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Study finds information lacking from FDA on implanted medical devices

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Information is lacking on most implanted medical devices cleared by the U.S. Food and Drug Administration despite a legal requirement that companies submit scientific evidence about the devices' substantial equivalence to other devices already on the market.

Under what is known as the 510(k) review, the FDA clears about 400 implanted medical devices without clinical testing each year for market that are considered moderate to high risk. The FDA has a process that requires the applicant to provide scientific evidence that the new device is "substantially equivalent" to devices already on the market. The companies are legally required to submit the evidence to the FDA and to make publicly available at least a summary of the evidence.

The authors examined what kind of evidence companies submitted about their devices and whether it was publicly available by using FDA databases. The authors identified the first two implanted medical devices approved in each of five categories for each year from 2008 through 2012, and their sample of 50 devices included total hip implants, vascular embolization devices and surgical mesh. They also identified 1,105 "predicates," or devices already on the market, that companies listed for their devices.

Scientific data to support a claim of substantial equivalence were publicly available for 8 of the 50 (16 percent) newly cleared implants and 31 of their 1,105 (3 percent) predicate devices. Most of the evidence was nonclinical data and some of it also evaluated the safety or

effectiveness of the devices.

"For implants cleared between 2008 and 2012, however, we repeatedly found that scientific evidence of the substantial equivalence, safety or effectiveness of medical devices was not publicly available in accordance with the legal requirements. To protect the public health and allow for independent judgment of the quality of the scientific evidence that supports the marketing of medical devices, the FDA should enforce the law." Diana Zuckerman, Ph.D, of the National Center for Health Research, Washington, and colleagues said in their *JAMA Internal Medicine* article.

Post-Approval Studies to Assess Safety, Efficacy of Devices After FDA OK

Small sample sizes and delays on agreement of protocol may hinder the clinical usefulness of post-approval studies (PASs) on medical devices ordered by the FDA.

Post-market surveillance is part of evaluating the safety and effectiveness of medical devices, which typically are approved by the FDA with less clinical data than medications. One of the FDAs most important tools to do this surveillance of high-risk devices is to order PASs. The FDA has ordered hundreds of these over the past decade but a systematic evaluation of the program has not been published. The authors examined the number and characteristics of PASs ordered by the agency.

The authors gathered information from the FDA website, which is the publicly available source of information on PASs.

Between January 2005 and December 2011, the FDA ordered 223 studies of 158 medical devices, including studies for 93 (48 percent) new

high-risk devices that were approved. The median required sample size for a study was 350 patients. If a study protocol was not in place when the device was approved, a median of 180 days passed before a protocol could be agreed upon. The FDA has never issued a warning letter or a penalty because of study delays, lack of progress or any other issue related to a PAS. The most common result of a PAS finding after the study was completed was that the FDA requested a labeling change for 31 studies (53 percent). The FDA included indepth information on the PASs website for 54 of 58 completed studies (93 percent).

"Given our findings – in particular, that only 1 of 223 studies has resulted in any action other than a labeling change – we encourage the agency to work together with all stakeholders to evaluate how these studies can more effectively be used to improve the public health." Ian S. Reynolds, M.P.H., of The Pew Charitable Trusts, Washington, and colleagues said in their paper.

Commentary: Improving Medical Device Regulation, Work in Progress

In a related commentary, Elisabeth M. Dietrich, M.P.H., of the University of California, San Francisco, and Joshua M. Sharfstein, M.D., of the Maryland Department of Health and Mental Hygiene, Baltimore, write: "The mission of the FDA is to protect the public health by providing reasonable assurance that marketed medical devices are safe and effective and to promote the public health by streamlining regulatory processes and eliminating unnecessary barriers to medical device innovation. At times, the agency has rightfully been criticized for pursuing one goal at the expense of the other. In recent years, the FDA's Center for Devices and Radiological Health has been actively undertaking reforms to advance both goals simultaneously and to improve the scientific rigor of its operations. It is important to recognize and support this progress, even as the FDA's performance continues to

be monitored through research and oversight."

Viewpoint: The FDA's Unique Device Identification System, Better Postmarket Data on the Safety and Effectiveness of Medical Devices by Josh Rising, M.D., M.P.H., and Ben Moscovitch, M.A., of the Pew Charitable Trusts, Washington, also was published.

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