Implications of I.O.M.

Wednesday, August 03, 2011

The other day, the Institute of Medicine came out with its long-awaited – and it seems to us, rather short on specifics – report, "Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35 Years," on the FDA's §510k "substantial equivalence" clearance process for (some/most) medical devices. Here's a link to the report on the IOM's website, where it is available for free, either to read or download. We're not going to try competing with the FDA wonks on this one. If you're interested in the product development/administrative/policy aspects of what the IOM recommended, we suggest that you go to someplace like the FDA Law Blog.

The IOM's major recommendation is to ditch the §510k process altogether. We're not going to discuss whether doing that is, a good idea (because that might make some devices safer) or a bad idea (because that might make a lot more devices more expensive and slower to get to market). We're product liability lawyers, so we're interested in what the impact of the recommendations might be on medical device litigation.

Anyway, if we're doing free association, and the term were "510k medical device," our response would undoubtedly be "Lohr" – as in Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996) – yeah, we're lawyers, we're weird that way. Lohr was decided in the midst of the Bone Screw litigation craziness, and we had just won a major ruling that blew out probably 90% of that litigation on preemption grounds. See In re Orthopedic Bone Screw Products Liability Litigation, 1996 WL 221784 (E.D. Pa. April 8, 1996). Less than three months later, along comes Lohr and holds that there's no preemption in §510k cases. Aside from everything else, that cost our client another five years of litigation, and tens of millions of dollars in legal fees, before we finally won that MDL the hard way, with over 180 post-remand summary judgment motions (and Buckman), and several decisive state-court rulings.

So the Lohr decision occupies a very special position in our personal ninth circle of litigation hell. And Lohr is founded in large part upon its evaluation of the §510k process as largely unrelated to device safety:

The company's defense exaggerates the importance of the §510(k) process and the FDA letter to the company regarding the [product's] substantial equivalence to a grandfathered device. As the court below noted, "[t]he 510(k) process is focused on equivalence, not safety." As a result, substantial equivalence determinations provide little protection to the public. These determinations simply

compare a post-1976 device to a pre-1976 device to ascertain whether the later device is no more dangerous and no less effective than the earlier device. If the earlier device poses a severe risk or is ineffective, then the later device may also be risky or ineffective." The design of the [product], as with the design of pre-1976 and other "substantially equivalent" devices, has never been formally reviewed under the MDA for safety or efficacy.

Lohr, 518 U.S. at 492-93 (various citations and quotation marks omitted).

More recently, the Supreme Court in Riegel v. Medtronic, Inc., 552 U.S. 312 (2008), distinguished Lohr and held that where the FDA does, in fact, conduct "safety review," such review does impose "requirements" within the meaning of the express preemption clause of the Medical Device Amendment – so there is preemption:

Premarket approval, in contrast, imposes "requirements" under the MDA as we interpreted it in Lohr. . . . [I]t is in no sense an exemption from federal safety review-it is federal safety review. Thus, the attributes that Lohr found lacking in § 510(k) review are present here. While §510(k) is "focused on equivalence, not safety," id., at 493, premarket approval is focused on safety, not equivalence. While devices that enter the market through §510(k) have "never been formally reviewed under the MDA for safety or efficacy," ibid., the FDA may grant premarket approval only after it determines that a device offers a reasonable assurance of safety and effectiveness. And while the FDA does not "require" that a device allowed to enter the market as a substantial equivalent "take any particular form for any particular reason," ibid., at 493, the FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness.

Riegel, 552 U.S. at 323 (also removing citations and quote marks).

The IOM recommends changing all that. It proposes the elimination of the "substantial equivalence" process found non-preemptive in Lohr and its replacement with a safety-oriented system that has many of the same attributes of the PMA system described in Riegel. Specifically:

- 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. IOM Report Conclusion 7-1.

- The thresholds [for device approval] should be stringent enough to satisfy the agency's objective of ensuring that marketed medical devices will be safe and effective throughout their life cycles. Id. at 158.

- [T]he current 510(k) process . . . [should] be replaced with an integrated premarket and postmarket regulatory framework that effectively provides a reasonable assurance of safety and effectiveness throughout the device life cycle. Id. Recommendation 7-1

- It is essential that the new regulatory framework be based on sound science. . . . The FDA should carefully consider what types of evidence are necessary to demonstrate a reasonable assurance of safety and effectiveness in the new framework. Id. at 158-59.

- The FDA should . . . be clear that its role in facilitating innovation in medical devices is to develop regulatory thresholds that are rigorous enough to satisfy the agency's primary objective of ensuring that marketed medical devices will be safe and effective throughout their life cycles. Id. at 159.

- The [new approval] process should be based on sound science[,] . . . apply relevant and appropriate regulatory authorities and standards throughout the life cycle to ensure safety and effectiveness[, and] should be risk-based. Id.

- The Food and Drug Administration should investigate the viability of a modified de novo process as a mechanism for evaluating the safety and effectiveness of Class II devices. Id. at Recommendation 7-4.

To paraphrase Riegel – these proposals look like a form of "safety review" to us. They appear to do what Riegel says the FDA has to do for there to be express MDA preemption. The proposals focus on safety without any reference to equivalency. The "new framework" would condition approval on "reasonable assurance of safety and effectiveness." And the IOM's "standards" seem to be mandatory, given its "primary objective" of ensuring safety.

So as lawyers trying to win cases, as opposed to business people trying to get new products approved as efficiently as possible, we're favorably inclined towards at least some of the IOM's proposals. To replace the §510k process with the IOM's proposals seems to us to be the same thing as replacing Lohr with Riegel – and we're all for that.

Finally, on a completely different point, we were also impressed with the IOM's discussion of off label use. Report at 78-80 (yeah, we actually did at least skim the whole blasted thing). There's background information in here – the discussion of "intended use" in particular – that we think could be useful in mounting a First Amendment challenge to the FDA's prohibition against truthful off-label promotion.