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MEDICAL DEVICES

Shortcomings in FDA's Premarket Review, Postmarket Surveillance, and Inspections of Device Manufacturing Establishments

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Highlights

Highlights of GAO-09-370T, a testimony before the Subcommittee on Health, Committee on Energy and Commerce, House of Representatives

Why GAO Did This Study

Americans depend on the Food and Drug Administration (FDA) to provide assurance that medical devices sold in the United States are safe and effective. FDA classifies medical device types into three classes, with class I including those with the lowest risk to patients (such as forceps) and class III including those with the greatest risk (such as pacemakers). FDA's responsibilities include premarket and postmarket oversight—spanning, for example, both premarket review of devices and postmarket surveillance (the collection and analysis of data on marketed devices). These responsibilities apply to all devices marketed in the United States, regardless of whether they are manufactured domestically or overseas. In 2009, GAO added FDA's oversight of medical products, including devices, to its list of high-risk areas warranting attention by Congress and the executive branch.

GAO was asked to testify on recent work related to FDA's responsibilities for medical devices, including premarket review, postmarket surveillance, and inspection of manufacturing establishments. This statement is based on a recent GAO report, *Medical Devices: FDA Should Take Steps to Ensure That High-Risk Device Types Are Approved through the Most Stringent Premarket Review Process* (GAO-09-190, January 15, 2009) and on other GAO reports and testimonies related to FDA oversight.

View GAO-09-370T or key components.
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What GAO Found

GAO found that FDA does not review all class III devices through its most stringent premarket review process. Unless exempt by regulation, new devices must clear FDA premarket review through either the 510(k) premarket notification process, which is used to determine if a new device is substantially equivalent to another legally marketed device, or through the more stringent premarket approval (PMA) process, which requires the manufacturer to supply evidence providing reasonable assurance that the device is safe and effective. In 1976, Congress envisioned that FDA would eventually approve all class III devices through the more stringent PMA process, but this process remains incomplete. GAO found that in fiscal years 2003 through 2007, FDA cleared 228 submissions representing 24 types of class III devices through the 510(k) process. GAO recommended in its January 2009 report that FDA expeditiously take steps to issue regulations requiring PMAs for or reclassifying class III device types currently allowed to enter the market via the 510(k) process. In response, in April 2009, FDA required manufacturers to submit information on the safety and effectiveness of these types of devices. However, FDA did not specify a time frame for how quickly it will reclassify them or require PMAs for those device types that remain in class III.

FDA also faces challenges in postmarket surveillance of medical devices. In 2008, GAO reported that the number of adverse event reports associated with medical devices increased substantially from 2000 to 2006. Both GAO and FDA, however, have identified shortcomings in FDA's postmarket oversight. For example, in 2006 FDA reported that the agency's ability to understand the risks related to the use of medical devices is limited by the fact that the volume of submitted reports exceeded FDA's ability to consistently enter or review the reports in a routine manner. In 2008, FDA officials told us that while they have a number of strategies to prioritize their reviews of adverse event reports, they still cannot review all the reports they receive.

Finally, GAO has found that FDA has not conducted required inspections of manufacturing establishments, another key FDA responsibility for medical devices marketed in the United States. In 2008, GAO reported that FDA has not met a statutory requirement to inspect certain domestic manufacturing establishments every 2 years. Instead, FDA officials estimated that the agency has inspected domestic establishments every 3 years (for class III devices) or 5 years (for class II devices). There is no comparable requirement to inspect foreign establishments, and FDA officials estimate that they have been inspected every 6 years (for class III devices) or 27 years (for class II devices). GAO reported that FDA has taken some steps to address shortcomings related to inspections of foreign establishments, but GAO has not evaluated whether these changes will improve FDA's inspection program.

Taken together, these shortcomings in both premarket and postmarket activities raise serious concerns about FDA's regulation of medical devices.