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The IOM Report on Reform of the 510(k) Device Clearance Process and Beyond

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In the second step of the Food and Drug Administration's (FDA) initiative to assess and reform the 510(k) clearance process for Class II medical devices, the Institute of Medicine released its commissioned report on July 29, 2011, recommending that the FDA replace the 510(k) clearance process with a new regulatory framework. The IOM report should be noted by stakeholders for the significance of this recommendation and the extent to which it may impact the direction and scope of upcoming FDA changes to the medical device clearance process.

On July 29, 2011, the Institute of Medicine (IOM) released its highly anticipated report, "Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35 Years." The report includes the organization's controversial recommendation that the U.S. Food and Drug Administration (FDA) abandon the current 510(k) process and establish in its place a new regulatory framework for "moderate risk" Class II devices that "provides a reasonable assurance of safety and effectiveness." Although the recommendation is not expected to be adopted, stakeholders should carefully consider the extent to which the report may influence the FDA's and Congress' respective regulatory and legislative agendas, as well as the FDA's implementation of potentially significant changes to the 510(k) pre-market clearance process. The FDA will hold a public meeting on the IOM report on September 16, 2011. Comments on the report are due September 30, 2011.

Background

In September 2009, the FDA Center for Devices and Radiological Health (CDRH) undertook an initiative to explore and evaluate ways to improve the 510(k) clearance process in view of concerns raised both within and outside the FDA regarding the process. The first part of the initiative consisted of an evaluation by two internal committees convened by CDRH, resulting in the August 2010 publication of two preliminary reports that proposed actions for improving and addressing identified deficiencies in the 510(k) process. For the second part of the initiative, CDRH commissioned an independent evaluation of the 510(k) process by the IOM and initially tasked the institute with addressing two questions:

- Does the current 510(k) 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) process optimally?

Following its review of public comment on the two FDA preliminary reports, CDRH released on January 19, 2011, its 510(k) and Science Report Recommendations, as well as a plan of action to implement 25 proposed recommendations for improving the 510(k) process. The FDA stated it would implement 18 of the actions through new guidance for the FDA and industry, improved staff training and other regulatory changes to the FDA's administrative processes. Additionally, CDRH requested feedback from the IOM on seven particular recommendations as to which stakeholders raised significant concerns and which would have the greatest impact on medical device development. These seven recommendations suggested the FDA:

- Seek greater authorities to require post-market surveillance studies as a condition of clearance for certain devices
- Consider defining the scope and grounds for the exercise of CDRH's authority to fully or partially rescind a 510(k) clearance
- Clarify when a device should no longer be available for use as a predicate
- Develop guidance defining class IIb devices for which clinical information, manufacturing information or, potentially, additional evaluation in the post-market setting would typically be necessary to support a substantial equivalence determination
- Consolidate the concepts of "indication for use" and "intended use" into a single term, "intended use"
- Explore the possibility of pursuing a statutory amendment that would provide the FDA with the express authority to consider an off-label use when determining the "intended use" of a device
- Consider the possibility of requiring each 510(k) submitter to keep at least one unit of the device under review available for CDRH to access upon request

With the release of its report, however, the IOM noted that the request for consideration of these seven recommendations was made near the end of its review. Accordingly, while the IOM was unable to "study fully the seven recommendations," the report "address[es] many of the broader issues related to those recommendations … ."

The IOM Report

The most significant proposal in the IOM's report is its recommendation that the FDA replace the current 510(k) review process "as soon as reasonably possible" with a new "integrated premarket and postmarket regulatory framework." Notably, the IOM concluded that the current statutory and regulatory 510(k) framework, which uses "substantial equivalence" to a predicate device as the standard for clearance, is not designed to evaluate the safety and effectiveness of medical devices for which a 510(k) notification is submitted. Rather, in its view, the 510(k)

process set forth in the Federal Food, Drug and Cosmetic Act (FDCA) is designed only to evaluate the similarity of a new medical device to a medical device that was on the market at the time of enactment of the Medical Device Amendments (MDA) of 1976 ("preamendment" devices). Thus, according to the IOM, because such preamendment devices have never been systematically assessed to determine their safety and effectiveness, successive 510(k) clearances (*i.e.*, clearances that build upon previous predicate devices) do not constitute a determination of safety or effectiveness.

Although the IOM recommends that the FDA develop a new regulatory framework for the review of 510(k) devices, it also concludes that the FDA currently lacks the necessary information with which to develop the new framework. Therefore, the IOM suggests that the FDA should consider a modified *de novo* review process as a pilot program that can be used to gather information and experience regarding how to develop and implement a process that evaluates the safety and effectiveness of medical devices in accordance with the IOM's recommendation. Additionally, the IOM proposes a list of general features that it finds characterize the ideal medical device regulatory framework. Specifically the process should:

- Be based on sound science
- Be clear, predictable, straightforward and fair
- Be self-sustaining and self-improving
- Facilitate innovation that improves public health by making medical devices available in a timely manner and ensuring their safety and effectiveness throughout their lifecycle
- Apply relevant and appropriate regulatory authorities and standards throughout the life cycle of devices to ensure safety and effectiveness
- Be risk-based

Also significant are the IOM's recommendations regarding the FDA's post-market surveillance programs. In contrast to its proposal to overhaul the 510(k) process, the IOM's findings and recommendations regarding the FDA's post-market activities, as to which the FDA has concurred are due for reform, may be more likely to be adopted, if only in part. With regard to the FDA's current post-market surveillance system, the IOM notes shortcomings such as the fact that the regulatory obligation to investigate and report adverse events falls largely upon device manufacturers and health care facilities, and the FDA's inability to adequately integrate post-market data into the pre-market review process. The result, the IOM found, is that the FDA lacks comprehensive and reliable data on the safety and effectiveness of marketed devices. The IOM recommends that the FDA prioritize post-marketing surveillance by, for instance, more effectively utilizing existing post-market tools, integrating pre-market and post-market data systems,

improving communication with patients and providers concerning problems with medical devices on the market and identifying limitations in its post-market enforcement tools. Additionally, the IOM implores Congress to ensure the FDA's post-market surveillance programs are adequately funded, noting the past adverse effects that inadequate financing has had on the agency's efforts.

Finally, other notable recommendations of the IOM include developing a continuous quality improvement program that tracks historical 510(k) decisions and commissioning an evaluation of the extent to which the current 510(k) process promotes innovation in the medical device industry. The IOM adopts an expansive definition of "innovation" in assessing the 510(k) program, asserting the term should extend beyond the timely introduction of a new technology for an existing medical device, or evaluating the number of devices on the market, to include "improving the quality of, efficiency of, or access to healthcare."

Implications

Despite the largely critical reception the IOM report has received, stakeholders should take note of the report for its potential to influence the FDA's and Congress' respective rulemaking and legislative agendas in the months ahead, as well as the current negotiations between the FDA and industry on medical device user fees under the Medical Device User Fee and Modernization Act (MDUFMA).

More specifically, reaction to the IOM report has been swift and strong. For example, on the same day of the release of the report, CDRH signaled that it does not believe or anticipate that the statutory or regulatory foundation for the 510(k) process should or will be revamped at this time. In a press release dated July 29, 2011, CDRH Director Jeffrey E. Shuren, M.D., J.D., stated, "[w]e appreciate the IOM's report on the 510(k) program … . 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." While subsequent press reports and statements attributed to IOM committee members focused largely on the broader consensus relating to the IOM's recommendations for improvements in post-market surveillance, on August 10, 2011, two members of the IOM committee published an opinion article in the *New England Journal of Medicine*, in which they reiterated the committee's view that "the time has come for a forward-looking regulatory system [for moderate risk devices], rather than one focused on past products."

As noted above, the commission of the IOM report constitutes part of a larger initiative by CDRH to improve the transparency and predictability of the 510(k) process in response to concerns raised by industry and other stakeholders. For example, on July 27, 2011, the FDA issued a draft guidance regarding 510(k) device modifications, which sets forth revised standards and criteria for assessing when a device modification warrants a new 510(k) submission. The updated guidance will likely lead to increased submissions for device modifications and may be

indicative of the FDA's approach with respect to other initiatives in its January 2011 plan of action. Similarly, on August 15, 2011, the FDA released a draft guidance on its current expectations for the design of a clinical trial intended to support an application for pre-market approval of a high-risk device (PMA). In issuing the guidance, the FDA noted that the guidance may also be used in designing clinical trials to support 510(k) submissions. Further, on August 16, 2011, the FDA issued a draft guidance titled "Procedures for Handling Section 522 Postmarket Surveillance Studies," which relates to post-market surveillance orders issued by the FDA for marketed Class II and III devices. Among other things, the draft guidance addresses new authority under Section 522 relating to devices used in pediatric populations, and suggests the potential for greater FDA use of its Section 522 authority, as well as its enhanced expectations for post-market study plan content and reporting. To the extent the IOM report includes a discussion of issues that have relevance to items on the FDA's 510(k) reform initiative, it may be particularly worthwhile for stakeholders to submit comments to the IOM report.

Additionally, it remains unclear what, if any, actions the FDA will take on the seven more controversial recommendations it had presented to the IOM for consideration. It is likely that the FDA will continue to evaluate or pursue at least some of these proposals, the more significant of which include clarifying when a device should no longer be available for use as a predicate, developing a new Class II(b) for which clinical information will be required and the expansion of the FDA's authority to require post-market surveillance studies as a condition of 510(k) clearance. Based on the potentially far-reaching impact of any such changes on the development and marketing of medical devices, stakeholders should also consider submitting comments to the FDA on these recommendations. Finally, although the upcoming MDUFMA user fee package is considered to be a potential vehicle for legislative reforms of the medical device review program, it is unlikely in the current legislative environment that the IOM report, by itself, will have a significant impact on the MDUFMA negotiations beyond the ultimate user fee package.