

Markey To Call for Closure of Dangerous Medical Device Loophole

WASHINGTON, D.C. – Today, Congressman Edward J. Markey (D-Mass.), a senior member of the Energy and Commerce Committee, which has jurisdiction over the Food and Drug Administration (FDA), will be joined by a patient, surgeon and health advocate at the release of a new report prepared by the Congressman that shines a light on a federal loophole that requires FDA to clear devices that prove their similarity to an earlier model, even if that model was recalled for a major safety defect. This loophole has allowed a number of defective products to enter the market and cause serious harm, and in some cases even death. Rep. Markey will call for closing this loophole in the law to ensure that new medical devices are not cleared by the FDA if they are based on an product that was recalled because it caused serious harm to patients.

WHAT: Press conference with patient, surgeon, womens health advocate on reforming approval process for flawed medical devices

WHO:

- Rep. Edward J. Markey (D-Mass.)
- Jaye Nevarez, vaginal mesh implant patient
- Dr. Tom Margolis, pelvic surgeon
- Cynthia A. Pearson, Executive Director, The National Women's Health Network

WHEN: TODAY, Thursday, March 22, 2012, 11 a.m.

WHERE: House Triangle, U.S. Capitol, Washington D.C.

Four years ago, Jaye Nevarez, a 50 year-old mother of three, was a healthy truck driver who earned a decent living and paid her bills on time. However, she now lives in constant pain caused by a vaginal mesh implant she received in 2008. The debilitating pain forced Jaye to quit her job. She cannot walk without the help of a cane or a walker. She lost her insurance, and costly medical bills led to the recent foreclosure of her longtime home where she lives with her 79-year old mother.

Dr. Tom Margolis is a pelvic surgeon in California who has performed scores of "salvage" operations on women who have experienced serious complications from vaginal mesh implants over the last decade. He has witnessed first-hand the injuries caused by defective vaginal mesh implants, including bleeding, life-threatening infections, and severe and chronic pain.

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Thousands of patients like Jaye have suffered grave health effects from faulty medical devices cleared by the Food and Drug Administration (FDA) solely because the devices were deemed to be similar to other previously approved devices. Under current law, the majority of new medical devices go through what is known as the 510(k) process. Rather than conducting clinical trials to show safety and effectiveness, a 510(k) device must only be "substantially equivalent" to an already-approved device, even if the original device was recalled for major safety problems. As long as the device meets the "substantial equivalence" threshold, FDA has no legal authority to reject the application.

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](#) [1] (SOUND Devices Act). This bill closes a major loophole in the device approval process known as the 510(k) by ensuring that a new device is not cleared by the FDA if it is based on an earlier product that was pulled from the market for causing serious harm to patients. The SOUND Devices Act provides FDA the ability to reject a device application based on a predicate that has been recalled or is in the process of being removed from the market for major safety problems.

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[1] <http://markey.house.gov/press-release/markey-waxman-schakowsky-delauro-introduce-legislation-close-loophole-flawed-medical>