MAY 2019

A PUBLICATION OF LAW BULLETIN MEDIA

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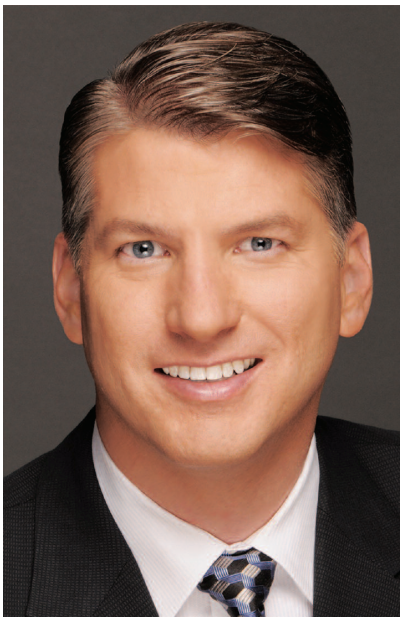

BEYOND MAUDE

The FDA has vast, hidden databases on medical devices

By THOMAS A. DEMETRIO and KENNETH T. LUMB

Medical devices are regulated in the U.S. by the Food and Drug Administration pursuant to the Medical Device Regulation Act of 1976 and the Food, Drug and Cosmetics Act of 1938 and by their implementing regulations.

The FDA's regulatory scheme consists of three regulatory paths based on the relative perceived risk of the proposed device. Class I devices are very simple devices defined as low-risk and most are exempt from any regulatory process at all.

Class II devices are also supposed to be simple devices but may have higher potential risks. They are subject to premarket notification — known as 510(k) notification — to demonstrate safety and efficacy, a requirement that can be satisfied simply by showing substantial equivalence, that is, having the same intended use and substantially similar characteristics as a device already legally on the market.

Class III devices sustain or support life or present a significant risk of illness or injury. These devices require premarket approval by the FDA which must be supported by a significantly more information, including clinical data.

Premarket notification or approval, however, is only part of a manufacturer's regulatory responsibility. To protect patient safety, manufacturers are also supposed to monitor the safety of their devices after they are sold.

To that end, the FDA maintains the Manufacturer and User Device Experience, or MAUDE, database. The MAUDE database houses medical device reports submitted to the FDA by mandatory reporters such as manufacturers, importers and device user facilities and voluntary reporters such as health-care professionals, patients and consumers.

These reports are supposed to be publicly available to provide information for manufacturers, researchers and government regulators regarding specific device malfunctions and unintended effects, but also to illustrate patterns or trends that may indicate a potential safety problem.

Though some would argue that post-market surveillance fails to adequately protect patient safety even when it works as intended, recent reporting by Christina Jewett of Kaiser Health News website illustrates that the system is badly broken and is not working as intended.

The website found the FDA has created and expanded a vast and hidden repository of reports on medical device related malfunctions and injuries, shielding millions of reports from public view.

Kaiser Health News uncovered this repository by examining public records for cryptic or "oblique" references to reporting exemptions. After "months of questions" to the FDA, the agency eventually admitted the existence of reporting-exemption programs and "thousands of never-before-acknowledged instances of malfunctions or harm."

For instance, an internal "alternative summary reporting repository" has allowed manufacturers to secretly report more than 1.1 million incidents since 2016. Under this program, deaths must still be reported to MAUDE, but, according to the FDA, the hidden database includes reports regarding serious injuries and malfunctions for about 100 different devices, including surgical staplers, balloon pumps and mechanical ventilators.

In another extremely obscure program, the FDA has allowed manufacturers to report thousands of injuries and even deaths to private registries used by medical societies, in lieu of public MAUDE reporting. These programs, created without any public notice or formal regulatory amendment, allow any device maker to request an exemption. Exemptions apply even to "risky and controversial" products, according to Kaiser Health News, including pelvic meshes.

The alternative summary reporting system was launched in 2000, in an effort to reduce the paperwork regarding thousands of similar or identical incidents. Instead of filing individual reports, a manufacturer with an exemption could send the FDA a quarterly or yearly spreadsheet listing injuries or malfunctions. The original list of exemptions included only a few devices and was made public.

In the last two decades, however, the program has metastasized, providing secrecy and cover for injury and death reports related to some of the most controversial products on the market, including pelvic mesh, surgical staplers and the da Vinci surgical robotic system.

According the Kaiser Health News, there is little, if any, awareness of the exemptions outside the FDA. Physicians, medical device and patient safety experts, and even former FDA officials interviewed by the website, were all shocked when informed of their existence.

Armed with this new knowledge, trial lawyers handling medical device cases should seek out lists of exemptions for relevant devices or manufacturers, alternative summary reports and any other nonpublic reports through discovery and Freedom of Information Act requests. In litigation, forewarned is forearmed. CL

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