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The Institute of Medicine's Broad Recommendations for Replacing the 510(k) Clearance Process

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On July 29, 2011, the Institute of Medicine of the National Academy of Sciences released its eagerly awaited report titled, "The FDA 510(k) Clearance Process at 35 Years." The FDA had asked the Institute of Medicine ("IOM") to answer two specific questions: 1) Does the current 510(k) clearance process optimally protect patients and promote innovation in support of public health?; and 2) if not, what legislative, regulatory, or administrative changes are recommended to optimally achieve the goals of the 510(k) clearance process? The IOM committee charged with answering these questions has produced a sweeping set of recommendations, advocating the replacement of the 510(k) clearance process¹ and major changes in the way the FDA regulates and monitors medical devices. As broad as the IOM's recommendations are, they are equally short on detail, so it remains to be seen what influence the report will ultimately have on medical device regulation in the United States. Nevertheless, the IOM's call for major changes is likely to lend significant momentum to efforts by groups both within and outside of the industry to reform the FDA's approach to regulating medical devices.

IOM COMMITTEE CONCLUDES THE 510(K) CLEARANCE PROCESS IS NOT WORTH SAVING

The most surprising conclusion of the IOM report is that the 510(k) process is "not intended to evaluate the safety and effectiveness of medical devices" and "cannot be transformed into a premarket evaluation of safety and effectiveness as long as the standard for clearance is substantial equivalence to any previously cleared device." Dr. David Challoner, chairman of the IOM committee, summarized this conclusion more succinctly, calling the 510(k) clearance process "fatally flawed."² The committee attacked the substantial equivalence standard by claiming that, in practice, the assessment of substantial equivalence "generally does not require evidence of safety or effectiveness of a device." The IOM committee also noted that many of the medical devices that serve as predicate devices, to which substantial equivalence must be demonstrated, were themselves never reviewed for safety or effectiveness and pointed to the lack of good post marketing information on the safety and effectiveness of these predicate devices. The impact of this statement is startling, especially since the same committee explicitly acknowledged it "does not believe . . . that there is a public-health crisis related to unsafe or ineffective medical devices."

¹ The statutory basis of the 510(k) clearance process is found in the Food, Drug, and Cosmetic Act, 21 U.S.C. § 360.

² Andrew Seaman, "U.S. advisers call for overhaul of FDA device approval process," Reuters, July 29, 2011, available at: http://www.msnbc.msn.com/id/43943085/ns/health-health_care/t/us-advisers-call-overhaul-fda-device-approval-process/ (accessed July 29, 2011).

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IOM COMMITTEE UNCERTAIN WHETHER 510(K) CLEARANCE PROCESS FACILITATES OR INHIBITS INNOVATION

The committee essentially punted on the question of whether the 510(k) process promotes innovation in support of public health. Indeed, the committee challenges whether *promoting* innovation is even a proper mission for the FDA, asserting that the “FDA should not be the arbitrator of what constitutes innovation, nor should it seek to channel device development and premarket review toward agency-determined public-health priorities.” Instead of *promoting* innovation, the committee believes the FDA should *facilitate* innovation by “making safe and effective Class II [moderate-risk] medical devices available to consumers in a timely manner.” Interestingly, the committee simultaneously rejects industry-favored surrogate measures of innovation such as “ease of premarket review” and “relative speed to market compared with the European Union premarket process.” The committee apparently believes that the FDA could facilitate innovation by developing clear guidance and standards for the device clearance process, but notes the FDA is “persistently hindered in fully developing those materials by a lack of or limitations on human, fiscal, and technologic resources and capabilities.”

IOM COMMITTEE RECOMMENDS A NEW MEDICAL DEVICE CLEARANCE PROCESS

The committee does not recommend a revision of the 510(k) process, but rather its replacement with a new regulatory scheme for medical devices. Many of the committee’s recommendations for the new process are vague and nonspecific—e.g., the new process should be “based on sound science” and “be clear, predictable, straightforward, and fair.” However, the committee does make one specific recommendation—investigating the feasibility of modifying the current “de novo” process as a replacement for the 510(k) process, especially for Class II (moderate-risk) devices. Some low- or moderate-risk medical devices are nevertheless classified as high-risk Class III devices simply because there is no substantially equivalent predicate device currently on the market. Normally, such devices would have to be cleared under the very rigorous premarketing approval (“PMA”) protocol. The “de novo” process allows such devices to be down-classified by the FDA as Class I or II devices.³ Although no substantially equivalent devices are available to permit clearance through the 510(k) process, devices that are down-classified to Class II through the “de novo” process can be cleared for marketing, usually after a set of “special controls” are specifically developed for that device to ensure safety and effectiveness. Such special controls could include special labeling requirements, mandatory performance standards, or required postmarketing surveillance programs.⁴ The committee recommends modifying the current de novo system, conceding that the current “de novo” process is “time-consuming and difficult for both the FDA and manufacturers to navigate.” The report is short on specifics for such modifications, but does mention options such as expanded use of external expertise, more meetings with manufacturers, and the use of “conditional” clearances.

IOM COMMITTEE RECOMMENDS GREATER POSTMARKETING SURVEILLANCE

A few of the committee’s recommendations advocate the increased implementation of postmarketing surveillance programs. These programs are necessary, the committee claims, because individual medical devices are often used by a relatively small number of patients, making it unfeasible to perform large premarketing safety and efficacy studies. The committee found “substantial weakness” in the current postmarketing surveillance of medical devices and urged that more funding and a higher priority be devoted to these programs. The committee also believes that postmarketing surveillance data could help inform the design of a new regulatory framework for medical devices.

³ A brief description of the de novo process is available at: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134578.htm#denovo> (accessed July 29, 2011).

⁴ Down-classified Class I devices can similarly be cleared for marketing through the de novo process by the adoption of “general controls” such as good manufacturing processes and compliance with U.S. labeling requirements.

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IOM COMMITTEE URGES GREATER FDA SCRUTINY OF THE FDA

Perhaps one of the reasons the committee urges greater postmarketing surveillance is to provide more information so that the FDA can better scrutinize their own clearance decisions. The committee recommends that the FDA “develop and implement a program of continuous quality-improvement to track regulatory decisions of medical devices,” essentially a quality assurance program to monitor the consequences of the FDA’s clearance decisions for medical devices. The FDA is apparently far from being able to implement such a quality-assurance program, with the committee finding “inadequate information technology and management infrastructure” for tracking important medical device information. The committee urges upgrades in these areas with the ultimate goal of having the FDA develop a business model “grounded in continuous quality improvement.”

OTHER RECOMMENDATIONS

The IOM committee offers a number of other recommendations, including the appointment of a commission to study the effects of the medical device regulatory process on facilitating or inhibiting innovation in the medical device industry. The committee also recommends more agency focus on nonmechanical elements of medical devices, such as the safety and efficacy of software programs—a nod to the constantly developing technology used in modern medical devices. The committee also notes that the FDA, after 35 years, has not completed the task of determining the need to require PMAs for, or need to reclassify, Class III devices that were cleared for marketing before the 1976 Medical Device Amendments to the Food, Drug, and Cosmetic Act. The committee notes the FDA’s lack of resources for this retrofitting project, but urges the FDA to expedite completion of this task.

POTENTIAL IMPACT OF THE IOM REPORT

The IOM’s report has drawn fierce criticism from the medical device industry even before its release, and Dr. Jeffrey E. Shuren, director of the FDA’s Center for Devices and Radiological Health, is on the record in opposition to any proposal to scrap completely the 510(k) system.⁵ Congressional approval would be required for any major changes to the current medical device clearance process, and it seems highly unlikely that the 510(k) clearance process will be scrapped completely in light of both industry and FDA opposition. Nevertheless, the IOM’s unambiguous call for revising the process makes it more likely that some changes will be made to the way the FDA regulates and clears medical devices for marketing. Such revisions will require a period of public commentary, presenting a major opportunity for both industry and consumers to shape the future of medical device regulation in the United States.

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⁵ Barry Meier, “Study faults approval process for medical devices,” New York Times, July 29, 2011, available at: <http://www.nytimes.com/2011/07/30/business/study-calls-approval-process-for-medical-devices-flawed.html> (accessed on July 29, 2011).

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