GAO Confirms Total Device Decision Times Taking Longer, FDA Not Meeting Some Goals

GAO conducted this study (GAO-12-418) because questions have been raised as to whether the Food and Drug Administration (FDA) is sufficiently meeting the performance goals and whether devices are reaching the market in a timely manner.

How FDA Reviews and Approves Medical Devices

The FDA oversees medical devices sold in the United States. New medical 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 premarket approval (PMA) process, which requires evidence providing reasonable assurance that the device is safe and effective. FDA designates PMAs as either original or expedited based on whether the device is intended to treat or diagnose life-threatening or irreversibly debilitating conditions and address an unmet medical need. The FDA collects user fees from the medical device industry to support the process of reviewing device submissions. As part of this agreement, FDA commits to performance goals that include time frames within which FDA is to take action on medical device submissions.

Key GAO Findings

- "FDA was inconsistent in meeting performance goals for PMA submissions. FDA review time and time to final decision for both types of PMAs [original and expedited] 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)." (summary page)

- "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…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." (summary page)

- "While FDA has met most of the goals for the time frames within the agency was to review and take action on 510(k) and PMA device submissions, the time that elapses before a final decision has been increasing." (page 40)

- "FDA is taking steps that may address the increasing time to final decision. 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." (page 40)

Performance Goals Do Not Tell a Complete Picture: The Number of Review Cycles, Requests for Additional Information, and Total Time to Final Decisions Are Increasing Substantially

"…FDA may 'stop the clock' on a 510(k) review by sending a letter asking the sponsor to submit additional information (known as an AI letter). This completes the review cycle but does not end the review process. The clock will resume (and a new review cycle will begin) when FDA receives a response from the sponsor. As a result, FDA may meet its 510(k) performance goals even if the time to final decision is longer than the time frame allotted for the performance goal." (page 7)

"For FYs 2003 through 2010, FDA met all Tier 1 and Tier 2 performance goals for 510(k)s. In addition, FDA review time for 510(k)s decreased slightly during this period, but time to final decision increased substantially. The average number of review cycles and FDA's requests for additional information for 510(k) submissions also increased during this period." (page 11)

"The average number of review cycles per 510(k) increased substantially (39 percent**)** from FYs 2003 through 2010, rising from 1.47 cycles for the FY 2003 cohort to 2.04 cycles for the FY 2010 cohort." (page 17)

"In addition, the percentage of 510(k)s receiving a first-cycle decision of substantially equivalent decreased from 54 percent for the FY 2003 cohort to 20 percent for the FY 2010 cohort, while the percentage receiving first-cycle AI requests exhibited a corresponding increase." (page 18)

"The percentage of 510(k)s that received a final decision of substantially equivalent also decreased in recent years—from a high of 87.9 percent for the FY 2005 cohort down to 75.1 percent for the FY 2010 cohort. The percentage of 510(k)s receiving a final decision of not substantially equivalent increased for each cohort from FYs 2003 through 2010, rising from just 2.9 percent to 6.4 percent." (page 19)

FDA Was Inconsistent in Meeting Performance Goals for PMAs: FDA Review Time and Time to Final Decision Generally Increased

"For FYs 2003 through 2010, FDA met most of the goals for original PMAs but fell short on most of the goals for expedited PMAs. In addition, FDA review time and time to final decision for both types of PMAs generally increased during this period. Finally, the average number of review cycles increased for certain PMAs while the percentage of PMAs approved after one review cycle generally decreased." (page 20)

"Since FY 2003, FDA met the original PMA performance goals for four of the seven completed cohorts that had goals in place, but met the goals for only two of the seven expedited PMA cohorts with goals." (page 21)

"FDA review time for both original and expedited PMAs was highly variable but generally increased across our analysis period, while time to final decision also increased for original PMAs. Specifically, average FDA review time for original PMAs increased from 211 days in the FY 2003 cohort to 264 days in the FY 2008 cohort, then fell in the FY 2009 cohort to 217 days. When we added off-the-clock time (during which FDA waited for the sponsor to provide additional information or correct deficiencies in the submission), average time to final decision for the FY 2003 through 2008 cohorts fluctuated from year to year but trended upward from 462 days for the FY 2003 cohort to 627 days for the FY 2008 cohort." (page 29)

"The results for expedited PMAs fluctuated even more dramatically than for original PMAs—likely due to the small number of submissions (about 7 per year on average). Average FDA review time for expedited PMAs generally increased over the period that user fees have been in effect, from 241 days for the FY 2003 cohort to 356 days for the FY 2008 cohort, than fell to 245 days for the FY 2009 cohort. The average time to final decision for expedited PMAs was highly variable but overall declined somewhat during this period from 704 days for the FY 2003 cohort to 545 days for the FY 2009 cohort." (page 31)

"The average number of review cycles increased for certain PMAs while the percentage of PMAs approved after one review cycle generally decreased." (page 33)

Stakeholders Noted Concerns with the Medical Device Review Process

"The industry groups and consumer advocacy groups we interviewed noted a number of issues related to FDA's review of medical device submissions. The most commonly mentioned issue raised by industry and consumer advocacy stakeholder groups was insufficient communication between FDA and stakeholders through the review process." (page 34)

"…stakeholders noted that FDA does not clearly communicate to stakeholders the regulatory standards that it uses to evaluate submissions. In particular, industry stakeholders noted problems with the regulatory guidance documents issued by FDA. These stakeholders noted that these guidance documents are often unclear, out of date, and not comprehensive." (page 34)

"Two consumer advocacy group stakeholders also noted that FDA does not sufficiently seek patient input during reviews. One stakeholder noted that it is important for FDA to incorporate patient perspectives into its reviews of medical devices because patients might weigh the benefits and risks of a certain device differently than FDA reviewers." (page 34)