



**American Hospital
Association**

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April 3, 2012

The Honorable Jeff Merkley
United States Senate
313 Hart Senate Office Building
Washington, D.C. 20510

Dear Senator Merkley:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations, and our 42,000 individual members, the American Hospital Association (AHA) is pleased to support your bill, the *Ensuring Safe Medical Devices for Patients Act* (S. 2193).

By requiring the Food and Drug Administration (FDA) by the end of 2012 to issue a Unique Device Identifier (UDI) final rule that would establish a medical device tracking system, your legislation would enable hospitals to more accurately and efficiently track implantable devices that have been recalled. The growing number of medical device recalls, coupled with the increased use of devices, underscores the urgency in creating a UDI system. It is critical for patient safety, and it will save lives.

America's hospitals and other stakeholders anxiously await the UDI final rule, which has been delayed at the Office of Management and Budget for more than six months. We believe patients should not wait any longer. By requiring timely action by the FDA in issuing and implementing a final rule, your bill recognizes the immediate need of establishing a UDI system to protect patients who receive implantable medical devices.

In addition, your bill adds medical devices to the Sentinel post-marketing surveillance initiative, a national, integrated, electronic system that currently monitors prescription drug safety after FDA approval. This would provide for quicker identification of devices that need to be recalled, and it will help many patients.

We applaud you for your leadership on this issue. We look forward to working with your office and other stakeholders toward passage of this legislation.

Sincerely,

Rick Pollack
Executive Vice President

