62 percent of recalls (see fig. 6). Based on interviews with FDA officials in four district offices, we found that decisions to conduct such inspections, given their overall inspection workload, are a matter of resources and timing. Some district officials also said that the decision to conduct a recall-related inspection is based on the firm's recall history and indicated that FDA may be less likely to inspect a firm with a history of completing recalls successfully. Finally, some of these officials FDA said that this is because firms that have successfully completed recalls generally provide the necessary information, such as determinations of the root cause of the recall, as part of their correction or removal reports.

**Figure 6: Percentage of Our Sample of Class I Medical Device Recalls Initiated from 2005 through 2009 for Which Recall-Related Inspections Were Conducted, by FDA District Office**



Source: GAO analysis of FDA medical device recall files.

Note: We selected a sample of 53 recalls for in-depth review by identifying the four FDA district offices that had the largest number of available recall files to review. This figure includes 49 of the 53 recalls in our sample of class I recalls. FDA identified the problem that led to the remaining 4 recalls—1 from the Detroit and 3 from the Minneapolis district offices—through postmarket establishment inspections, unrelated to recalls. Therefore, FDA did not conduct additional inspections upon the initiation of these recalls.

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FDA generally followed its procedures by classifying each of the 53 recalls in our sample and providing written notification to the recalling firms. However, for 28 of the 53 recalls, FDA did not make its classification determination within 31 days as outlined in its procedures.<sup>35</sup> The amount of time from recall initiation to classification varied, ranging from a few days to several months, with an average of 47 days.

Representatives from two device manufacturer associations and several device manufacturers expressed concern about the length of time it can take FDA to classify recalls. For a class I recall, firms must make greater efforts to identify and contact customers than for class II recalls. Thus, delays in FDA's classification can affect firms' decisions. For example, officials indicated that if they send out a recall notice that they believe will be a class II, and after a significant amount of time FDA informs them it is a class I recall, the firm will have to revise the notice to indicate that the risks posed by the recall were more severe than they initially anticipated. The firm will also have to identify additional customers and device users to contact, in order to meet FDA's recommendation that they conduct 100 percent effectiveness checks for class I recalls. Firm officials said that they will then send out the revised notice, which can create confusion about whether this is a new recall or whether it is an update with new instructions for the already ongoing recall.

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## Firms Faced Challenges in Correcting or Removing All Recalled Devices

Our review of firms' action in conducting recalls found that the status of recalls varied and that firms face challenges in correcting or removing all recalled products. Of the 53 recalls we reviewed, we found 13 were ongoing, 10 were completed—meaning that an FDA district office concluded that the firm had essentially fulfilled their responsibilities for correcting or removing the devices—and 30 were terminated—meaning FDA headquarters determined that firms' corrective actions taken were sufficient to prevent a recurrence of the problems that led to the recall (see fig. 7).<sup>36</sup>

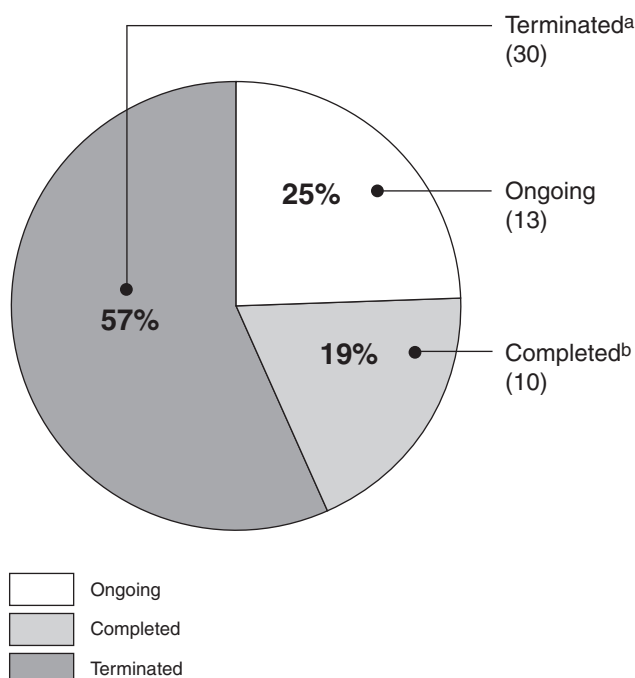
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<sup>35</sup>FDA's guidance at the time of our review recommended that CDRH classify a recall within 31 calendar days of obtaining information needed to classify the recall.

<sup>36</sup>We 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.



**Figure 7: Status of Our Sample of 53 Class I Medical Device Recalls Initiated from 2005 through 2009**



Source: GAO analysis of FDA medical device recall files.

Note: We obtained the current status of these recalls through our reviews of FDA's recall files and discussions with FDA district office officials between December 2010 and February 2011. Percentages may not sum to 100 because of rounding.

<sup>a</sup>Terminated—FDA headquarters determined that firms' corrective actions taken were sufficient to prevent a recurrence of the problems that led to the recall.

<sup>b</sup>Completed—An FDA district office concluded that the firm had essentially fulfilled their responsibilities for correcting or removing the devices.

Of the 40 recalls in our sample that were either completed or terminated—meaning that FDA concluded that the firm had taken sufficient effort to correct or remove recalled devices—we found that for 19 (48 percent) of these recalls, firms were able to correct or remove all products. In the other 21 recalls (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. Although recalling firms took steps to notify customers and device users, they were often unable to correct or remove all devices. This was because firms could not

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locate some of the customers or device users, or these customers or device users could not locate the device subject to recall. In other cases this was because the devices had been disposed of (such as defective syringes), or were sold at retail outlets (such as glucose test strips) to individuals who may not have known about the 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. Finally, users occasionally were unwilling to return a device. For example, one recall involved a magnetic device designed to treat a variety of medical problems such as lower back pain, fibromyalgia, and arthritis. This device was never cleared or approved by FDA, and despite FDA warnings about the device, users who had purchased units refused to return them. Details concerning the 21 recalls for which firms were not able to correct or remove all devices are presented in appendix II.

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### FDA's Oversight of Recalls Is Inconsistent and Narrow in Scope and Its Procedures Are Unclear

Our review of FDA's actions for conducting and overseeing recalls revealed that FDA generally conducted audit checks for the class I recalls we reviewed, but we found unclear procedures led to numerous inconsistencies in how different investigators conducted these checks and made their determinations about the effectiveness of recalls. FDA conducted audit checks for 45 of the 53 recalls (85 percent) we reviewed.<sup>37</sup> Our analysis of 2,196 audit check forms associated with these recalls found that audit checks completed for nearly 90 percent of the recalls contained a variety of inconsistencies in how the audit checks were implemented and documented.<sup>38</sup> 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. Specifically, we found the following.

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<sup>37</sup>FDA's procedures note that audit checks should be conducted for all class I recalls. In 8 of the 53 recalls FDA did not conduct audit checks. In six of these cases, the recall file contained written documentation explaining why audit checks were not conducted.

<sup>38</sup>For 2 of the 45 recalls there was evidence that FDA conducted audit checks, but FDA did not provide copies of the audit check forms. Thus, the 2,196 audit checks forms we reviewed were for a total of 43 recalls.

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- Some investigators' audit checks concluded that recalls were effective, despite noting problems (such as device users not following the firm's instructions), while other investigators concluded that similar instances were ineffective. For example, in 2008 a firm initiated a recall of an implantable pump because of problems in the connection between a catheter and the pump, which could result in improper amounts of medication being delivered to a patient. The firm's recall notification alerted physicians to this problem, and provided instructions for monitoring patients who already had the implanted pump and for revising future implant procedures. As part of the audit check program for this recall, FDA's investigators contacted a sample of physicians to determine whether they received the notification and followed the instructions. Our review found that out of 68 audit checks, there were 14 instances where the investigators noted that physicians either did not receive the recall notification, or did not remember receiving it, and thus could not have followed the recall notice instructions. In 8 of these 14 instances, investigators concluded that the recall was ineffective, noting that the physicians did not implement the recall instructions. In contrast, in the other 6 instances they concluded the recall was effective, even though physicians could not have followed the recall instructions. In some cases this was because the firm provided evidence that they had notified the physician, and in others the investigator noted that the physician did not have any pumps on hand.
  - Some investigators determined that device users were not notified of the recall by the recalling firm, but instead learned of the recall through other means. In some of these instances, investigators' audit checks concluded that recalls were effective, while in other similar cases investigators concluded the checks were ineffective.
  - Some investigators wrote detailed comments on the audit check form as to why the investigator determined the recall was effective or ineffective, while others did not. Without comments, it may be difficult for FDA supervisors and district recall coordinators to verify whether an investigator correctly determined whether the recall was effective or ineffective.
  - Some investigators noted actions they took when they discovered problems with recalls, 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 facilitate the recall. For example, in 2009 a firm initiated a recall of an automated external defibrillator because of reports that some of these devices failed to discharge sufficient

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energy due to problems with batteries. The firm issued a notice that instructed users to replace batteries and update software for the devices. As part of the audit checks for this recall, FDA investigators contacted a sample of users of the device, to check whether they received the recall notification and followed the firm's recall instructions. Our review found that out of 67 audit checks, there were 35 instances where investigators noted problems with the recall—generally that the user did not receive the notice or failed to follow recall instructions. In 29 of these cases, the FDA investigator noted taking actions, including providing the recall notice or instructing the user to contact the recalling firm so they could obtain software needed to perform the needed actions. However, in 6 cases we found no indication that the FDA investigator took actions to ensure the recall was carried out effectively.

FDA officials at both ORA 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. Officials told us that when determining whether or not a check is effective, investigators should be assessing whether the recalling firm provided the notice and instructions to the customers or device users, and whether the customers or users followed instructions. They acknowledged, however, that some investigators may approach these checks differently, and that this may be an area where clarification of the agency's procedures is needed. During our interviews with officials from the Detroit, Los Angeles, Minneapolis, and New England district offices, some officials said that audit checks are typically conducted by new investigators, and that investigators receive classroom and on-the-job training on how to conduct such checks. Some district officials also noted that audit checks are reviewed by a supervisor as well as the recall coordinator in the district office that is monitoring the recall, and this serves as a quality control function to ensure consistency. Also, officials from FDA headquarters and some district offices stated that they have attempted to institute measures to improve the audit check process. Specifically, they noted that they recently updated the audit check form to more precisely reflect what makes a recall ineffective. Also, ORA officials indicated that they plan to automate the audit check forms, which will make the forms accessible to officials in FDA's headquarters. FDA officials said that they are considering applications for analyzing the automated data, but have not completed any specific plans.

In addition to the inconsistencies, we found other gaps in FDA's oversight related to the audit checks. First, FDA's audit checks were often narrow in scope, in that FDA instructs investigators to contact only a small number

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of customers or device users—between 2 percent and 10 percent of those affected by the recall. Therefore, if there are thousands of customers or device users, the audit checks provide FDA with a means to contact a relatively small number of them. For the 45 recalls for which FDA completed checks, we found the number of audit checks conducted varied widely, from 2 to 271, with an average of 51 audit checks per recall.<sup>39</sup> Second, FDA investigators did not always conduct the assigned number of audit checks. We compared the number of audit checks that should have been conducted based on the audit check assignments to the numbers of checks actually completed. We found that for 17 of the 45 recalls (38 percent) fewer than the assigned number were conducted. Third, even though most checks were done in person, consistent with FDA’s procedures, over 22 percent of the checks were done by telephone. In these cases, the audit check relied extensively on anecdotal information provided by the customer or device user. According to FDA, the number of checks it can perform is limited by available resources. Based on our review of files, we found that if patients or consumers are involved (e.g., if FDA needed to contact someone with an implantable device), these were often done by telephone. We also found checks that were done by telephone for other device users including hospitals, retailers, and doctors’ offices.

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### Gaps in FDA’s Completion and Termination Process Increase the Risk That Unsafe Medical Devices May Continue to Be Used

We found FDA lacks specific criteria for making decisions about whether recalling firms have adequately completed their recalls—a key oversight activity of the recall process. 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, our review of FDA’s recall procedures found—and FDA officials confirmed—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 before a recall should be considered completed. For example, FDA does not have a benchmark recovery rate or threshold to assess whether firms effectively completed recalls, although the recovery rates of devices could be expected to vary, depending on whether a recalled device was a large piece of hospital equipment or a disposable device, such as a syringe.

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<sup>39</sup>For two recalls, FDA was unable to locate the audit check forms. Thus, we have excluded these recalls from the calculation of the average number of audit checks.

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Representatives from medical device firms stated that there are no criteria or guidance from FDA on the percentage of recalled products that must be corrected or removed. Further, these firm representatives said that FDA is generally satisfied with three attempts at communicating with customers and device users affected by the recall.

In addition, for a majority of the class I recalls we reviewed, FDA's actions to ensure that recalls were complete were inconsistent with its procedures for overseeing recalls. According to FDA's procedures, districts should conduct a limited postrecall inspection to verify that the recall is complete, and to witness destruction of defective products, if applicable. In 21 of the 40 completed and terminated recalls (53 percent) we found no documented evidence that FDA took actions besides audit checks to verify that the recall was complete. In the other 48 percent of recalls, FDA made an assessment via inspection, witnessing destruction of devices, or verifying that software corrections were completed.

Another gap we found in the recall process is that FDA does not maintain sufficient documentation to justify its termination decisions. Although FDA may request that firms submit corrective and preventative action plans for review and approval before a recall can be terminated, we found little documentation on how FDA assessed whether such plans were sufficient when it terminated recalls. When we asked to review documentation justifying the decisions for the 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."<sup>40</sup> Without such documentation, we were unable to assess the extent to which FDA's termination process appropriately evaluated recalling firms' corrective actions.

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<sup>40</sup>See [GAO/AIMD-00-21.3.1](#).

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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 files in our sample, 30 were terminated—meaning FDA headquarters determined that firms developed sufficient corrective actions to prevent a recurrence of problems which led to the recalls. For 73 percent of the terminated recalls, FDA did not make its termination decision within 3 months of the recall’s completion, as indicated by FDA procedures. Overall, termination decisions took between 10 and 800 business days from completion to termination, with an average of 187 business days. Failure to make termination decisions in a timely manner increases the risk that patients and healthcare providers may continue to use unsafe or defective devices. For example, one firm requested termination from FDA for its recall of a portable external defibrillator in February 2006. However, FDA did not begin its termination assessment until May 2010. In this case, officials indicated that, due to staff turnover in the district office, they were unaware that this recall was still ongoing until a new recall coordinator searched for ongoing recalls. In 2010, following an FDA inquiry, the firm stated that it had not received confirmation of a required upgrade from 91 end users and an additional 13 devices could not be located. Because FDA did not follow up on this recall until 2010, 4 years had elapsed before the agency became aware that the recalling firm had not corrected or removed a substantial number of devices subject to the recall. According to FDA officials, their ability to terminate recalls in a timely manner is affected by resources, and termination decisions are a lower priority than other issues because the recalling firm has completed its actions.

We found at least one instance where FDA’s failure to make a timely termination assessment allowed for a potentially unsafe product to be reintroduced 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 postoperatively, 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 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

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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.

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## Conclusions

The medical device recall process is complex, requiring the coordination and timely action of potentially thousands of parties. It is an important tool used by firms and FDA to protect the public and mitigate health risks from unsafe or ineffective devices. While the recall process may not eliminate 100 percent of health risks associated with recalled devices, careful implementation and evaluation are critical to minimizing health risks.

FDA has a key role in identifying and minimizing the public health risks presented by defective or unsafe devices. In this regard, FDA has opportunities to close some of the gaps that currently exist in the medical device recall process, and enhance its oversight of device recalls. As currently structured, FDA's approach to oversight of medical device recalls is reactive—responding to individual recalls as they occur. Rather than pursuing a strictly case-by-case approach to overseeing recalls, FDA could take a more proactive approach to its oversight. The agency has a plethora of data available on thousands of recalls, but at present, is not effectively reviewing and analyzing these data in a systematic manner. More routine analyses of these data could help FDA identify trends in the numbers and types of devices being recalled, as well as the underlying causes of device recalls. Such information would provide FDA with a better understanding of the risks presented by defective or unsafe devices, which could lead the agency to proactively identify strategies and measures needed to address systemic problems with the design or manufacture of individual devices or entire categories of devices. Armed with the results of these types of analyses, FDA could then be in a position to help mitigate safety risks before they occur, and thus minimize the need for recalls. This is particularly important for the devices involved in the highest-risk recalls, which place the public at risk of serious health consequences, including death.



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Furthermore, while the agency has devoted substantial resources to monitoring individual recalls, opportunities for enhancing its oversight of specific recalls also exist. A key FDA mechanism for overseeing individual recalls—audit checks of a small portion of customers and device users involved in the recall—are often implemented inconsistently. This is due to unclear procedures that investigators are using for implementing and documenting audit checks and making their final assessments. As a result, investigators can make inconsistent determinations about whether firms, customers, and device users have effectively conducted a recall. Additionally, FDA lacks clear criteria for determining whether firms have successfully completed recalls, and has failed to maintain important documentation justifying its decisions to terminate the highest-risk recalls. This impedes independent assessments of FDA’s decision making and leaves the agency vulnerable to questions about the basis it used to determine that recalling firms fulfilled all their responsibilities when conducting recalls. By addressing these weaknesses, FDA could reduce the risk that defective or unsafe medical devices remain on the market, potentially endangering public health.

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## Recommendations for Executive Action

To enhance FDA’s oversight of medical device recalls, and in particular, those medical device recalls that pose the highest risk, we recommend that the Commissioner of FDA take the following four actions:

- Create a program to routinely and systematically assess medical device recall information, and use this information to proactively identify strategies for mitigating health risks presented by defective or unsafe devices. This assessment should be designed, at a minimum, to identify trends in the numbers and types of recalls, devices most frequently being recalled, and underlying causes of recalls.
- Clarify procedures for conducting medical device recall audit checks to improve the ability of investigators to perform these checks in a consistent manner.
- Develop explicit criteria for assessing whether recalling firms have performed an effective correction or removal action.
- Document the agency’s basis for terminating individual recalls.

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## Agency Comments

We provided a draft of this report to HHS for review. HHS's written comments are reprinted in appendix III. HHS agreed with our conclusions and recommendations and stated that the agency is committed to exploring each of our recommendations fully. HHS reported that FDA plans to convene a working group to both evaluate improvements to the recall process and to develop strategies to implement our recommendations. According to HHS, FDA recognizes that standardized guidance will strengthen the management of the recall process. In addition, HHS elaborated on some of FDA's efforts to enhance its oversight by, for example, developing more routine analysis and reporting of recall data. HHS also provided technical comments, which we incorporated as appropriate. We are greatly encouraged by the agency's response, and believe its expeditious implementation of the recommendations will serve to enhance the safety of medical devices used by millions of Americans each day.

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As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to the Commissioner of FDA and appropriate congressional committees. The report also will be available at no charge on GAO's Web site at <http://www.gao.gov>.

If you or your staffs have any questions about this report, please contact me at (202) 512-7114 or [crossem@gao.gov](mailto:crossem@gao.gov). Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report are listed in appendix IV.



Marcia Crosse  
Director, Health Care

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# Appendix I: Tools to Help Identify Recalled Devices and Planned Initiatives for Assisting with Device Recalls

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Several key stakeholders involved in the medical device recall process, including recalling firms, device distributors, and device users—such as hospitals—share responsibilities for effectively implementing recalls. To implement an effective recall, stakeholders need mechanisms to ensure timely and open communication about the recalls, and a means of locating devices subject to recall. This appendix describes the recall notification and tracking systems available to help manage device recalls. It also provides information on the status of the Food and Drug Administration’s (FDA) unique device identification (UDI) initiative—which is intended to enable the identification of a device throughout distribution and use.

To obtain this information, we interviewed officials from FDA and key stakeholders, including representatives of firms providing subscription-based recall alert information, manufacturers, distributors, group purchasing organizations, hospital systems, and patient safety groups. Through these interviews we obtained information on what these stakeholders considered to be the key challenges they face in implementing device recalls. We also obtained information about mechanisms which, in particular, hospital systems use to help identify devices subject to recall. Further, we reviewed FDA’s progress in implementing its UDI initiative. To accomplish this, we examined published studies on this initiative, reviewed stakeholder comments submitted for FDA’s public meetings on the UDI, and interviewed FDA officials responsible for managing the UDI program.<sup>1</sup>

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## Many Stakeholders Use Electronic Recall Notification and Tracking Systems to Help Manage Device Recalls

We learned through stakeholder interviews that instead of relying solely on notifications from medical device manufacturers, health care providers and other stakeholders have come to rely on other sources of information to stay abreast of potential recalls. Furthermore, these electronic communication technologies are evolving and, over time, stakeholders have begun recognizing that they can play a role in helping to effectively implement recalls.

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<sup>1</sup>Published studies we reviewed include: Eastern Research Group, Inc., *ERG Final Report: Unique Identification for Medical Devices*, a report prepared for FDA, March 2006, and Susan J. Griffey, Andy Martin, Marjorie Odle, and M.J. Wylie, *SSS-GHX Development of the Prototype Unique Device Identifier Database: Report of a Pilot Test on Usability and Feasibility*, a report prepared for FDA, (November 2009).

Our interviews with stakeholders revealed that a number of different privately developed, subscription-based electronic notification and tracking systems are available to help identify and process recalls. Stakeholders indicated that these systems are primarily used by hospitals, but that the systems are available to others involved in recalls as well. Available services identify recalls from a number of sources, including device manufacturers and FDA’s Web site. The services compile lists of recalls and send electronic messages about recalls to paid subscribers. These services vary in sophistication and price. One service we learned about was limited to periodic electronic notification of all recalls at a cost of about \$500 per year. Others include software to help individual hospitals specifically delegate responsibility within their hospital system to specific officials who will manage certain aspects of the recalls—such as removing recalled products from inventory—and for tracking the progress of the recalls. These systems can cost several thousand dollars per year. Owners of these systems that we spoke to indicated that hundreds of hospitals subscribe to their systems (see table 5).

Table 5: Examples of Available Recall Alert Services

| Type of system                                   | Service provided   | Primary customers   | Source of information in alerts   |
|--|--|---|---|
| E-mail alerts                                    | Sends e-mail alerts to hospitals every 7-10 days or immediately for urgent recalls.  | Hospitals   | FDA, manufacturers, and subscribers   |
| Weekly newsletter, Web-based alerts and tracking | An alert service and optional Web-based recall and safety alert tracking system that helps clients to acquire, distribute, and manage recalls. | Primarily hospitals, but also government agencies and manufacturers   | FDA, manufacturers, and subscribers   |
| Web-based customized alerts and tracking         | A customized Web-based recall management service that alerts appropriate personnel of recalls and allows them to track a recall’s progress.    | Designed for hospitals but used by others including outpatient centers, nursing homes, and day care centers | FDA, manufacturers, subscribers, U.S. Army Medical Material Agency, and Consumer Products Safety Commission |

Source: GAO analysis of information from medical device recall stakeholders.

Stakeholders we interviewed identified several operational benefits of using recall notification systems. First, they indicated these systems allow for an increased ability to identify the universe of recalls rather than simply relying on receiving notices from recalling firms. Second, stakeholders indicated that quality assurance measures used by the systems help ensure that the recall notifications contain sufficiently detailed and accurate information. They indicated that personnel working for such systems will review the recall notifications they compile prior to sending them to the subscribers. If needed, those providing the recall alert

services will contact the recalling firm and update the notice for the subscribers if information is unclear or missing. Third, stakeholders indicated that such systems can help ensure that recall notifications are routed to specific personnel within an institution responsible for managing the recall, reducing the likelihood that implementing the recall is delayed or overlooked. Officials from some hospitals we spoke with indicated that manufacturers will frequently notify the department in a hospital that received the product, which may not be the best point of contact for ensuring recalled devices are corrected or removed. However, one hospital system indicated that by using the more sophisticated alert systems, they are able to automatically forward recall alerts to key personnel specifically identified by the hospital. This ensures that only the appropriate departments at the hospital are alerted. Finally, stakeholders stated that these systems allow hospitals to identify and process recalls sooner.

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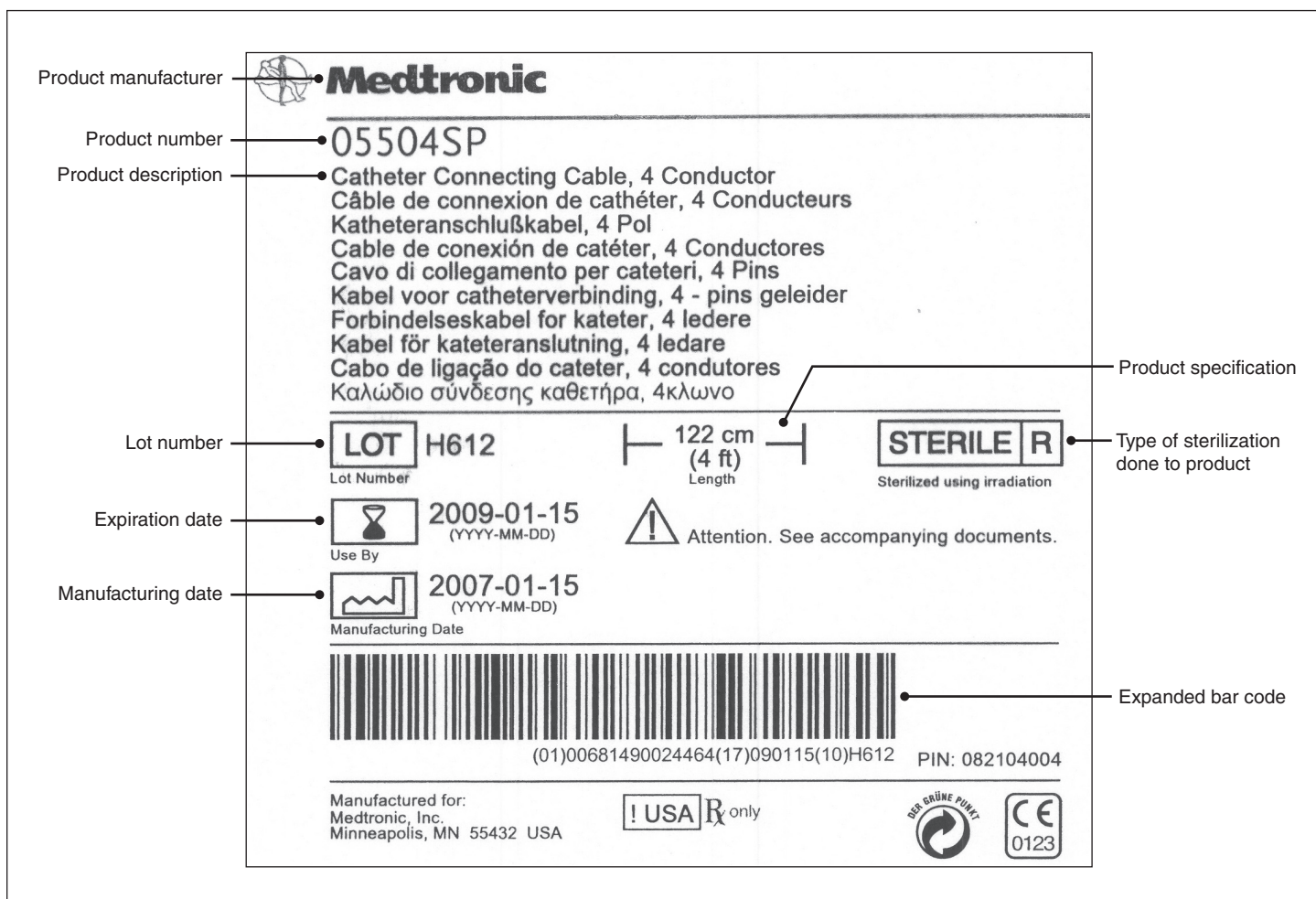
## Status of UDI Initiative

The Food and Drug Administration Amendments Act of 2007 (FDAAA) required FDA to develop a UDI system—a major initiative to better track and identify devices.<sup>2</sup> Through the UDI, FDA plans to require that the label of a device bear a unique identifier that is able to identify the device throughout its distribution and use. Figure 8 displays an example of the key attributes that might be included in a UDI. In this example, the label includes key information, such as a device’s lot number and expiration date which could be scanned into databases.

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<sup>2</sup>Pub. L. No. 110-85, § 226, 121 Stat. 823, 854.

Figure 8: Example of a Potential Unique Device Identification Label



Source: Medtronic.

FDA has been working on the UDI since 2005, prior to the enactment of FDAAA, and has made some preliminary decisions about the system. According to FDA, it currently has a proposed schedule that calls for implementation of the UDI in phases over several years.

Key activities completed for the UDI include the following.

- April 14-15, 2005: FDA held a workshop to obtain comments from various stakeholders on the UDI. A draft report about the UDI prepared by a contractor for FDA, known as “The White Paper,” was provided to attendees prior to the workshop to use as background for workshop discussions.
- August 17, 2005: The White Paper was issued and provided information on technologies and standards available for the UDI initiative and the possible benefits of automatic identification of devices. The paper also identified key issues FDA should consider moving forward, including costs of the UDI. Also, the paper incorporated stakeholder comments from the workshop held in April 2005.<sup>3</sup>
- March 22, 2006: Another contractor issued a report outlining the possible benefits of the UDI and decisions FDA must make to implement the system, including the technology needed to use the UDI.<sup>4</sup>
- August 11, 2006: FDA formally solicited comments in the Federal Register for the UDI initiative.<sup>5</sup>
- September 27, 2007: FDAAA enacted, requiring FDA to develop and implement the UDI.
- February 12, 2009: FDA held a public workshop on the UDI to identify remaining issues related to the establishment of a UDI system and to request comments on this topic.
- November 20, 2009: FDA published the results of a pilot test of the UDI. The results included several recommendations for the future of the UDI

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<sup>3</sup>The ECRI Institute, *Task 4 White Paper - Automatic Identification of Medical Devices - Final Version*, a report prepared for FDA, August 2005.

<sup>4</sup>Eastern Research Group, Inc., *ERG Final Report: Unique Identification for Medical Devices*, a report prepared for FDA, March 2006.

<sup>5</sup>Docket No. FDA-2008-N-0661, CDRH 200866. Unique Device Identification System; Public Workshop; Request for Comments.

including specific enhancements that could enhance the UDI's functionality.<sup>6</sup>

- November 30, 2010: Another report on pilot activities was published containing feedback from organizations that will label the devices and internal FDA stakeholders. The report stated that fewer concerns remain as FDA is close to releasing the UDI regulation.<sup>7</sup>

According to FDA, the UDI implementation schedule calls for a phased approach that will take several years to reach full-scale implementation. FDA is currently working on a proposed rule and intends to publish it and seek public comments in spring 2011, and issue a final rule 12 to 18 months later. According to FDA's senior advisor for the UDI, the proposed rule will include several key decisions that FDA, based on its prior studies, has reached regarding the UDI. These key decisions include the following.

- Provisions for a UDI database that FDA will maintain. Manufacturers will send key information about their devices to FDA, which will maintain a database containing a device identifier for all devices distributed in the United States.
- Flexibility to allow manufacturers to decide how to label their devices using automatic identification and data capture. This could mean using a linear or two-dimensional bar code, or radio frequency identification.<sup>8</sup>

In addition, FDA indicated that there are other issues for which they have not yet made final decisions, and they are still assessing these before they issue a proposed rule. These include the following.

- The labeling requirements for different devices, for example, riskier devices may be labeled with a unique identifier individually, while disposable, low-risk devices may be labeled based on how they are packaged (e.g., bandages will have their UDI identifier on their box).

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<sup>6</sup>Susan J. Griffey, Andy Martin, Marjorie Odle, MJ Wylie, *SSS-GHX Development of the Prototype Unique Device Identifier Database: Report of a Pilot Test on Usability and Feasibility*, a report prepared for FDA, (November 2009).

<sup>7</sup>FDA, *Results of FDA Pilot Activities To Explore Opportunities and Challenges With the Implementation of a Unique Device Identifier System* (Washington, D.C., 2010).

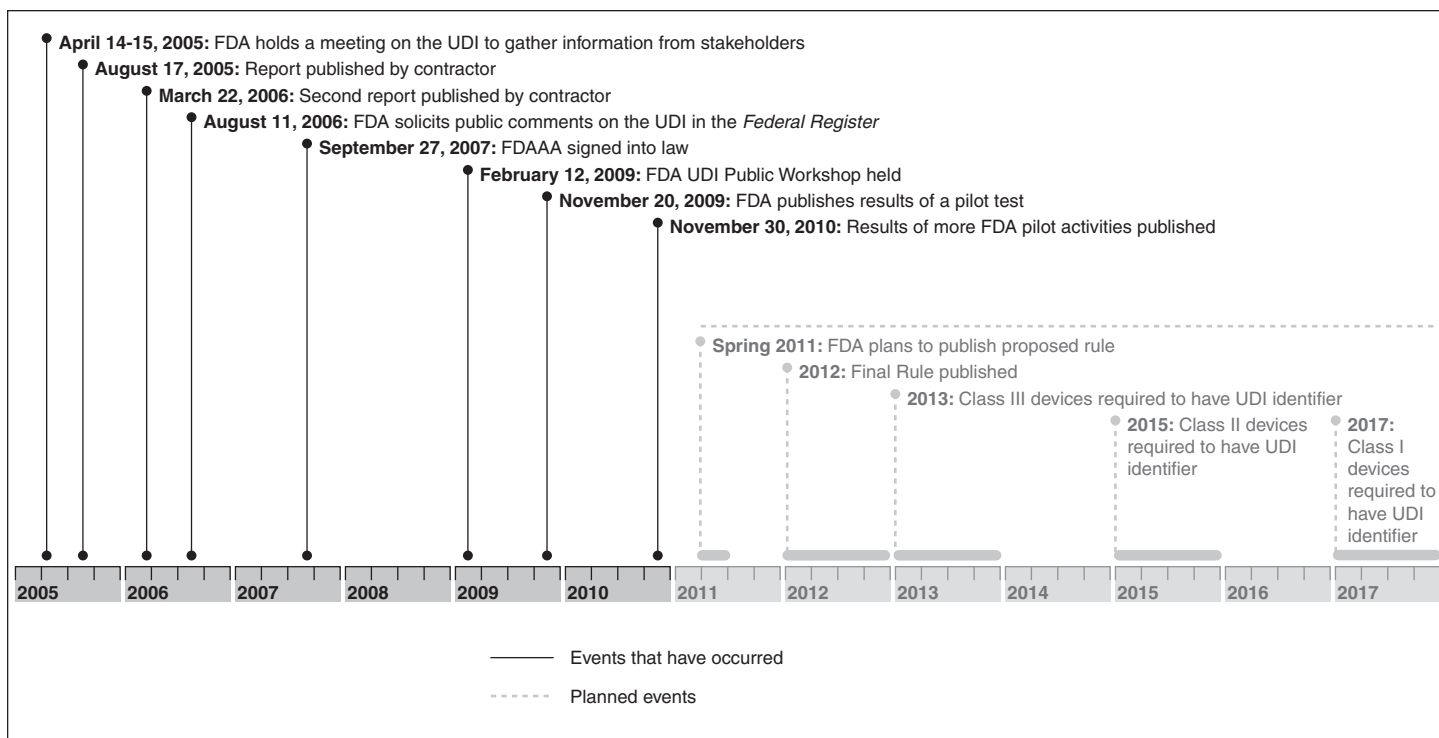
<sup>8</sup>A two-dimensional barcode stores information horizontally and vertically allowing the two-dimensional barcodes to store more information than linear bar codes, which store information only horizontally. Radio frequency identification allows for information about a device to be transmitted between a tag on the device and a reader using radio waves.



- If the UDI should have a phased implementation schedule for administering the identifiers, for example, class III devices—the most risky devices, including some that are implantable—may use the UDI within 1 year of publishing the final rule, while class II and class I devices might follow meeting the UDI requirement within 3 and 5 years, respectively.

Figure 9 presents a timeline of key activities since FDA began assessing the UDI and its planned implementation schedule.

**Figure 9: Timeline of Events for the Development of the Unique Device Identification Initiative**



Source: GAO analysis of FDA information.

An FDA official said that the agency expects that the UDI will provide benefits beyond increased precision in identifying recalled devices, and that some benefits of the UDI will be realized immediately after its implementation. According to the UDI senior advisor, these benefits include improved tracking of adverse events associated with medical devices and prevention of device counterfeiting. He also stated that many manufacturers already use identifiers on their devices and should have little problem adapting to the new UDI system.

Despite the potential benefits of the UDI, some stakeholders expressed concern that the success of UDIs depends on hospitals' ability to utilize these identifiers, and that it may be years before the benefits to the recall process are realized. Manufacturers we contacted stated that many hospitals do not use the lot and serial numbers currently provided by manufacturers to track devices, and FDA does not have authority to require providers to use the UDI. This concern was also reflected in comments from officials at several hospitals that we contacted. Some indicated that they do not have inventory systems in place that enable them to track devices throughout their hospitals. Therefore, they must manually search their inventory, sometimes at multiple locations. Locating a recalled device can be particularly difficult because a device may contain multiple identification numbers assigned by manufacturers and distributors for their own tracking purposes. Without upgrades to these hospitals' systems, officials acknowledged that the UDI will be less effective in enhancing patient safety. FDA's UDI senior advisor stated that larger hospitals might be more eager to adopt the technology necessary to track devices using the UDI once it is implemented, but acknowledged that benefits for the recall process are greatly dependent on hospitals' implementation of the UDI, which could take up to 10 years for many hospitals, especially smaller ones.

# Appendix II: Class I Medical Device Recalls from Our Sample for Which Firms Were Unable to Correct or Remove All Devices

In some instances recalling firms are not able to correct or remove all of the devices subject to a recall. Of the 53 class I recalls in our sample of recalls that were initiated during the period of January 1, 2005, through December 31, 2009, there were recalled medical devices that firms were unable to correct or remove. Table 6 includes information on the number of devices subject to these 21 recalls, the number corrected or removed, and if available, reasons firms provided to FDA explaining why they could not correct or remove 100 percent of the devices.

**Table 6: Class I Medical Device Recalls for Which Firms Were Unable to Correct or Remove All Devices**

| Recalled device                         | Reason for recall   | Number of devices recalled <sup>a</sup> | Number of devices corrected or removed <sup>a</sup> | Number of devices outstanding <sup>a</sup> | Reasons for incomplete recovery   |
|---|---|---|---|--|---|
| Centrifuge rotor                        | Catastrophic failure or explosion                                 | 42 <sup>b</sup>                         | 32 <sup>b</sup>                                     | 10 <sup>b</sup>                            | Could not locate some users or devices  |
| Endoscopic injector                     | Could inject into vital organ and cause death                     | 9,984                                   | 4,114   | 5,870                                      | Users could not locate many devices, others were already used                             |
| Insulin syringe                         | Package mislabeled, contains incorrect dose of insulin            | 471,000                                 | 61,351  | 409,649                                    | Probably used by consumers or thrown away   |
| Intra-aortic balloon and control system | Fault in connector may result in incorrect pump volume            | 13,570 <sup>b</sup>                     | 1,174 <sup>b</sup>                                  | 12,396 <sup>b</sup>                        | Some users did not respond, other devices were already used                               |
| Blood glucose test strip                | Counterfeit device results in inaccurate test results             | 5,292                                   | 1,786   | 3,506                                      | Presumed used or thrown away  |
| Denervation probe                       | Mislabeled as sterile   | 539 <sup>c</sup>                        | 27 <sup>c</sup>                                     | 512 <sup>c</sup>                           | Many users sterilized devices themselves and then used them                               |
| Heating pad                             | Electrical problems, leading to fires, burns, and property damage | 408,599                                 | 119   | 408,480                                    | Firm assumed most had been disposed of (recall was initiated 6 years after manufacturing) |
| Glucose monitoring system               | Displaying American units for Canadian customers                  | 33 <sup>b</sup>                         | 32 <sup>b</sup>                                     | 1 <sup>b</sup>                             | Recalling firm could not locate the device  |
| Infusion set                            | Improper venting, leading to fluctuating insulin delivery         | Unknown <sup>d</sup>                    | 424,506   | Unknown <sup>d</sup>                       | Single-use sets; impossible to know how many were available for use                       |
| Ventricular catheter                    | Catheter becomes detached from base after implantation            | 3,048                                   | Unknown <sup>d</sup>                                | Unknown <sup>d</sup>                       | Recalling firm did not indicate final disposition of all recalled devices                 |

**Appendix II: Class I Medical Device Recalls  
from Our Sample for Which Firms Were  
Unable to Correct or Remove All Devices**

| <b>Recalled device</b>                           | <b>Reason for recall</b>  | <b>Number of devices recalled<sup>a</sup></b> | <b>Number of devices corrected or removed<sup>a</sup></b> | <b>Number of devices outstanding<sup>a</sup></b> | <b>Reasons for incomplete recovery</b>   |
|--|---|---|---|--|--|
| IV extension sets                                | Manufacturing defect, possibly resulting in improper functioning and embolism | 99  | 56  | 43   | No reason given  |
| Needle and infusion sets                         | Needles “punch out,” sending the core into a patient’s body                   | Unknown <sup>d</sup>                          | 13,988  | Unknown <sup>d</sup>                             | Firm did not list total number of devices or all devices were recovered                        |
| Ventilator                                       | Flow valve failures   | 277   | 276   | 1  | Missing from a nursing home (police report was filed)  |
| Ventilator                                       | Power supply failures   | 2,270   | Unknown <sup>d</sup>                                      | Unknown <sup>d</sup>                             | Recalling firm could not account for all devices and noted that some customers did not respond |
| Catheter   | Catheter may crack  | 70  | 55  | 15   | Devices were used  |
| Automatic implantable cardioverter defibrillator | Possible short-circuiting of the device                                       | 14,010  | 13,839  | 171  | Sold, but no implant record available  |
| Pacemaker  | Device’s seal may degrade allowing excess moisture within the pacemaker       | 23,987  | 22,255  | 1,732  | Sold, but no implant record available  |
| Implantable programmable pump                    | Pumps may detach, interrupting drug flow                                      | 1,742   | 1,497   | 245  | Some devices remain implanted or have an undetermined status                                   |
| Implantable programmable pump                    | Pump motor may stall causing drug delivery to stop abruptly                   | 23,895 <sup>c</sup>                           | Unknown <sup>d</sup>                                      | Unknown <sup>d</sup>                             | Hundreds of users did not reply  |
| Carotid stent system                             | Possible detachment in the stent delivery system                              | 1,570   | 619   | 951  | Devices were either used or disposed at the users’ facilities                                  |
| Implantable defibrillator                        | Potential for a short circuit and loss of device function                     | 6,911   | 6,787   | 124  | Sold, but no implant record available  |

Source: GAO analysis of FDA recall files.


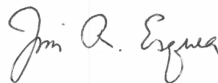
<sup>a</sup>Numbers reflect units of distribution. In some cases, devices are sold individually, and in other instances multiple devices are sold in a package (e.g., glucose strips).

<sup>b</sup>Includes units distributed to Canada.

<sup>c</sup>Includes worldwide units.

<sup>d</sup>Documentation provided by FDA did not include these numbers.

# Appendix III: Comments from the Department of Health and Human Services

|  |  |  |
|--|--|--|
|   | <b>DEPARTMENT OF HEALTH &amp; HUMAN SERVICES</b> | Office of the Assistant Secretary<br>for Legislation |
|  |  | Washington, D.C. 20201                               |
| <b>MAY 26 2010</b>   |  |  |
| Marcia Crosse<br>Director, Health Care<br>U.S. Government Accountability Office<br>441 G Street N.W.<br>Washington, DC 20548   |  |  |
| Dear Ms. Crosse:   |  |  |
| Attached are comments on the U.S. Government Accountability Office's (GAO) draft report entitled, "MEDICAL DEVICES: FDA Should Enhance Its Oversight of Recalls" (GAO-11-468). |  |  |
| The Department appreciates the opportunity to review this draft report prior to publication.   |  |  |
| Sincerely,   |  |  |
|    |  |  |
| Jim R. Esquea<br>Assistant Secretary for Legislation   |  |  |
| Attachment   |  |  |

**GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "MEDICAL DEVICES: FDA SHOULD ENHANCE ITS OVERSIGHT OF RECALLS" (GAO-11-468)**

The Department appreciates the opportunity to review and comment on this draft report.

In general, the Food and Drug Administration (FDA) believes GAO's draft report accurately describes the FDA's medical device recall program. The agency agrees with GAO's conclusions and recommendations and is committed to exploring each recommendation fully and to making appropriate implementation decisions based on the results of its internal analysis.

The FDA agrees that agency recall data is a robust resource, the assessment of which can help mitigate health risks presented by defective or unsafe devices. The FDA also agrees that the agency does not currently conduct some of the analyses described in the GAO report. Although industry is responsible for analysis of design and manufacturing-related risks of individual medical devices, the FDA has an important role in recall data analysis and performs a variety of routine analyses to inform its regulatory activities. The FDA compiles recall information for every product code (medical device type), each medical device brand name, and every individual firm. The FDA aggregates recall information on related products for each 510(k) submission reviewed, each Establishment Inspection Report (EIR) review, and all adverse event analyses. The FDA's risk-based work plan uses recall data as one data source to identify types of medical devices and industry segments that should be priorities for inspection. Likewise, the FDA uses recall data to support its risk-based site selection model, which identifies individual facilities likely to have quality system violations. Every cross-Center team begins with a recall analysis similar to that provided for the Automated External Defibrillator effort cited in the GAO report. Recent cross-Center teams have focused on infusion pumps and ventilators.

*Recommendation 1: Create a program to routinely and systematically assess medical device recall information, and use this information to proactively identify strategies for mitigating health risks presented by defective or unsafe devices. This assessment should be designed, at a minimum, to identify trends in the numbers and types of recalls, devices most frequently being recalled, and underlying causes of recalls.*

The FDA agrees it should assess medical device recall information more routinely and systematically, and that it should use this information to mitigate health risks. The FDA plans to perform a systematic evaluation of potential recall analyses. The agency plans to consider recall processing times, recalled device types and medical specialties, types of device failures observed, quality of recall notifications, and other elements that elevate the risk to public health. Based on the evaluation, the agency will develop more routine analysis and reporting. In the meantime, the FDA plans to continue to analyze numbers and types of recalls on a yearly basis.

*Recommendation 2: Clarify procedures for conducting medical device recall audit checks to improve the ability of investigators to perform these checks in a consistent manner.*

**GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN  
SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S  
(GAO) DRAFT REPORT ENTITLED, "MEDICAL DEVICES: FDA SHOULD  
ENHANCE ITS OVERSIGHT OF RECALLS" (GAO-11-468)**

The FDA generally agrees it should update and clarify its recall audit check procedures and is committed to reevaluating its procedures for conducting recall audit checks. In recent years, the agency has experienced significant increases in the number of recalls of FDA-regulated products, some of which involve the largest and most complex recalls in FDA history. To address these issues and to better understand the current recall business processes, the FDA has undertaken a recall process improvement study that is intended to examine the overall recall process in protecting the public health and removing violative products from the marketplace. This study was recently completed, and the FDA plans to convene a working group to evaluate the results and to develop a strategy for the implementation of the recommendations. Furthermore, the FDA will continually review its recall procedures to determine whether specific additions, updates, and clarifications may be needed to the recall program, including the audit check process.

In addition, the FDA has already begun implementing some initiatives for improving the recall audit check process, which currently is manual, for all FDA-regulated products. For example, and as noted in GAO's report, the FDA has invested in automating its current recall audit check process, which will allow the agency to automate the creation, issuance, assigning, and tracking of recall audit check assignments, as well as to establish an electronic mechanism for reporting or documenting recall audit check results.

*Recommendation 3: Develop explicit criteria for assessing whether recalling firms have performed an effective correction or removal action.*

The FDA generally agrees it should clarify its criteria for assessing whether recalling firms have performed an effective correction or removal action. The FDA acknowledges it needs to update its process and procedures, and recognizes that standardized guidance will strengthen the management of the recall process and promote a consistent approach for assessing recalling firms' efforts and effectiveness in correcting or removing violative products from the marketplace. The FDA is committed to continually analyzing the procedures and the criteria it uses to determine when recalling firms have performed an effective correction or removal action. The FDA working group which will be tasked with evaluating the results of the recently completed recall process improvement study will use the study results to develop an informed strategy for implementing this recommendation.

*Recommendation 4: Document the agency's basis for terminating individual recalls.*

The FDA generally agrees that the agency should document its termination decisions and is committed to reevaluating its recall termination procedures and documentation. The FDA working group that will be tasked with evaluating the results of the recently-completed recall process improvement study will consider the study results to make recommendations to FDA management on the need for specific additions, updates, and clarifications to the recall termination process.

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# Appendix IV: GAO Contact and Staff Acknowledgments

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## GAO Contact

Marcia Crosse, (202) 512-7114 or [crossem@gao.gov](mailto:crossem@gao.gov)

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## Staff Acknowledgments

In addition to the contact named above, Geri Redican-Bigott, Assistant Director; Kaycee Glavich; Cathleen Hamann; Eagan Kemp; Julian Klazkin; Zachary Levinson; David Lichtenfeld; Daniel Ries; Christina C. Serna; and Katherine Wunderink made key contributions to this report.



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