The Institute of Medicine Recommends FDA Abandon the 510(k) Premarket Clearance Process

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In September 2009, the US Food and Drug Administration (FDA or Agency) requested that the Institute of Medicine (IOM) evaluate the premarket clearance process for medical devices set forth in section 510(k) of the Federal Food, Drug, and Cosmetic Act. The IOM is the health arm of the National Academy of Sciences and serves as an independent, non-partisan organization that regularly advises federal agencies and other entities on public health matters. At the same time it commissioned the IOM to review the 510(k) process, FDA conducted an internal, parallel assessment and released its own plan to improve the current process on January 19, 2011 (5 MELR 47, 1/26/11). The plan included a number of action items and recommendations that FDA intends to implement through 2011 and beyond. Since the IOM anticipated releasing its report in July 2011, FDA delayed action and requested feedback from IOM on a number of items in FDA’s plan that had received concerned comments from stakeholders. In addition to those seven specific items, FDA asked the IOM to address two broad questions related to the 510(k) process:

- Does the current 510(k) clearance process protect patients optimally and promote innovation in support of public health?
If not, what legislative, regulatory or administrative changes are recommended to achieve the goals of the 510(k) clearance process optimally?

Conclusions and Recommendations of the IOM Report

On July 29, 2011, the IOM released its highly-anticipated report, Medical Devices and the Public’s Health: The FDA 510(k) Clearance Process at 35 Years (5 MELR 503, 8/10/11). To the surprise of both FDA and the regulated community, the IOM concluded that the current 510(k) clearance process is not well-suited to evaluate the safety and effectiveness of medical devices, and cannot be amended to adequately assess the safety and effectiveness of medical devices. The IOM committee failed to reach a conclusion as to whether the 510(k) system facilitates or inhibits innovation, citing to a lack of information on the subject.

As a result of its conclusion that the current system cannot be “fixed,” the IOM report recommended that FDA abandon the 510(k) process, which requires new Class II medical devices to show “substantial equivalence” to a predicate device in order to gain clearance for marketing, in favor of a new system focused primarily on the safety and effectiveness of the devices. As a starting point, the IOM recommended that FDA use the current de novo reclassification process—the process by which the Agency currently streamlines the review of new, low-risk medical devices that are not substantially equivalent to a marketed predicate device and would otherwise be subject to the more rigorous premarket approval (PMA) process—as a basic framework for the new system.

In addition to discussion of the PMA process, much of the IOM’s report focused on the lack of adequate postmarket information on the safety and effectiveness of medical devices. The IOM committee recommended FDA pair the new premarket clearance process with increased postmarket monitoring and enforcement to optimize the system’s effectiveness. The IOM noted that increased postmarket surveillance could lead to a more efficient and timely premarket review process.

Finally, in concert with its recommendation that FDA design a new premarket clearance process, the IOM proposed a number of specific changes to FDA’s current policies and procedures. These recommendations include:

- Instituting a continuous quality-improvement program to track regulatory decisions on medical devices, identify potential process improvements in the medical device regulatory framework, and address emerging issues that affect decision-making;
- Commissioning a separate study to determine the effect of the regulatory process on innovation in the medical-device industry;
- Updating procedures to ensure the safety and effectiveness of software used as, and in, medical devices; and
- Reclassifying or calling for PMAs on all Class III devices that remain eligible for 510(k) clearance.

IOM Response to FDA Recommendations

In addition to its full report, IOM responded separately to the seven recommendations on which FDA requested feedback from IOM in January 2011. In a letter to FDA dated July 20, 2011, the IOM committee categorized the seven recommendations into two groups that addressed the general topics of (1) increased postmarket enforcement authority for FDA, and (2) alterations to the current 510(k) framework.

In its letter, the IOM stated that FDA already has tools to address safety concerns that arise in a device’s postmarket period, but that FDA rarely uses those tools. The IOM recommended FDA identify the limitations on its current regulatory tools and seek to address those limitations. In response to FDA’s proposed alterations to the current 510(k) process, the IOM declined to give specific feedback, choosing instead to encourage FDA to use its resources to design a new premarket clearance system rather than modify the current 510(k) process.

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In many respects, the highly anticipated IOM report represents a missed opportunity to shape and focus the dialogue on the future of medical device regulation. The IOM report will invariably be an important part of the discussion regarding the efficiency and timeliness of the premarket clearance process for medical devices. However, the IOM’s recommendation to completely redesign the current 510(k) process and refusal to propose modifications to address the most pressing limitations of the current system limits its usefulness in the current dialogue.

It is unlikely that FDA will adopt the reforms recommended by the IOM. In a statement released minutes after the official publication of the IOM report, Dr. Jeffrey Shuren, director of FDA’s Center for Devices and Radiological Health, stated that “FDA believes that the 510(k) process should not be eliminated but we are open to additional proposals and approaches for continued improvement of our device review programs.” Unfortunately, it was on these precise issues that the IOM declined to comment.

FDA opened a public docket to receive comments on the IOM report, and the Agency is planning a public meeting in the coming weeks (set for Sept. 16 in Silver Spring, Md.) to discuss the conclusions and recommendations made by the IOM.

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1 Institute of Medicine, Letter to Dr. Jeffrey Shuren from Dr. David Challoner, Chair of the Committee on the Public-Health Effectiveness of the FDA 510(k) Clearance Process (July 20, 2011).