

Why GAO Did This Study

The Food and Drug Administration (FDA) within the Department of Health and Human Services (HHS) is responsible for overseeing the safety and effectiveness of medical devices sold in the United States. New devices are generally subject to FDA review via the 510(k) process, which determines if a device is substantially equivalent to another legally marketed device, or the more stringent premarket approval (PMA) process, which requires evidence providing reasonable assurance that the device is safe and effective. The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) authorized FDA to collect user fees from the medical device industry to support the process of reviewing device submissions. FDA also committed to performance goals that include time frames within which FDA is to take action on a proportion of medical device submissions. MDUFMA was reauthorized in 2007.

Questions have been raised as to whether FDA is sufficiently meeting the performance goals and whether devices are reaching the market in a timely manner. In preparation for reauthorization, GAO was asked to (1) examine trends in FDA's 510(k) review performance from fiscal years (FY) 2003-2010, (2) examine trends in FDA's PMA review performance from FYs 2003-2010, and (3) describe stakeholder issues with FDA's review processes and steps FDA is taking that may address these issues. To do this work, GAO examined FDA medical device review data, reviewed FDA user fee data, interviewed FDA staff regarding the medical device review process and FDA data, and interviewed three industry groups and four consumer advocacy groups.

View [GAO-12-418](#). For more information, contact Marcia Crosse at (202) 512-7114 or crossem@gao.gov.

MEDICAL DEVICES

FDA Has Met Most Performance Goals but Device Reviews Are Taking Longer

What GAO Found

Even though FDA met all medical device performance goals for 510(k)s, the elapsed time from submission to final decision has increased substantially in recent years. This time to final decision includes the days FDA spends reviewing a submission as well as the days FDA spends waiting for a device sponsor to submit additional information in response to a request by the agency. FDA review time excludes this waiting time, and FDA review time alone is used to determine whether the agency met its performance goals. Each fiscal year since FY 2005 (the first year that 510(k) performance goals were in place), FDA has reviewed over 90 percent of 510(k) submissions within 90 days, thus meeting the first of two 510(k) performance goals. FDA also met the second goal for all 3 fiscal years it was in place by reviewing at least 98 percent of 510(k) submissions within 150 days. Although FDA has not yet completed reviewing all of the FY 2011 submissions, the agency was exceeding both of these performance goals for those submissions on which it had taken action. Although FDA review time decreased slightly from FY 2003 through FY 2010, the time that elapsed before FDA's final decision increased substantially. Specifically, from FY 2005 through FY 2010, the average time to final decision for 510(k)s increased 61 percent, from 100 days to 161 days.

FDA was inconsistent in meeting performance goals for PMA submissions. FDA designates PMAs as either original or expedited; those that FDA considers eligible for expedited review are devices intended to (a) treat or diagnose life-threatening or irreversibly debilitating conditions and (b) address an unmet medical need. While FDA met the performance goals for original PMA submissions for 4 out of 7 years the goals were in place, it met those goals for expedited PMA submissions only twice out of 7 years. FDA review time and time to final decision for both types of PMAs were highly variable but generally increased in recent years. For example, the average time to final decision for original PMAs increased from 462 days for FY 2003 to 627 days for FY 2008 (the most recent year for which complete data are available).

The three industry groups and four consumer advocacy groups GAO interviewed noted a number of issues related to FDA's review of medical device submissions. The four issues most commonly raised by stakeholders included (1) insufficient communication between FDA and stakeholders throughout the review process, (2) a lack of predictability and consistency in reviews, (3) an increase in time to final decision, and (4) inadequate assurance of the safety and effectiveness of approved or cleared devices. FDA is taking steps—including issuing new guidance documents, enhancing reviewer training, and developing an electronic system for reporting adverse events—that may address many of these issues. It is important for the agency to monitor the impact of those steps in ensuring that safe and effective medical devices are reaching the market in a timely manner.

In commenting on a draft of this report, HHS generally agreed with GAO's findings and noted that FDA has identified some of the same performance trends in its annual reports to Congress. HHS also called attention to the activities FDA has undertaken to improve the medical device review process.