FOR IMMEDIATE RELEASE:
December 15, 2011
Contacts: Ken Willis (Kohl)
(202) 224-5364
Jill Kozeny (Grassley)
(202) 224-1308
Kate Hansen (Blumenthal)
(202) 224-2823

GRASSLEY, BLUMENTHAL AND KOHL SEEK TO IMPROVE MEDICAL DEVICE SAFETY

Senators Also Seek Answers on Post-Market Safety and Recalls from Five Device Makers

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<http://www.gao.gov/new.items/d11468.pdffor 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.