Markey, Merkley Call on FDA to Reform Medical Devices Databases

Today, Representative Edward J. Markey (D-Mass.) and Senator Jeff Merkley (D-Ore.) sent a letter to the Food and Drug Administration (FDA) calling on the agency to overhaul and streamline the federal databases that provide information to the public about the safety of medical devices that rarely undergo clinical trials in humans before being sold on the market. In the absence of legislation that would close the current loophole in federal law that allows defective devices to enter the market and jeopardize patient safety, the lawmakers are urging reforms be made immediately to the FDA's main medical device databases. The updates would provide device manufacturers, the public, and medical professionals with better information about devices recalled for serious design flaws and to help avoid future injuries.

In February, Reps. Markey, Henry A. Waxman (D-Calif.), Jan Schakowsky (D-Ill.), and Rosa DeLauro (D-Conn.) introduced H.R. 3847, the Safety Of Untested and New Devices Act of 2012 (SOUND Devices Act) [1]. The legislation closes the major loophole in the 510(k) device approval process by allowing FDA to reject an application for a new device if it was modeled after an earlier product that was pulled from the market for causing serious harm to patients. The legislation is pending in the House of Representatives.

"These database improvements would enhance the transparency of the 510(k) process and help manufacturers avoid using recalled devices as predicates that may put their own devices at risk for future enforcement action," write Rep. Markey and Senator Merkley in the letter to the FDA. "These changes would also enhance awareness among the public and medical professionals of the potential dangers of medical devices that are based on flawed predicates."

A copy of the letter to the FDA can be found HERE [2].

The federal loophole in the 510(k) device approval process – named after its section in the law –requires the FDA to clear medical devices that demonstrate their similarity to an earlier model, even if that previous model was recalled for a major safety defect. This loophole has enabled a number of defective products, such as bladder mesh implants, to enter the market and cause serious harm, and in some cases even death. The updates to the 510(k) databases requested by the lawmakers would reflect if a medical device was subject to a recall due to a design flaw, as well as if the medical device was cleared by the FDA on the basis of a previous design that was recalled for a serious flaw.

In the letter to the FDA, Rep. Markey and Senator Merkley request responses to questions that include:

- Is the FDA willing to update its 510(k) database so that it clearly indicates devices that have been recalled for serious design flaws that could adversely affect safety or effectiveness?
- Will the FDA update the database within 30 days after completing its review of a manufacturer's root-cause analysis that concludes that a flaw triggering the recall was a serious one that could adversely affect safety or effectiveness?
- Will the FDA include in the database past recalls clearly marked for serious design flaws that could adversely affect safety or effectiveness, so device manufacturers and the public have comprehensive information about problematic predicates?
- Is the FDA willing to revise its 510(k) Premarket Notification database to notify the public that a certain product repeats the same design flaw that caused a predicate's recall?

Links:
[1] http://markey.house.gov/press-release/markey-waxman-schakowsky-delauro-introduce-legislation-close-loophole-flawed-medical
[2] http://markey.house.gov/document/2012/letter-fda-501k-database