

News Release . . .

United States Senate

FOR IMMEDIATE RELEASE

March 15, 2012

Contact: Julie Edwards (Merkley) – 202-224-8841

Jill Kozeny (Grassley) – 202-224-1308

Adam Bozzi (Bennet) – 202-224-5852

Ken Willis (Kohl) – 202-224-5364

## **Senators Introduce Bipartisan Effort to Make Medical Devices Safer**

*The Ensuring Safe Medical Devices for Patients Act would implement long overdue reforms and help save lives*

**Washington, DC** – Today, Oregon’s Senator Jeff Merkley, with Senators Chuck Grassley (R-IA), Michael Bennet (D-CO) and Herb Kohl (D-WI), introduced the bipartisan Ensuring Safe Medical Devices for Patients Act. The bill would give the Food and Drug Administration the tools it needs to improve oversight of medical devices. Defective medical devices have been associated with thousands of deaths in recent years.

“When seniors undergo hip replacement surgery or heart patients need a cardiac stent, they shouldn’t have to worry that the device that is supposed to improve their health could actually make them sicker,” **Merkley said**. “Strong post-marketing surveillance of medical devices will ensure that those that are defective or cause harm can be quickly identified, patients and their physicians can be notified, and dangerous products can be removed from the market. These common sense reforms will not only protect patients, but improve efficiency in the health care system. I look forward to working my colleagues for Senate adoption of this important initiative to improve the health and safety of Americans who rely on medical devices to improve, sustain, and in many cases, save their lives.”

“The post-market surveillance work of the FDA needs to be empowered to be able to use the important and valuable information about drugs and devices that becomes available when millions of people start using them, compared to what can be known before a drug or device goes on the market. This legislation would deliver some of the necessary tools to the FDA to make it more effective in looking out for patients,” **Grassley said**.

“Coloradans expect the medical devices they use to help keep them healthy,” **Bennet said.** “With all the pressures of battling a health problem, the last thing someone should fear is that these devices will harm them, or worse. This bill would go a great distance toward helping the FDA work efficiently to make sure Coloradans and Americans are using safe products to help them sustain a higher quality of life.”

“As the Senate Special Committee on Aging heard first-hand last year, faulty medical devices, especially those implanted in the body, can have a disastrous impact on the health of those who use them,” **Kohl said.** “Innovative technology has provided valuable, life-saving medical devices that have prolonged life and reduced suffering, but the drive toward getting new technologies to market shouldn’t be done at the risk of patient safety. This legislation will help achieve that needed and delicate balance between safety and innovation.”

Safety problems and recalls of certain medical devices, including metal-on-metal hips, surgical mesh, and implantable programmable infusion pumps have called into question whether the FDA and its Center for Devices and Radiologic Health (CDRH) have the tools needed to protect patients and keep harmful devices off the market. An average of 700 different medical devices has been recalled every year since 2005. Harmful or defective devices were associated with the death of almost 5,000 Americans in 2009 alone.

The legislation builds on two important, bipartisan initiatives to improve the oversight of medical devices:

- Requires FDA to issue a final Unique Device Identifier (UDI) rule by the end of 2012, requiring implantable devices to carry a unique numerical identifier so products can be tracked through the distribution chain and once they are being used with patients. The UDI program was created nearly five years ago but FDA has not implemented it.
- Adds medical devices to the Sentinel post-marketing surveillance initiative, launched in 2008. Sentinel is a national, integrated, electronic system which currently monitors prescription drug safety after FDA approval, once the drugs are being marketed to patients.

The bill has been endorsed by Consumers Union, National Women’s Health Network, National Research Center for Women and Families, Health Care Supply Chain Association, the Premier Healthcare Alliance, Association of American Medical Colleges, Alliance for Advancing Nonprofit Health Care, National Association For Continence, MedicAlert Foundation, Public Citizen, and Union of Concerned Scientists.