

For Immediate Release

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Truth in Medicine applauds Senators Standing Up for Patients

Congratulations to Senator Herbert Kohl, Senator Richard Blumenthal and Senator Chuck Grassley for their bi-partisan Medical Device Patient Safety Act. Truth in Medicine applauds and supports their actions and sees this as a spectacular win for patients. Bravo!

The 35 year old 510(k) Pre-market Notification (PMN) clearance process has been scrutinized by the Government Accounting Office (GAO), the Institute of Medicine (IOM) and the United States Food and Drug Administration (FDA) over the last 3 years, yet the FDA still operates under this antiquated law.

Written to give the FDA medical device regulation authority and, at the same time, eliminate unfair competition between devices already on the market and new devices entering the market after 1976, there is no requirement of safety or efficacy, only substantial equivalence. This concept has long since lost its validity. The distortion of the PMN process over the last 35 years rivals a good game of "gossip". Many of today's medical devices sold as "substantially equivalent" in no way resemble their predicate devices sold before 1976. The FDA's 510(k) does not protect patients. The Medical Device Patient Safety Act is a huge step toward making serious changes to the 510 (k) necessary to protect patients.

Truth in Medicine has been sounding the alarm over the use, misuse and overuse of synthetic surgical mesh for hernia repair, bladder suspension and pelvic organ prolapse repair. Truth in Medicine and its members have been showing up and speaking out in Washington, D.C. and across the nation over the last five years. Testimony at the Institute of Medicine's (IOM) 510 (k) workshops in March, June and July 2010, testimony at the FDA's Center for Devices and Radiological Health (CDRH) Town Hall meetings March and May 2011, attendance at the Senate Special Committee on Aging Congressional Hearing April 2011 (and statements entered into the Congressional Record for the hearing), testimony at the FDA's ObGyn Advisory Panel Meeting Sept 8-9, 2011 and testimony at the FDA/IOM meeting Sept 16, 2011 all highlighted the devastating complications of synthetic surgical mesh for hernia repair, bladder suspension and pelvic organ prolapse repair.

Truth in Medicine sponsored events also spotlighted the serious harm, and even deaths, from the implantation of surgical mesh. It sponsored two conferences, one in September 2009, "Surviving the Complications of Synthetic Surgical Mesh" in Ft Lauderdale, FL and one in October 2010 "Alternatives to Synthetics" in Washington, D.C., a "Mesh Out" Rally on the steps of the U.S. Capitol October 2010 and a Capitol Hill briefing in May 2011 "Baby Boomers and Medical Devices: a Dangerous Mix for Healthcare" with world renowned urologist and pelvic repair specialist, Dr. Shlomo Raz at UCLA in Los Angeles, California.

Direct input to the FDA/CDRH by Lana Keeton, President and Founder, James P. Shull, Vice-President, and Janet Holt, Director, Regulatory Affairs of Truth in Medicine, through

conference calls and in person meetings were instrumental in getting the FDA to issue two Public Health Notifications (PHN - Oct 2008 & July 2011) warning of the serious complications of transvaginal placement of mesh. The FDA also issued cautions on the use of mesh for hernia repair and bladder suspension. Meetings with the FDA's Surgical Mesh Investigative Team, including Dr. Jeffrey Shuren, Director of the CDRH, and other senior personnel in March, November 2010 and May, November 2011 show the FDA's serious concern for the harm caused by mesh.

While Industry's latest argument is, "it's not the device, it's the doctor", Ms. Keeton illustrated the fallacy of this position to the FDA in her latest meeting with the FDA's Surgical Mesh Investigative Team, November 17, 2011. Adverse Events on the MAUDE database do not include a patient's operative report, patients are not independently examined and the FDA does not regulate doctors. So how does industry arrive at this position? The defect is in the device, not the doctor, if the average surgeon is unable to successfully implant synthetic mesh. It is a useability of the design defect, not doctor error.

Permanent disability should not be the outcome of a "minimally invasive outpatient procedure". Truth in Medicine continues its' fight to stop the carnage caused by defective, untested medical devices by its support of the passage of the Medical Device Patient Safety Act. Our team, our incredibly talented Board of Directors, makes all this possible. A special thanks to Lorraine Evans, Director/Liasion to the U.K. and Europe, Kelly Villoch, Creative Director and Barbara Buttrick Smith, Secretary, for their dedication and perseverance to educating and supporting mesh injured patients and to stopping others from being harmed.

As Ms. Keeton puts it, "We are not going away. We will keep showing up anytime, anyplace necessary to turn the tide against patient harm by bad medical devices, especially synthetic surgical mesh."

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GRASSLEY, BLUMENTHAL AND KOHL SEEK TO IMPROVE MEDICAL DEVICE SAFETY
12/15/11

WASHINGTON –U.S. Senators Chuck Grassley (R-Iowa), Richard Blumenthal (D-Conn.) and Herb Kohl (D-Wis.) today introduced legislation to help protect patients from unsafe medical devices and improve the management of recalls.

The Medical Device Patient Safety Act would give the Food and Drug Administration (FDA) important tools to discover problems with faulty medical devices sooner and to better manage recalls when problems do occur, without slowing down the approval process for new devices.

The bipartisan legislation would allow the FDA to require post-market clinical studies for medical devices that pose potential safety risks, if they were approved through the expedited 510(k) review process. The bill also would implement Government Accountability Office (GAO) [recommendations](#) for improving recalls and give the FDA new authority to require conditional clearance pending safety studies for devices reviewed under the fast-track, 510(k) approval process.

"This reform legislation should be part of the reauthorization of the medical device user fee law next year," Grassley said. "The reforms incorporate well-founded recommendations from the Government Accountability Office and reflect the value of having a robust post-market surveillance operation in the FDA. Important information can be learned about product safety after a device is on the market, and when there are problems, the sooner the response, the better."

"Unsafe medical devices pose severe dangers to patients and impede approval of new, safe devices – causing significant costs to our economy as well as health," said Blumenthal. "This bill will help protect people from dangerous unsafe medical devices by demanding more consumer safeguards, improving recall management, avoiding costly recalls, and preventing irreversible injury to patients. By removing unsafe devices from the market more quickly and efficiently, we're preserving a faster approval track for safe and effective products to reach patients."

"Faulty medical devices, especially those implanted in the body, can have disastrous health impacts on patients," Kohl said. "This legislation will help ensure that FDA can act quickly and decisively when there's a problem, and that the drive toward getting new technologies to market won't come at the risk of patient safety."

Grassley, Blumenthal and Kohl have also sent investigative letters to five companies that recalled faulty medical devices requesting detailed information about how the companies conduct post-market surveillance and how the companies manage recalls when a product is pulled from the market. Letters were sent to Johnson & Johnson, for its DePuy metal-on-metal hip implant, which was the subject of a worldwide recall and an April 13, 2011, hearing of the Senate Special Committee on Aging; Medtronic for its Infuse product; Boston Scientific for Guidant's defibrillators; CR Bard for vaginal and hernia mesh products; and, Zimmer Holdings for its knee replacements.

"As the Special Committee on Aging's recent oversight hearing detailed, effective post-marketing surveillance practices allow companies to recognize problems with medical

devices in a timely fashion, preventing expensive recalls later, and can also save lives and prevent unnecessary suffering," the letters state.

Background on 501(k)

FDA can clear new medical devices through the 510(k) process, named after section 510(k) of the Food, Drug, and Cosmetic Act, if the product is found to be substantially equivalent to a product already on the market. A device is considered substantially equivalent if the company shows it is at least as safe and effective as the predicate device.

While the FDA can request clinical study data, the 510(k) process is still considered a "fast-track" approval compared to the more lengthy Premarket Approval, or PMA, process. The 510(k) clearance process is intended for moderate risk devices, while the PMA process is intended for high risk devices.