FDA Law Update Blog
Current Issues Affecting FDA-Regulated Companies
Presented By SheppardMullin

Institute of Medicine Report: Dead on Arrival

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On Friday, July 29, 2011, the Institute of Medicine of the National Academies (IOM) released its long awaited report on the premarket clearance process under section 510(k) of the Federal Food Drug and Cosmetic Act.[1] The premarket clearance submission, commonly known as a 510(k), allows manufacturers to market a medical device based on its similarity, or "substantial equivalence," to one or more marketed devices (called "predicate devices"). The 510(k) process is the most widely used pathway for marketing medical devices through the U.S. Food and Drug Administration ("FDA"), and is intended for intermediate risk devices.[2] The report was anticipated to provide clear action items to the agency to strengthen the 510(k) process and make it more responsive to companies developing emerging medical technology. Instead, the recommendations made by the IOM committee only heighten the current uncertainty with the future direction of the 510(k) process.

The IOM committee was convened sixteen (16) months ago to address perceived problems with the 510(k) process based on comments from groups such as Public Citizen regarding the safety and effectiveness of 510(k) cleared devices and concerns raised following the clearance and subsequent rescission of the ReGen Biologics Menaflex Collagen Meniscus Implant.[3] The FDA tasked the IOM committee with answering the following questions:

1. Does the current 510(k) clearance process optimally protect patients and promote innovation in support of public health?

2. If not, what legislative, regulatory, or administrative changes are recommended to optimally achieve the goals of the 510(k) clearance process?

During the IOM committee's review, the FDA commenced a concurrent internal review of the 510(k) process and came to its own preliminary conclusions on ways to strengthen the existing system.[4] The FDA has started to act on its internal conclusions by developing a twenty-five (25) item action plan that the FDA hopes to implement over the course of 2011.[5] The FDA has begun to implement this action plan, as evidenced by the recent release of revised draft guidance on when a new 510(k) may be required for a change to an existing device.[6]

In publishing its action plan, the FDA expressed the hope that the IOM committee's report would help to resolve debate on some of the FDA's more controversial proposals regarding the 510(k) process.[7] There was also a hope that the IOM report would potentially bring an end to the period of self-reflection that had seemed to paralyze and significantly slow device decisions at the agency. A carefully thought out set of proposals could also help frame the discussions between FDA and industry on modifications to the 510(k) process.

The IOM's report, however, citing "the legislative and regulatory history of the 510(k) program," determined that the 510(k) process was never "designed to determine whether a new device provides a reasonable assurance of safety and effectiveness or whether it promotes innovation."[8] As such, the IOM recommended that the 510(k) process be abandoned in favor of a new process that would serve as "an integrated premarket and postmarket regulatory framework that effectively provides a reasonable assurance of safety and effectiveness throughout the device life cycle."[9] Implementing such a framework would require development by the FDA and the enactment of legislation by Congress.

There are flaws with the IOM committee's reasoning, most significant of which is their finding that substantial equivalence has no relationship to safety and efficacy. The IOM premises this on the concern that substantial equivalence only requires that devices be as safe and effective as their predicate. This ignores the fact that substantial equivalence serves as an iterative process where technological improvements in medical devices are captured as each new generation serves as the predicate for the next generation. Further, as the FDA has the ability to reclassify devices or implement special controls, it has the ability to move devices that could previously be cleared into a higher class

requiring regulatory approval (and clinical data of safety and effectiveness), or make specific testing requirements and standards mandatory on new devices.

Notwithstanding the flaws in the IOM committee's reasoning, there are no actual recommendations on what sort of model would serve in the 510(k) process's stead. The IOM committee only comments "that available information is [not] adequate to inform the design of an appropriate [replacement] framework."[10] Despite the arduous process involved with researching and developing legislation, the time required to pass such legislation, and then the efforts required to write and implement regulations and guidance to inform such legislation, the IOM committee states that "further investment in the 510(k) process is [not] a wise use of the FDA's scarce resources."1[11]

It is unrealistic to presume that the IOM committee's overall recommendations could ever be acted on, particularly in the present political environment. The recommendations, however, will serve as powerful ammunition for those seeking to severely limit industry's access to the 510(k) pathway. For its part, the FDA was critical of the report, stating that "FDA believes that the 510(k) process should not be eliminated."[12] While the FDA has opened a public docket to receive comments on the IOM committee's report, a greater concern will be the continued pressure on legislators by some groups to tighten controls over the 510(k) process or eliminate innovation-promoting aspects of the Federal Food, Drug and Cosmetic Act, such as the least burdensome provisions. Industry must continue its pressure on legislators and the FDA to encourage innovation in medical technology and its speedy introduction to patients.

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[1] The prepublication copy of the IOM's report is available on its website. IOM, Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35 Years (Washington, DC: The National Academies Press, 2011) (*available at* http://www.iom.edu/Reports/2011/Medical-Devices-and-the-Publics-Health-The-FDA-510k-Clearance-Process-at-35-Years.aspx, *hereinafter* IOM Report).

[2] Intermediate risk devices are generally categorized as Class II devices, although some Class I devices and transitional Class III devices also utilize the 510(k) process.

[3] Comments included statements such as "devices with no meaningful evidence of effectiveness that would never be approved, were they drugs, instead can be approved when they're devices," and "[t]he 510(k) process is a loophole that's swallowed the law." Ingrid Mezo, Scrutinizing 510(k)s: Critical Voices Get Heard In Congress, The Gray Sheet (July 16, 2007), at 6-7 (*quoting Peter Lurie, Deputy Director of Public Citizen's Health Research Group*).

[4] The preliminary report and recommendations are detailed in two (2) reports, CDRH Preliminary Internal Evaluations, Volume I: 510(k) Working Group Preliminary Report and Recommendations (*at* http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/UCM220784.pdf), and CDRH Preliminary Internal Evaluations, Volume II: Task Force Utilization of Science in Regulatory Decision Making Preliminary Report and Recommendations (*at* http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/UCM220783.pdf).

[5] FDA, Plan of Action for Implementation of 510(k) and Science Recommendations (*at* http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/UCM239450.pdf).

[6] FDA, Guidance for Industry and FDA Staff - 510(k) Device Modifications: Deciding When to Submit a 510(k) for a Change to an Existing Device, Draft Guidance (Jul. 27, 2011) (*at* http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm265274.htm).

[7] In announcing its action plan, the FDA commented that it planned to "give the IOM an opportunity to provide feedback" on certain recommendations before implementing

them. FDA, 510(k) and Science Report Recommendations: Summary and Overview of Comments and Next Steps (at http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/UCM239449.pdf).

[8] IOM Report at xi.

[9] IOM Report at 6.

[10] *Id.*

[11] *Id.*

[12] FDA, Press Release, “FDA to seek public comment on IOM recommendations” (Jul. 29, 2011) (*at* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm265908.htm).