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Contact: Giselle Barry (Markey), 202-225-2836
Karen Lightfoot (Waxman) 202-225-5735
Adjoa Adofo (Schakowsky) 202-225-2111
Kaelan Richards (DeLauro) 202-225-3661

Markey, Waxman, Schakowsky, DeLauro Introduce Legislation To Close Loophole In Flawed Medical Device Approval Process

SOUND Devices Act will protect consumers by ensuring new medical devices are not approved based on defective products

WASHINGTON, D.C. – Thousands of patients have suffered grave health effects from faulty medical devices cleared by the Food and Drug Administration (FDA) solely because they were considered similar to other devices – even if the original device was recalled for major safety problems. To protect patients from defective devices, today Reps. Edward J. Markey (D-Mass.), 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). 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. This bill addresses the devastating effects that resulted from defective bladder mesh implants and metal-on-metal hip implants, helping to ensure this never happens again.

"If an automobile is recalled for a major safety problem, we wouldn't allow future models to repeat this same flaw, and the same should be true for the medical devices used in our bodies," said Rep. Markey. "The SOUND Devices Act is based on the common sense principle that patients should not be put at risk by devices that are allowed to be sold only by proving their similarity to a defective product. The SOUND Devices Act closes a significant loophole that currently puts patients at serious risk of debilitating injury by ensuring that devices do not mimic the mistakes made by other products."

Approximately 90 percent of medical devices authorized for commercial sale go through the 510(k) process. Under the 510(k) process, devices do not need to undergo clinical testing in

humans before being sold. Instead, FDA clears the device based on its similarity to a product that is already on the market, known as a "predicate." Once a device has been cleared by showing "substantial equivalence" to another product, it can then be used as a "predicate" for future devices. However, the FDA does not have clear authority to reject a 510(k) device application even in cases where the company is claiming that their product is similar to one that has fundamental design flaws. FDA has acknowledged this flaw and is "concerned that allowing a device to be used as a predicate after it has been removed from the market due to safety problems would place patients at risk" because the new device could repeat the exact same problems of the previous version.

"The vast majority of medical devices sold in the United States are cleared for sale by FDA based on their being found to be substantially equivalent to another medical device already on the market," said Rep. Waxman**. "This legislation fixes a glaring loophole in that regulatory framework. It gives FDA authority to deny clearance if the predicate on which the clearance is based was voluntarily recalled because it was unsafe due to an intrinsic flaw in its design or technology."**

"The SOUND Devices Act is necessary to close a major loophole in the 510(k) medical device approval process," said Rep. Schakowsky. **"This legislation will help to ensure that approved medical devices are both safe and effective. Our first priority should be protecting patients. The SOUND Devices Act gives FDA the added authority it needs to improve patient health and safety."**

"This is a critical step forward in protecting American consumers," said Rep. DeLauro. **"The FDA must have the ability to reject 510(k) clearance for devices that have been previously approved, such as breast implants, and voluntarily recalled because of a safety issue. The SOUND Act would close the current loophole in the 501(k) process and give the FDA the authority needed to fulfill its responsibility to protect the public health."**

Specifically, 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;
- Requires companies to inform FDA if any products in their new device's "predicate lineage" have caused serious harm and to explain how theirs avoids past mistakes;
- Instructs FDA to maintain a publicly accessibly database that companies can use to determine whether a device can be used as a predicate;
- Strengthens reporting requirements so that companies and the public can easily determine why a recall occurred (information that is often missing in the case of voluntary recalls);

- Calls for FDA to review the safety of high-risk devices if a product in their "predicate lineage" is recalled due to major safety problems.

Several instances have occurred in which a predicate was recalled due to major safety concerns, calling into question the safety of later devices cleared by FDA based on their similarity to the faulty product.

- Thousands of women have been seriously injured by defective bladder slings that cut into their bladders causing nerve damage, bleeding, and pain. Though the manufacturer has recalled the sling in 1999, FDA has continued approving implants that trace their origin back to this faulty device.
- Thousands of lawsuits have been filed claiming that metal-on-metal hip implants, which were cleared through the 510(k) process, are failing prematurely and causing metal poisoning. Though the manufacturer has recalled the implant device, the FDA does not have clear authority to reject applications for new hip implant applications claiming "substantial equivalence" to the faulty product. FDA could order post-market studies, but that would not prevent the flawed device from being used as a predicate.

The following groups have endorsed the SOUND Devices Act. Their endorsement letter can be found HERE. (http://markey.house.gov/document/2012/sound-endorsement-letter)

Annie Appleseed Project, Breast Cancer Action, Center for Medical Consumers, Community Access National Network, Consumers Union, Institute for Ethics and Emerging Technologies, Jacobs Institute of Women's Health, National Consumers League, National Physician's Alliance, National Research Center for Women & Families/Cancer Prevention & Treatment Fund, National Women's Health Network, Our Bodies Ourselves, Public Citizen, Reproductive Health, Technologies Project, The TMJ Association, Ltd., Truth in Medicine Incorporated, Union of Concerned Scientists, Scientific Integrity Program, U.S. PIRG, and Woody Matters.

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