APS Advancing Patient Safety Coalition

June 18, 2007

The Honorable John Dingell, Chairman
House Energy and Commerce Cmte.
2125 Rayburn House Office Bldg.
Washington, DC 20515

The Honorable Joe Barton, Ranking Member
House Energy and Commerce Cmte.
2322A Rayburn House Office Bldg.
Washington, DC 20515

The Honorable Frank Pallone, Chairman
Health Subcommittee
House Energy and Commerce Cmte.
2125 Rayburn House Office Bldg.
Washington, DC 20515

The Honorable Nathan Deal, Ranking Member
Health Subcommittee
House Energy and Commerce Cmte.
2322A Rayburn House Office Bldg.
Washington, DC 20515

Dear Chairman Dingell, Ranking Member Barton, Chairman Pallone and Ranking Member Deal:

As members of the Advancing Patient Safety Coalition, we are committed to improving the quality of patient care. To that end, we ask that you include language in the Medical Device User Fee Amendments of 2007 legislation crafted by Representatives Doyle (D-PA) and Hooley (D-OR). This important patient safety language requires the Food and Drug Administration to move forward on promulgating regulations establishing a national unique device identification (UDI) system for medical devices.

Unlike medications, and virtually every other product in commerce, medical devices cannot be identified in a systematic and consistent manner. The resulting *ad hoc* approach results in increased clinical risks to patients. These clinical risks include implanting a defective, counterfeit, or recalled product, inability to track the recipient of a faulty product (recalls) and inability to track adverse events appropriately. We can simply and quickly identify each and every jar of peanut butter that might have salmonella and remove them from store shelves in hours but we cannot do that reliably today with potentially life threatening defective medical devices.

Every year, more than 600 medical devices are recalled –10 percent of which can potentially cause serious health problems or death – and the percentage of health problems continues to rise. Manufacturers also issue countless device corrections each year that have serious health implications for patients, such as adding new instructions to devices to prevent device misuse and potential harm.

Even safe medical devices can pose dangerous health threats to patients if used together with other incompatible devices or machinery. For instance, certain pacemakers can negatively interact with the magnetic fields in magnetic resonance imaging (MRI) machines, causing life-threatening injuries – and even death – to patients undergoing routine imaging procedures. Without an industry-wide identification and tracking system for medical devices however, healthcare providers cannot identify device incompatibilities in time to avoid these devastating patient safety errors.

We look forward to working with you on this important patient safety issue.

Sincerely,

AAMC
AARP
American Association of Orthopaedic Surgeons
American College of Obstetricians and Gynecologists
American Heart Association
American Hospital Association
American Medical Association
Catholic Health Association
Federation of American Hospitals
Joint Commission
National Association For Continence
National Rural Health Association
Novation
Premier Inc.
Texas Health Resources
The Society of Healthcare Epidemiology of American
University HealthSystem Consortium
Valley Health System
VHA Inc.
West Penn Allegheny Health System
West Virginia United Health System
White River Health System