

IN EVERY ISSUE

# Medical Devices Face Stricter Regulations

BY JO CAVALLO

In January, the Government Accountability Office issued a report to Congress chastising the Food and Drug Administration for not moving fast enough in implementing stricter regulations in its approval process of Class III medical devices.

Class III-designated devices, which support or sustain life and carry the highest level of risk to consumers, undergo the most rigorous regulatory review and include products such as MammoSite, a radiation therapy system used in early-stage breast cancer patients, heart valves, and silicone gel-filled breast implants. (The da Vinci Surgical System, used in the treatment of prostate and other cancers, is classified as a Class II device, which like a Class III device gets close regulatory scrutiny but does not require premarket approval.)

Unlike new drugs, not all medical devices require human trials and may go directly from laboratory to marketplace. But before Class III devices can be cleared by the FDA for public use they must go through either a 510(k) premarket notification process, which determines whether a new device is substantially equivalent to another legally marketed product, or the stricter PMA (premarket approval) process, which requires that the manufacturer provide evidence that the device is safe and effective.

The GAO report faulted the FDA for not applying the PMA process to all Class III devices, which it was instructed to do in 1990 after a law was passed requiring the FDA to either reclassify Class III devices to a lower designation or establish deadlines for when Class III devices would have to undergo the PMA process.

Some medical experts wonder, however, whether requiring that all Class III medical devices be subjected to the more time--intensive—and costlier—PMA process will stall progress and delay getting new devices to clinicians and ultimately to patients.

“There is no [approval] system that is going to be 100 percent perfect,” says Howard M. Sandler, MD, chair of radiation oncology at Cedars-Sinai Medical Center in Los Angeles and spokesperson for the American Society for Radiation Oncology. “Manufacturers have a strong interest in having their devices go through the speedier and less expensive 510(k) process, and the FDA does its best to apply the rules in a uniform way. And in a minority of cases, the end result may not be ultimately satisfactory. But the vast majority of medical devices are approved appropriately and I worry that a dramatic tightening of the device

approval process will lead to a dramatic reduction in device innovation.”

Sandler cites the controversy surrounding MammoSite, which was cleared under the 510(k) premarket notification process to treat early-stage breast cancer in just five days instead of the six weeks typically required for conventional radiation therapy. Using the standard for new drug approval, which could take 10 to 15 years to complete, new devices like MammoSite, says Sandler, might never reach patients.

“Maybe in some abstract way to get to the truth we would require that kind of clinical trial to be completed and analyzed before a medical device is approved. On the other hand, there’s reasonably good evidence in carefully selected women that MammoSite works as well as six weeks of external beam radiation therapy.”

According to the FDA, most of the Class III devices in question have either already gone through the PMA process or have been reclassified. Peper Long, FDA spokesperson in the Center for Devices and Radiological Health, says the agency is now putting together the procedural steps to notify the remaining manufacturers to submit a PMA for their Class III devices or risk reclassification of their products.

The bottom line: Be an informed health consumer, says Sandler, and ask your doctor about the safety and effectiveness of any medical device prescribed for you.