Medtronic in FDA Consent Decree Over Its SynchroMed Infusion Pump

Medtronic agrees to stop widespread distribution of the product

By Thomas M. Burton  The Wall Street Journal

Federal authorities reached a proposed consent agreement with medical device maker Medtronic Inc. over flaws in its SynchroMed drug-infusion pump for cancer and pain medicine, a device that has been linked to serious injuries and deaths in recent years.

The Justice Department, working with the Food and Drug Administration, filed the consent decree along with a legal complaint alleging that Medtronic and two executives—Chairman and Chief Executive S. Omar Ishrak and Senior Vice President Thomas M. Tefft—have distributed “adulterated” devices. The complaint alleges that the pumps weren’t manufactured in accordance with current good manufacturing processes.

Asked if Medtronic admits the allegations in the government complaint, a Medtronic spokeswoman, Cindy Resman, said, “We’re addressing these issues, and we’re agreeing to these specific steps” to remedy the problems.

Under the proposed decree, Medtronic agreed to stop manufacturing and distributing new versions of the SynchroMed II implantable pump except in extraordinary cases, such as when a treating physician certifies that the pump is medically necessary. The device also dispenses medicine to alleviate severe chronic spasticity.

The government alleges that the Minneapolis device maker repeatedly failed to correct violations of FDA quality regulations. Inspections in 2006 and in 2013 uncovered what the government termed “significant violations” of quality regulations, such as those related to complaint handling, corrective and preventive action. Such measures are supposed to ensure that a malfunction leading to injury or death gets investigated, and that changes are made.

In 2012, the FDA issued a warning letter to Medtronic that cited the company for failing to correct problems with the devices, including their potential to stall due to motor corrosion and to fail to deliver medication.

The company won’t be allowed to resume widely distributing the SynchroMed II pump system until it gets permission from the FDA. Medtronic said the SynchroMed system has been used in more than 230,000 patients since it was introduced more than 25 years ago.

The company stressed that it can continue to provide doctors with access to the device. “For patients needing a replacement drug infusion pump, Medtronic is required to collect a physician
certification before providing” the device, Medtronic said. “For new patients, Medtronic is required to collect physician medical necessity certification before providing a SynchroMed drug infusion pump.” It said that “efforts are well under way to address issues included in the consent decree.”

In 2013, Medtronic notified physicians of four potential defects with the pump and said that 14 deaths were associated with SynchroMed. Most took place when patients either were deprived of medication and entered withdrawal, or after overdoses.

All four issues with the device were classified by the FDA as Class 1 recalls, a status meaning that they can lead to serious injury or death. The company said 11 of the deaths occurred from 1996 through April 2013.

Before the agreement becomes final, a federal judge needs to sign off on terms of the decree, which was filed in U.S. District Court in Minnesota. Government officials said in the court filings that FDA inspectors “repeatedly observed and documented violations” of federal quality regulations.

“Defendants promised corrections at the conclusion of each inspection,” government attorneys wrote. “FDA has repeatedly warned” Medtronic and its executives of violations, the government said.

The government, in court filings, said several responses from the company promised corrections, but that “none of these responses contained adequate evidence that Defendants [Medtronic and its officials] have corrected their deviations.”