



March 6, 2007

Dear Member of Congress:

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 sign the Dear Colleague letter being circulated by Reps. Mike Doyle (D-PA) and Pete Sessions (R-TX) urging the Food and Drug Administration to require a national unique device identification (UDI) system for medical devices.

Unlike medications, and virtually every other product in commerce, medical devices can not 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. We support a regulated, mandatory UDI with a global nomenclature that complements the FDA National Drug Code system.

Improving Patient Safety/Recalls:

Clearly, a compelling patient safety interest lies in requiring a UDI system for medical devices, especially when a defective device is recalled. Today, the majority of hospitals must conduct recalls manually—a labor intensive and time consuming endeavor that does not guarantee a 100 percent success rate. Moreover, it is not possible to associate the use of a device with a particular patient. This greatly delays timely notification of patients if a particular device is recalled and can put patient safety at great risk.

Reducing Medical Errors:

Being able to correctly identify devices, track them through the healthcare system and inform the proper practitioner about any potential dangers will reduce errors and improve patient care. According to a March 2006 report by the Eastern Research Group (ERG), UDI has the potential to facilitate the identification of device compatibility problems. Some implantable materials have turned out to be incompatible with magnetic resonance imaging (MRI) devices resulting in injuries and deaths. ERG concluded that UDI systems might help reduce such episodes by facilitating communication of more information about implants and implant accessories and by helping to get the additional information into patients' medical records. Additionally, UDI systems could improve methods for ensuring patients with allergies are not treated with or touched by medical devices to which they are allergic (i.e., latex gloves).

Improving Adverse Event Reporting/Post Market Surveillance:

Accurate and reliable device tracking would also enable data mining so that FDA and manufacturers could better identify potential problems or device defects. Because of the increasing complexity and variety of devices, the potential for problems is escalating. Implementation of a UDI would be a valuable step in improving processes for monitoring adverse events related to medical devices, just as the FDA's recent decision to require barcoding on prescription drugs has enhanced patient safety by providing greater clarity in identifying medications.

Improving Efficiency:

Providers struggle to track devices through their inventories as the information is not available from the manufacturer. While it is true that many manufacturers bar code their products, there is no national repository of the information contained in the proprietary bar codes, which makes it meaningless to healthcare providers. Therefore, many health systems must create and manage their own bar coding systems and then contract with a third party to synchronize their data with the manufacturer, distributor, or other entity. This is a costly undertaking for providers and has the potential to generate errors by adding another layer to the process of tracking medical devices.

Enhancing Electronic Health Records/Clinical Data Flow:

Electronic health records (EHRs) will require that data standards are in place and used by all institutions in order to transfer clinical information. While much of the EHR discussion has centered on clinical procedures and orders, the ability for clinicians to have full information of the supplies and devices utilized during a patient's treatment will be required to improve patient care. Therefore, having a UDI for medical devices is a basic requirement that must be in place before automated identification systems are effective.

Detecting and Preventing Counterfeit Medical Devices:

The counterfeiting of medical devices is on the rise, threatening to compromise the safety of patients. An example was an October 2006 FDA warning about counterfeit blood glucose strips that were identified in the market. Another and more potentially detrimental example was when counterfeit surgical mesh entered the healthcare supply chain and was implanted in multiple patients. A consistent and unique method of identifying medical devices could have helped in the detection and prevention of these counterfeit items before they passed into the supply chain.

In closing, we urge you to sign onto the Doyle/Sessions letter to the FDA. Please have your staff contact Kenneth DeGraff in Rep. Doyle's office at 202.225.2135 or via e-mail at kenneth.degraff@mail.house.gov or Bobby Hillert with Rep. Sessions office at 202.225.2231 or via e-mail at robert.hillert@mail.house.gov. We look forward to working with you on this important issue that will ultimately improve patient safety, reduce medical errors, facilitate device recalls and improve device adverse event reporting.

Sincerely,

AAMC

AARP

Alpha-1 Association

Alpha-1 Foundation

American Association of Orthopaedic Surgeons

American College of Obstetricians and Gynecologists

American Hospital Association

American Nurses Association

Association for Professionals in Infection Control and Epidemiology (APIC)

Bon Secours Health System, Inc.

Catholic Health Association

Federation of American Hospitals

Joint Commission

National Association For Continence

National Rural Health Association

Novation

Premier Inc.

Texas Health Resources

The ERISA Industry Committee

The Society of Healthcare Epidemiology of America

University HealthSystem Consortium

VHA Inc.