

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.

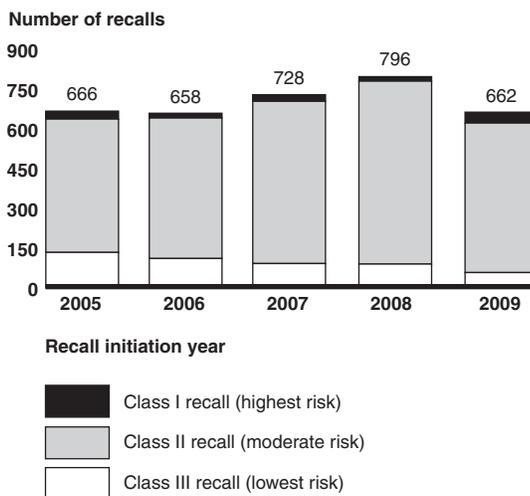
MEDICAL DEVICES

FDA Should Enhance Its Oversight of Recalls

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.