Most medical devices recalled because of serious risks did not undergo clinical trials

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Most medical devices recently recalled by the Food and Drug Administration because of very serious risks were initially approved through an expedited process or were exempt from regulatory review, according to a report posted online today that will be published in the June 14 print issue of *Archives of Internal Medicine*.

"Unlike prescription drugs, medical devices are reviewed by the U.S. Food and Drug Administration (FDA) using two alternative regulatory standards: (1) premarket approval, which requires clinical testing and inspections; or (2) the 510(k) process, which requires that the device be similar to a device already marketed (predicate device)," the authors write. "The second standard is intended for devices that the FDA deems to involve low or moderate risk."

Diana M. Zuckerman, Ph.D., of the National Research Center for Women & Families, Washington, D.C., and colleagues analyzed the FDA's list of high-risk device recalls from 2005 to 2009. Using FDA data, the authors determined whether recalled devices were approved by the more rigorous premarket approval process, the less stringent 510(k) process or were exempt from FDA review.

Between 2005 and 2009, 113 devices were recalled because the FDA determined those devices could cause serious health problems or death. Of these, 21 (19 percent) had been approved through the premarket approval process, 80 (71 percent) were approved through the 510(k) process and eight (7 percent) were exempt from regulation. "Of the

recalled devices cleared for market through the 510(k) process, 12 percent were marketed for risky or life-sustaining Class III indications, which are required by law to undergo a full premarket approval regulatory review," the authors write.

The high-risk recalls included devices with a broad range of clinical applications, but the most common were cardiovascular devices (31 percent). Of these, two-thirds (23, or 66 percent) were approved using the expedited 510(k) process and 12 (34 percent) were cleared through the postmarket approval process.

"The FDA's implementation of the 510(k) process has received considerable criticism from public health advocates and from other federal agencies in reports, medical journal articles and testimony before Congress," the authors write. U.S. courts have also recognized the shortcomings of the expedited process. However, the relatively small division of the FDA charged with device approvals does not receive sufficient funding from Congress to conduct premarket approval on every device, the authors note.

"When devices that were intentionally exempt from any FDA review were added to the 510(k) devices, they comprise more than three out of four of the high-risk recalls during the last five years," they conclude. "Thus, the standards used to determine whether a medical device is a high-risk or life-sustaining medical product prior to approval are clearly very different from the standards used to recall a medical device as life threatening. Our findings reveal critical flaws in the current FDA device review system and its implementation that will require either congressional action or major changes in regulatory policy."

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