

# BAPTIST HEALTHCARE SYSTEM

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

Dear Honorable von Eschenbach:

Baptist Healthcare System, Inc., is an organization committed to improving the quality of care for our patients. I am writing to urgently call upon the Food and Drug Administration (FDA) to require a national unique device identification (UDI) system for medical devices. Today, there are multiple and varied product numbering and coding systems. Therefore, Baptist Healthcare System, Inc. supports a regulated mandatory UDI with a global nomenclature, similar to the FDA National Drug Code system.

In response to the FDA's August 11, 2006 Request for Comments published in the *Federal Register*, we offer the following comments on how a national UDI system will improve patient safety, reduce medical errors, facilitate device recalls and improve adverse event reporting.

Improving patient safety interest lies in requiring a UDI system for medical devices, especially when a defective device is recalled. Automatic, standardized identification would facilitate and improve upon the tracking of these devices in the event of a recall or other safety concern. Highly publicized device recall cases provide strong evidence of the inefficient and often ineffective recall process.

Manufacturers also issue many "device corrections" that can have serious consequences for patients if not handled correctly, which can be facilitated, tracked and undertaken more expeditiously by hospitals with the use of UDI.

Being able to correctly identify devices, track them through the healthcare system and inform the proper practitioner about any potential dangers such as device compatibility problems will reduce errors and improve patient care. UDI systems could also improve methods for ensuring that patients with allergies are not treated with or touched by medical devices to which they are allergic (i.e., latex gloves).

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.

Thank you for the opportunity to provide comments on a UDI and reiterate Baptist Healthcare System, Inc. support for a regulated, mandatory UDI with a global nomenclature, similar to the FDA National Drug Code system. 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,



Tommy Smith

Cc: Sen. Mitch McConnell  
Sen. Jim Bunning

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