

## **Medical Device Patient Safety Act**

The Medical Device Patient Safety Act, introduced by Senators Grassley, Blumenthal and Kohl, would help protect patients from unsafe medical devices while fostering innovation by preserving the current system of medical device approvals. This bill gives the Food and Drug Administration (FDA) the tools to discover problems with faulty devices more quickly and better manage recalls when problems do occur, without delaying devices from reaching the market.

### **Bill Summary**

The Medical Device Patient Safety Act aims to improve post-market surveillance without stifling innovation or scrapping the current 510(k) approval system<sup>1</sup>. The legislation would help ensure that FDA can better identify when unsafe devices are on the market, and expedite the recall process once a serious problem is discovered.

The bill has two important goals. It improves FDA's handling of recalled devices, and enhances FDA's post-market surveillance and data collection tools.

- **Improved Recall Processes:** The bill implements the Government Accountability Office (GAO) recommendations to improve FDA's handling of medical device recalls. The legislation would require FDA to assess its recalls, determine whether a recall was implemented effectively, and terminate the recall once completed.
- **Enhance Post-Market Surveillance Tools:** This legislation would enhance FDA's ability to conduct post-market surveillance for 510(k) cleared devices by allowing FDA to require the collection of post-market data as a condition of approval. The authority would mirror the post-market studies that can be required as a condition of a Pre-Market Approval (PMA) for highest risk devices. Under this legislation, the FDA could require conditions of clearance for 510(k) cleared devices that may have safety concerns. If FDA found a device substantially equivalent to a predicate for a higher-risk device, FDA could clear the device for market through 510(k) but require companies to conduct clinical studies and collect and report more complete data.

### **Background**

FDA's oversight of medical devices has landed the agency on GAO's "high-risk list".<sup>2</sup> GAO cites its concerns about FDA's post-market surveillance of medical devices as a key reason for being on this list.

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<sup>1</sup> There are two approval pathways for medical devices: the Pre-Market Approval (PMA) process and the 510(k) program. The PMA process is used for high-risk, class III devices and requires clinical trial data. Through a PMA application, FDA decides whether to approve a device for the marketplace in a lengthy, expensive process. The 510(k) approval process is a fast-track program through which FDA clears, not approves, a device for sale. The 510(k) rules stipulate that a manufacturer demonstrate only that the medical device seeking approval is "Substantially Equivalent" (SE) to another device already being sold and used on the market, known as a "predicate."

<sup>2</sup> [http://www.gao.gov/highrisk/risks/safety-security/public\\_health.php](http://www.gao.gov/highrisk/risks/safety-security/public_health.php)

Once medical devices are cleared through the 510(k) process and put on the market, FDA has few resources and authorities to capture more data and effectively monitor the devices. GAO has consistently criticized the FDA's "gaps" in post-market surveillance, and questioned the ability of FDA to verify that devices are safe and effective through the 510(k) clearance system. Additionally, the Institute of Medicine report on the 510(k) system strongly criticizes the post-market surveillance capability of the FDA.<sup>3</sup>

The Senate Special Committee on Aging held a hearing on April 13, 2011 highlighting the problems with post-market safety and medical device recalls. The GAO testified to its report highlighting problems with FDA's management of medical device recalls, requested by Senators Grassley and Kohl.<sup>4</sup> Additionally, a patient testified to her problems with the DePuy hip implant, which is currently under worldwide recalls for leaking metal into patients' bodies. The manufacturer, DePuy, and FDA learned of problems with the metal-on-metal hips from foreign registries.<sup>5</sup>

### **Section by Section**

#### **Section 1. Short Title**

#### **Section 2. Oversight of Device Recalls by the Food and Drug Administration**

Creates a program to routinely and systematically assess (1) information submitted during a device recall and (2) information reported to the Secretary regarding a correction or removal of a device.

Requires FDA to (1) assess information submitted to proactively identify strategies for mitigating health risks presented by defective or unsafe devices and (2) develop explicit criteria of assessing whether the recall was done effectively.

Requires FDA to release the reason for ending the recall once the recall is completed.

#### **Section 3. Conditional Clearance of Certain Medical Devices**

Allows FDA to require post-market safety evaluations of medical devices cleared through the 510(k) process, including data collection, labeling information and post-market studies. Authorities mirror those conditions of clearance for PMA devices.

Provides FDA with authority to rescind the device's clearance if the conditions of clearance were not met, that is, if the medical device company did not perform the post-market studies as required.

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<sup>3</sup> Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35 Years. Institute of Medicine. July 29, 2011.

<sup>4</sup> Medical Devices: FDA Should Enhance Its Oversight of Recalls. GAO-11-468 June 14, 2011

<sup>5</sup> A Delicate Balance: FDA and the Reform of the Medical Device Approval Process. Senate Special Committee on Aging. April 13, 2011. [http://aging.senate.gov/hearing\\_detail.cfm?id=332473&](http://aging.senate.gov/hearing_detail.cfm?id=332473&)