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MEDICAL DEVICES

FDA Ordered Postmarket Studies to Better Understand Safety Issues, and Many Studies Are Ongoing

GAO Highlights

Highlights of GAO-15-815, a report to the Ranking Member, Subcommittee on Labor, Health and Human Services, Education, and Related Agencies, Committee on Appropriations, House of Representatives

Why GAO Did This Study

Americans depend on FDA—an agency within the Department of Health and Human Services (HHS)—to oversee the safety and effectiveness of medical devices sold in the United States. FDA's responsibilities begin before a new device is brought to market and continue after a device is on the market. As part of its postmarket efforts, FDA may order manufacturers to conduct two types of studies: (1) postapproval studies, ordered at the time of device approval, and (2) postmarket surveillance studies, generally ordered after a device is on the market.

GAO was asked to report on the characteristics and status of postmarket studies. This report describes (1) the types of devices for which FDA has ordered a postapproval study and the status of these studies, and (2) the types of devices for which FDA has ordered a postmarket surveillance study and the status of these studies. GAO analyzed FDA data—including data on medical specialty and study status as of February 2015—for (1) postapproval studies ordered from January 1, 2007, through February 23, 2015, and (2) postmarket surveillance studies ordered from May 1, 2008, through February 24, 2015. These represent the time periods for which FDA reported consistently tracking study data. GAO also reviewed documents, such as FDA guidance, and interviewed FDA officials.

HHS provided technical comments that were incorporated, as appropriate.

View GAO-15-815. For more information, contact Marcia Crosse at (202) 512-7114 or crossem@gao.gov.

What GAO Found

Fifty-six percent of the 313 medical device postapproval studies—studies that are ordered at the time of device approval—the Food and Drug Administration (FDA) ordered from January 1, 2007, through February 23, 2015, were for cardiovascular devices and most were making adequate progress. Postapproval studies are ordered to obtain additional information not available before devices are marketed, such as a device's performance over the course of long-term use. In terms of study design, 69 percent of the 313 postapproval studies ordered were prospective cohort studies—that is, studies in which a group using a particular device was compared to a second group not using that device, over a long period of time. Most (72 percent) of the postapproval studies were ongoing as of February 2015, 20 percent of studies were completed, and 8 percent were inactive because, for example, the device is no longer marketed. Ongoing postapproval studies that GAO reviewed had been ongoing for an average of a little more than 3 years; FDA considered most of them (182 studies) to be progressing adequately and the rest (43 studies) to have inadequate progress or to otherwise be delayed. According to FDA officials, a key reason for a study's delay may be limited patient enrollment in the postapproval study. On average, manufacturers completed postapproval studies in about 3 years, with the longest study taking almost 7 years, for the studies that GAO reviewed.

Ninety percent of the 392 medical device postmarket surveillance studies FDA ordered from May 1, 2008, through February 24, 2015, were for orthopedic devices and devices such as certain kinds of implantable surgical mesh following concerns with these types of devices, and many were consolidated into ongoing studies. Unlike postapproval studies, FDA may order postmarket surveillance studies at the time or after a device is approved or cleared for marketing—for example, if FDA becomes aware of a potential safety issue. Safety concerns about metal-on-metal hip implants, including potential bone and tissue damage from metal particles, led to an increase in such studies ordered in 2011. Forty percent of the 392 ordered studies were for implanted surgical mesh and other devices used in general and plastic surgery and obstetrics and gynecology procedures. FDA ordered most of these studies in 2012, following safety concerns associated with implanted surgical mesh, such as severe pain. Eighty-eight percent of the postmarket surveillance studies GAO analyzed were inactive as of February 2015. Inactive studies include those that were consolidated (108 studies), meaning that a manufacturer was able to combine an order for a postmarket surveillance study with other related study orders into a single study, such as combining studies of multiple device models into a single study; and those that were inactive for other reasons, such as if the order was for a device that is no longer marketed. The remaining 12 percent of the postmarket surveillance studies were either still ongoing (40 studies) or completed (8 studies). Of the 40 ongoing studies, more than half were progressing adequately, according to FDA, and had been ongoing for an average of a little less than 3 years; the rest were delayed and had been ongoing for an average of about 4 years as of February 2015. According to FDA, postmarket surveillance studies may be delayed for reasons similar to postapproval studies, such as difficulty enrolling patients into the study.