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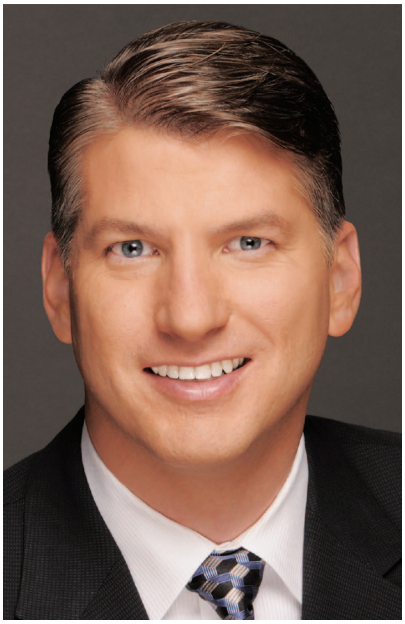

ROCKY ROAD

510(k) pathway not providing proper protections

By THOMAS A. DEMETRIO and KENNETH T. LUMB

According to the federal government, the U.S. remains the largest medical device market, with a market size of $156 billion in 2017 and a projected size of $208 billion by 2023, according to SelectUSA. The number of medical devices on the market is rapidly increasing, but the regulatory safety net that is supposed to protect patients from ineffective, dangerous, and defective products has a glaring hole in it, known as the 510(k) pathway.

Like prescription drugs, medical devices are regulated by the FDA. The medical device regulatory scheme, however, consists of three regulatory paths based on the relative perceived risk of the proposed device. Class III devices sustain or support life or present a significant risk of illness or injury. The devices require premarket FDA approval and must be supported by data and clinical trials.

Class I devices are simple ones defined as low-risk and most are exempt from any regulatory process at all. It is the Class II devices that are the Achilles' heel of the regulatory process. Class II devices are ostensibly also only simple devices — like surgical masks — that present some risk. As such, they are not subject to premarket approval by the FDA, but only premarket notification by the manufacturer to the FDA. This is the 510(k) pathway, after the relevant section in the Code of Federal Regulations.

In 510(k) premarket notification, the manufacturer is supposed to demonstrate the safety and efficacy of its device. But, this does not necessarily require any properly designed clinical trials. On the contrary, the 510(k) pathway relies primarily upon a showing of "substantial equivalence." That means having the same intended use and substantially similar characteristics as a device already legally on the market. The latter device is known as the predicate. If a manufacturer can demonstrate "substantial equivalence" to an existing product, no clinical data is required.

Though intended for products with a low risk of substantial patient harm, in practice this track is used for many devices with significant risks. This was exacerbated by the passage in 2002 of the Medical Device User Fee and Modernization Act, which allowed approval based on substantial equivalence to any number of predicates, regardless of whether the new device used the same materials or was for the same indication as the predicate device.

In early 2021, the FDA issued a Class I recall (the most serious kind) of the JET 7 reperfusion device, manufactured by Penumbra, due to the risk of injury or death from the device's susceptibility to damage. The JET 7 is a large-bore catheter used to extract clots and achieve recanalization after ischemic stroke. According to Kushal Kadakia, et al., writing in JAMA Internal Medicine, the FDA cleared the first Penumbra device, the Penumbra System, in 2007. At that time, it was one of only two devices cleared for marketing to treat ischemic stroke.

As Kadakia and colleagues report, the device was cleared using the 510(k) pathway with no clinical evidence required. The predicate device was the Merci Retriever, which itself had been cleared under 510(k) using another predicate device that actually had a different indication.

The JET 7, part of the system that was the result of a dozen different changes since 2007, began racking up adverse event reports soon after clearance. The first known patient death occurred just 4 months after clearance. More than 200 adverse event reports followed — all of which hinders clot removal and risks puncturing patients' arteries. The ultimate recall, Kadakia writes, came about because an activist investor sounded the alarm over patient deaths.

There is no question the manufacturer of these products is liable for the harm they cause. Because the FDA does not actually make a premarket determination of safety and efficacy under the 510(k) process, federal law does not preempt state tort law and manufacturers can be sued under state tort theories. But the manufacturer, who will remove most cases to federal court, is not the only culpable defendant.

Physicians who use the devices are arguably on notice that they come to market with no legitimate clinical evidence that the benefits outweigh the risks. How can a surgeon properly counsel a patient regarding the risks/benefits of a particular hip or knee implant if they are unproven?

Hospitals that purchase the devices may be just as culpable. Though medical facilities generally purchase the devices their surgeons request, don't the former have a duty to protect their patients from dangerous or unproven devices? Hospitals also have a responsibility to ensure each patient has informed consent before any procedure, which is impossible without access to the relevant information to make an informed choice. CL

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