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EDITORIAL

Time to Scrap the U.S. System of Medical Device Regulation?

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Last summer, a U.S. Institute of Medicine (IOM) panel said in a report that the U.S. Food and Drug Administration (FDA) should abandon its 35-year-old process of clearing medical devices. The FDA, which had 2 years previously asked the IOM experts for their ideas on how to improve the system, promptly dismissed the idea of scrapping it.

This comes as no surprise to those who view the *modus operandi* of the Food and Drug Administration as a crisis-legislation-adaptation cycle: a public health crisis prompts Congress to pass legislation, which the FDA then implements.[1] Because most crises have involved drugs and not devices, the approval processes are not comparable. New drugs must undergo clinical trials to show that they are safe and effective, yet most devices must show only that they are similar to other safe and effective devices in what is known as the 510(k) process. That process, created in 1976 to "grandfather in" devices that long had been used safely, became the standard for new device clearance.

The IOM panel said that this relatively streamlined 510(k) process is inadequate to protect patients. Yet manufacturers complain that FDA is too slow in clearing new devices, which drives up costs for companies and may force smaller companies out of business.

A recent technology report commented that while new technology continues to grow, FDA funding has lagged behind.[2] About 4,000 devices are cleared every year under 510(k) while only 50 are cleared under the more rigorous, more expensive premarket approval (PMA) application process for high-risk or original devices. The clinical trial requirement for a PMA is often met by a small study of a select group of patients.[3] The cost to the FDA for the PMA is about $800,000 per device, yet the 2012 standard fee for application processing is just $220,050 ($55,013 for small businesses).[4] While other fees may apply, in an era of budget cuts it is easy to see how there might be a financial disincentive to requiring a more rigorous process for certain medical devices.

However, even the 510(k) seems like overkill when the threat to patient safety appears minimal. Especially troubling to this author is the new Draft Guidance for Industry and Food and Drug Administration Staff—Mobile Medical Applications.[5] Although final guidance has not been issued at the time of writing, and although guidance does not have the force of law, manufacturers ignore such guidance at their peril if they wish their device to be cleared.

As *Telemedicine and e-Health News Alert* reports, "The Draft Guidance applies to mobile medical apps that meet FDA's definition of a medical device and 1) are used as an accessory to a regulated medical device; or 2) transform a mobile platform into a regulated medical device. For example, an app that analyzes glucose content in the blood of people with diabetes would have to obtain 510(k) premarket notification approval from the FDA. An app that allows users to simply write down their glucose readings or other numbers would be exempt."[6]

The FDA argues that a flawed mobile application could result in a misdiagnosis and consequent harm to the patient. In reality, few physicians would rely solely on a smartphone app for such an important facet of their practices. Meanwhile the developers of such apps will have to wait almost 5 months, the average time for 501(k) clearance, between development and marketing of their applications.

In the European Union, medical device manufacturers were not required to submit clinical data to show effectiveness until a 2010 directive took effect. However, most EU countries have additional regulations that require data showing effectiveness and perhaps cost effectiveness—not to be licensed (a process similar to FDA clearance), but to be covered as a benefit.[7] Similarly, the Centers for Medicare and Medicaid (CMS) in the United States have adopted a policy that requires patient enrollment in clinical trials supported by the device developers so that CMS can make an evidence-based determination that coverage is "reasonable and necessary."[3]

Therefore, it behooves those of us involved in medical device development to both conduct cost-effectiveness studies and participate in the political process by commenting on draft regulations. Only when all of us are engaged in changing policies that affect our livelihoods can the future of medical device technology be assured.

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