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IOM Recommends Replacing the 510(k) Device Process

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The Food and Drug Administration's process for clearing moderate-risk medical devices for marketing does not ensure safety and effectiveness and should be replaced, according to a report from the Institute of Medicine.

In the report, an IOM expert panel urged the FDA not to bother tinkering with the existing 510(k) process, but instead to work with Congress to create a new system for the premarket evaluation of certain medical devices. The new process should focus on determining safety and effectiveness before products hit the market, rather than basing premarket clearance on equivalence to an existing product, the panel recommended.

Under the 35-year-old 510(k) process, moderate-risk class II medical devices do not have to go through the FDA's rigorous premarket approval process, which requires manufacturers to submit the results of safety and efficacy testing. Instead, the 510(k) process allows device manufacturers to show that their product is "substantially equivalent" to a comparable product already on the market.

But the substantial equivalence test falls short, the IOM panel said, because the majority of the devices that are used for comparison were on the market before 1976 and were never reviewed for safety or effectiveness by the FDA. The IOM pointed out that the lack of review does not mean those devices, or their equivalent follow-on devices, are not safe. But the 510(k) process itself does not allow the FDA to vouch for the safety and effectiveness of a device, they wrote.

"We recognize that we are suggesting a paradigm shift that is likely to be disquieting to a variety of constituencies," Dr. David R. Challoner, the IOM panel chair and vice president emeritus for health affairs at the University of Florida, Gainesville, said during a press briefing to release the report. "I can assure you that our committee, after careful deliberation, is firmly together on the recommendations."

At this point, the FDA has no plans to replace the 510(k) program. In a statement, FDA officials said the process should not be eliminated but they will consider other proposals to improve their device review programs. Since commissioning the IOM report in 2009, the FDA has crafted its own action plan for improving the 510(k) process and its other device review programs.

"Many of the IOM findings parallel changes that are already underway at the FDA to improve how we regulate devices," Dr. Jeffrey Shuren, director of the FDA's Center for Devices and Radiological Health, said in a statement. "These actions, plus a sufficiently funded device review program, will contribute to a

stronger program.”

The agency is planning a meeting to give the public a chance to weigh in on the IOM report and is opening a public docket to allow people to submit their comments in writing.

The medical device industry has already dismissed the IOM’s recommendations. “The report’s conclusions do not deserve serious consideration from the Congress or the Administration,” Stephen J. Ubl, president and CEO of Advanced Medical Technology Association (AdvaMed), said in a statement. “It proposes abandoning efforts to address the serious problems with the administration of the current program by replacing it at some unknown date with an untried, unproven, and unspecified new legal structure. This would be a disservice to patients and the public health.”

The current process has a number of problems, from escalating review time to inconsistency in clearance decisions, according to AdvaMed. However, the FDA’s action plan, if properly implemented, could address many of these issues, the group said.

The IOM panel did not attempt to construct a new regulatory framework for the FDA, but panel members did offer some advice. In the 280-page report, the panel wrote that the improved process should be clear, fair, and predictable. It should also be able to ensure safety and effectiveness throughout the life of a product. And it should be based on science and a device’s level of risk.

The IOM panel also called on the FDA to take action on 26 device types that are classified as “high risk,” but eligible to be cleared for the market under the 510(k) process. These include automated external defibrillators, pacemaker electrodes, cranial electrotherapy stimulators, artificial hip joints, and membrane lungs for long-term pulmonary support. The FDA should either reclassify these devices into a lower-risk category or require them to go through the more rigorous premarket approval process, the IOM panel said. The FDA is already looking at this problem and plans to complete its review and reclassification of these device types by the end of 2012.

Even before the report was released, the IOM panel and its process were under fire from critics. In June, the Washington Legal Foundation called on the FDA to disregard any advice from the IOM on the 510(k) pathway. The group filed a citizen petition arguing that the IOM panel was not “fairly balanced” because it did not include individuals with experience in areas of importance to the committee’s charge, such as product developers who are familiar with the FDA clearance process or patients who would benefit from the medical devices. Achieving balance on the committee is critical, even if it means appointing individuals with conflicts of interest, the group wrote.

The IOM said the 12 members of the 510(k) expert panel had a range of relevant expertise related to the development and regulation of medical devices, postmarket surveillance, health sciences policy, consumer protection, and FDA processes.

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