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IOM Recommends Elimination of 510(k) Process

Consequences for the Defense Bar

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At the direction of the Food and Drug Administration (FDA), the Institute of Medicine (IOM)[1] recently reviewed the 510(k) clearance process for medical devices. On July 29, 2011, after a 16-month review, the IOM released its much-anticipated report titled *Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35 Years* (the "Report"), and called for the elimination of the 510(k) clearance process. This article examines the conclusions and recommendations of the Report and the process by which the IOM arrived at its conclusions. While recognizing that the Plaintiffs' bar will attempt to use the Report's conclusions to their advantage in products liability litigations, this article suggests that the Report's conclusions do not provide plaintiffs with new arguments. Moreover, the Article sets forth how defense counsel can benefit from the IOM's statements throughout the Report.

FDA's Charge

In 1976, Congress passed the Medical Device Amendments Act of 1976 (MDA) and classified medical devices into three major categories dependent on the degree of risk involved with the device and the ability of postmarket controls to manage the device.[2] (Report, 1). The MDA provided a mechanism for moderate-risk devices, not on the market at the time of the original enactment of the legislation, to be cleared for marketing by demonstrating to the FDA that the new devices were "substantially equivalent" to preamendment devices. (Report, 2). In its current form, this process, commonly referred to as the 510(k) clearance process,[3] is the way in which the "vast majority of the medical devices used in health care in the United States" are cleared for human use. (Report, xi).

Although "about one-third of devices entering the market" each year are brought to market through the 510(k) clearance process, debates about the ability of this process to produce safe and effective devices and to encourage innovation have become commonplace. (Report, 3). As recognized by the IOM, "the public, legislators, the Government Accountability Office, the Department of Health and Human Services Office of the

[1] Established in 1970, the IOM "is an independent, nonprofit organization that works outside of government to provide unbiased and authoritative advice to decision makers and the http://resources.iom.edu/widgets/timeline/index.html?keepThis=true&TB_iframe=true&height=710&width=1000;public." The IOM seeks to improve the nation's health and conducts studies mandated from Congress, federal agencies, and independent organizations, in furtherance of that goal. *About the IOM*, Institute of Medicine, http://www.iom.edu/About-IOM.aspx (last visited 8/20/11).

[2] Category I includes low-risk devices, Category II includes moderate-risk devices, and Category III includes high-risk devices.

[3] 510(k) refers to the requirement of Section 510(k) of the Federal Food, Drug, and Cosmetic Act that device manufacturers notify the FDA of their intent to market a medical device at least 90 days in advance. This time allows the "FDA to determine whether the device is equivalent to a device already placed into one of the three classification categories." *510(k) Clearances*, FDA, http://www.fda.gov/medicaldevices/productsandmedicalprocedures/deviceapprovalsandclearances/510kclearances/default.htm (last visited 8/17/11).

Inspector General, and the courts, including the Supreme Court, have all questioned the logic and value of the 510(k) clearance process." (Report, xi).

The FDA is currently conducting an internal assessment of the 510(k) clearance process to determine potential improvements. In addition to the FDA's internal efforts, in September 2009, the FDA asked the IOM to review the 510(k) clearance process, specifically directing the IOM to answer the following two 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?

(Report, 3-4).

To answer these questions, the IOM appointed the Committee on the Public-Health Effectiveness of the FDA 510(k) Clearance Process (the "Committee"). This Committee, comprised of twelve accomplished professionals in the medical, legal, and academic fields, met six times between March 2010 to January 2011. Before arriving at its conclusions and making its recommendations, the Committee reviewed the legislative history of the 510(k) process, its regulatory framework, how the 510(k) process fits into the larger medical-device regulatory framework, how the process is implemented by the FDA, available postmarket data on devices cleared through the 510(k) process, and the effect of other factors on medical-device regulation. (Report, 153).

Conclusions and Recommendations

In the Report, the Committee set forth its conclusions with respect to the FDA's two questions. Arguably, the Committee only implicitly answered a portion of the first question, and failed to respond to the second question entirely. In fairness to the IOM, the FDA was unclear in its use of the term "optimally," as it did not indicate if the IOM was to interpret this term in the context of the competing interests of the medical device industry or if it was asking the IOM to determine if the 510(k) process was the *best possible* way to protect patients and promote innovation.

With respect to the first part of question one, whether the current 510(k) clearance process optimally protects patients, the Committee did not provide a specific answer. Rather, it stated that the 510(k) clearance process was not designed to evaluate the safety and effectiveness of medical devices, with limited exceptions. (Report, 156). The Committee offered its additional conclusion that the 510(k) process "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." (Report, 156). The latter conclusion amounts to the Committee's implicit statement that the 510(k) process does not optimally protect patients because it does not evaluate safety and effectiveness.

Turning to the second part of question one, whether the 510(k) process promotes innovation in support of public health, the Committee concluded that information did not currently exist from which conclusions could be drawn as to whether the 510(k) clearance process facilities or inhibits innovation. (Report, 158).

In the second question, the FDA asked the Committee to provide recommendations for changes that would "optimally achieve the goals of the 510(k) clearance process." As a result of its conclusion that further investment in the 510(k) process was not a wise use of the FDA's limited resources, the Committee did not recommend specific changes to the 510(k) process. (Report, 6). Instead, it offered eight recommendations for developing an entirely new regulatory framework for Class II medical devices and to address "problems with other components of the medical-device regulatory framework." (Report, 6). In abbreviated form, the Committed offered the following recommendations to the FDA:

1. Develop an "integrated premarket and postmarket regulatory framework" for Class II medical devices that will provide "reasonable assurance of safety and effectiveness throughout the device life cycle;"

2. Develop a "'comprehensive strategy' to collect, analyze and act on medical device postmarket performance information;"

3. Review its postmarket regulatory authority for medical devices to identify and remedy potential limitations;

4. Investigate utilizing a "modified de novo process as a mechanism for evaluating the safety and effectiveness of Class II devices;"

5. Develop "a program of continuous quality-improvement" that will allow the FDA to "address emerging issues that affect decision-making;"

6. Commission another study to determine if and how the regulatory process for Class II devices either facilitates or inhibits innovation;

7. Develop procedures to "ensure the safety and effectiveness of software used in devices, software used as devices, and software used as a tool in producing devices;"

8. "Call for PMA [Premarket Approval] applications for or reclassify Class III devices that remain eligible for 510(k) clearance."

(Report, 158-165).

An overriding problem with the Committee's recommendations for a new regulatory framework stems from the fact that the Committee does not clearly provide if its recommendations are intended to address the goals of the 510(k) process as articulated by Congress or the goals of the FDA. This shortcoming is even more pronounced in light of the Committee's express recognition in the Report that the FDA's goals for the 510(k) process are very different than Congress' purpose in enacting the process. (Report, 154). Another problem with the Committee's recommendations is the IOM's apparent belief that the FDA should use its limited resources to develop an entirely new regulatory framework, without any assurance that Congress will ever enact legislation to make that framework a reality.

FDA Reaction to IOM Report

In response to the IOM Report, the FDA issued a news release the day the Report became publicly available. The FDA disagreed with the IOM's ultimate conclusions, stating "that the 510(k) program should not be eliminated." News Release, FDA, FDA to Seek Public Comment on IOM Recommendations (July 29, 2011), *available at* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm265908.htm. Jeffrey Shuren, M.D., director of the FDA's Center for Devices and Radiological Health, expressed the FDA's continued confidence in the 510(k) process, emphasizing that "[m]edical devices in the U.S. have a strong track record of safety and effectiveness" and that the 510(k) clearance process "has helped support a robust medical device industry in the U.S. and has helped bring lower-risk devices to market for the patients who need them." *Id.*

The FDA further explained that many of the IOM's recommendations paralleled changes that are already underway. These changes are part of the FDA's commitment to "an aggressive action plan" designed to improve the 510(k) process and device review programs in general, and resulted from the FDA's internal assessment of the 510(k) program.

The FDA has opened a public docket to receive comments on the IOM Report. On September 16, 2011, it will also hold a public meeting to discuss the IOM's recommendations.

Use of Report in Litigation

Plaintiffs will undoubtedly attempt to use the IOM Report to their advantage, calling attention to the Committee's conclusion that the 510(k) process must be replaced because it is not designed to evaluate the safety and effectiveness of medical devices. Although defense counsel should anticipate these arguments based on the Report, they are not new weapons in plaintiff counsel's arsenal, as plaintiffs' experts routinely emphasize the shortcomings of the 510(k) process. In fact, the Supreme Court in Medtronic, Inc. v. Lohr, 518 U.S. 470, 493 (1996), commented that the 510(k) process "'focused on *equivalence*, not safety.'" (citation omitted).

Moreover, there are findings in the Report that will benefit defense counsel in products liability litigations. Despite the ultimate conclusions of the Report, the Committee repeatedly makes statements indicating its confidence in the safety and effectiveness of medical devices currently on the market and cleared through the 510(k) process. For example, when setting forth its conclusions and recommendations, the Committee clarified that it was "not suggesting that all, many, or even any medical devices cleared through the 510(k) clearance process and currently on the market are unsafe or ineffective," but only that there was an inadequate basis on which to offer "highly confident conclusions about the safety and effectiveness of 510(k) cleared medical devices." (Report, 156). In another instance, the Committee provided that it did "not believe that there is a public-health crisis related to unsafe or ineffective medical devices," and that the continued use of 510(k) cleared medical devices in clinical practice "provides at least some level of confidence in their safety and effectiveness." (Report, 155).

Additionally, the Committee specifically noted that there are significant limitations when relying on recall data of 510(k) products as an indicator of the safety and effectiveness of medical devices. This recognition by the IOM lends support to defense counsel's arguments against plaintiff's attempts to exploit this data.

Conclusion

At first glance, the conclusions of the Report do appear controversial. However, upon further review, it becomes clear that the conclusions of the Report will not arm the plaintiff's bar with novel arguments and that prepared defense attorneys can even utilize portions of the Report to their advantage.

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