APS Advancing Patient Safety Coalition

March 26, 2008

The Honorable Andrew C. von Eschenbach, M.D., Commissioner
Food and Drug Administration
5600 Fishers Lane
Parklawn Bldg., Rm 14-7
Rockville, MD 20857

Dear Commissioner von Eschenbach:

We are writing to reiterate our strong interest in seeing the U.S. Food and Drug Administration (FDA) develop a mandatory unique device identification (UDI) system for medical devices and request a timeline from the FDA on its plans to publish a proposed rule. As you may know, the Advancing Patient Safety Coalition is a broad-based organization comprised of prominent hospital, physician, nursing, research, quality and patient advocacy organizations. The coalition is interested in this issue because UDI is a crucial factor to improving patient safety, reducing medical errors, facilitating device recalls, improving device adverse event reporting and improving post-market surveillance efforts.

Last fall, the coalition supported the successful efforts of Representatives Doyle (D-PA), Sessions (R-TX) and Hooley (D-OR) in enacting legislative language that requires your agency to create a UDI system for medical devices. The "Food and Drug Administration Amendments Act of 2007" (H.R. 3580), which contained this important language, was approved in the House by a wide margin of 405-7. The Senate then approved it unanimously and it was signed by the President.

A national UDI standard has great potential for our entire healthcare system. It will improve patient safety while increasing efficiency for manufacturers by reducing the potential for counterfeit products being used on a patient. A UDI standard would also help contribute to the success of EHRs and improve patient care by providing appropriate healthcare providers with accurate information.

We appreciate the great effort that the FDA has put into the national UDI standard issue under your leadership and all of its work to date. However, it is important that the agency move as quickly as possible in promulgating regulations.

We look forward to hearing about the FDA's timeline for publishing a proposed rule on a UDI system for medical devices as we all continue to work to enhance patient safety and improve health care efficiency.

Sincerely,

AAMC
Alliance for Advancing Nonprofit Health Care
Alpha-1 Association
Alpha-1 Foundation

American Association of Orthopaedic Surgeons
American Heart Association
American Hospital Association
Association for Healthcare Resource & Materials Management
Association for Professionals in Infection Control and Epidemiology (APIC)
Bon Secours Health System, Inc.
Catholic Health Association
COPD Foundation
Federation of American Hospitals
National Association For Continence
National Rural Health Association
Novation
PeaceHealth
Premier Inc
Texas Health Resources
The Society for Healthcare Epidemiology of America
University HealthSystem Consortium
VHA Inc.
West Penn Allegheny Health System
White River Health System