**APS Advancing Patient Safety Coalition**

June 4, 2012

The Honorable Tom Harkin
Chairman
Senate Committee on Health, Education,
Labor and Pensions
428 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Michael Enzi
Ranking Member
Senate Committee on Health, Education,
Labor and Pensions
835 Hart Senate Office Building
Washington, DC 20510

The Honorable Fred Upton
Chairman
House Energy & Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Henry Waxman
Ranking Member
House Energy & Commerce Committee
2322A Rayburn House Office Building
Washington, DC 20515

Dear Chairman Harkin, Ranking Member Enzi, Chairman Upton, and Ranking Member Waxman,

The Advancing Patient Safety Coalition is committed to improving patient safety through the establishment of a national unique device identification (UDI) system. As prominent hospital, physician, nursing, research, quality and patient advocacy organizations, we are writing to thank you for including language in the House and Senate medical device and user fee reauthorization bills that requires the release of the proposed regulation. We also ask that the final package include the additional provisions from the Senate bill that sets deadlines for the implementation of UDI as well.

As you know, the Food and Drug Administration Amendments Act of 2007 required the FDA to issue a regulation implementing a mandatory national UDI system, though it did not specify dates by which a final rule must be promulgated and a national UDI system implemented. While the FDA has developed a proposed rule on UDI, it has been held up in the Office of Management and Budget (OMB) clearance process since July, 2011.

We believe a UDI system is essential to help protect the safety of patients, reduce medical errors and strengthen the ability of the FDA and manufacturers to monitor adverse events. Every day that goes by without such electronic identification of medical devices is a threat to patient safety and increases costs in the healthcare system. UDI is the missing link to better ensuring patient safety. Implementing a national UDI system will not only reduce clinical risks to patients, but will also save an estimated $16 billion in costs annually which are incurred due to inefficiencies in the medical products supply chain[1].

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[1] Schneller, Eugene, and Larry Smeltzer. Strategic Management of the Health Care Supply Chain. 2006.

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During conference committee deliberations, we strongly urge you to ensure the inclusion of critical language in the final medical device and user fee reauthorization bill to finalize regulations within six months after the close of the comment period, and to implement a national UDI system within two years after the final regulation is issued.

We thank you again for recognizing the immediate importance of establishing a UDI system.

Sincerely,

AARP
Alliance for Advancing Nonprofit Health Care
Alpha-1 Association
Alpha-1 Foundation
American Association of Neurological Surgeons
American Association of Orthopaedic Surgeons
American Congress of Obstetricians and Gynecologists
American Heart Association
American Medical Association
American Nurses Association
Association for Professionals in Infection Control and Epidemiology
Association of American Medical Colleges
Catholic Health Association of the United States
Congress of Neurological Surgeons
COPD Foundation
Federation of American Hospitals
Georgia Hospital Association
MedicAlert Foundation
National Association for Continence
National Association of Public Hospitals and Health Systems
National Rural Health Association
Novation
PeaceHealth
Premier healthcare alliance
Society for Cardiovascular Angiography and Interventions
Society for Healthcare Epidemiology of America
Texas Health Resources
Truth in Medicine Incorporated
University HealthSystem Consortium
Valley Health System
VHA Inc.
West Virginia United Health System