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Shawna CC

November 2, 2006

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 Acting Commissioner von Eschenbach:

On behalf of Avera Holy Family Health, an organization committed to improving the quality of care for our patients, I write 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, Avera Holy Family Health supports a regulated, mandatory UDI with a global nomenclature, similar to the FDA National Drug Code system.

Specifically, 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 device adverse event reporting.

**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. 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. They are not technically recalls because they can be corrected by the user, but can often be just as serious as a Class I recall. For example, the majority of problems over the last several years with IV pumps

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were device correction issues, but involved battery failures that could result in severe patient outcomes if all the equipment was not located and the corrections were not made by the users.

#### **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, something that is currently being done by the FDA related to drug safety because of clarity in identifying drugs.

#### **Reducing Medical Errors:**

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. For example, some implantable materials have turned out to be incompatible with magnetic resonance imaging (MRI) devices resulting in injuries and deaths. UDI systems could also 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 Efficiency:**

Avera Holy Family Health struggles to track devices through our 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 health care providers. Therefore, Avera Holy Family Health and many other health systems must create and manage our 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 our hospital 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.

In closing, I thank you for the opportunity to provide comments on a UDI and reiterate Avera Holy Family Health 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,

A handwritten signature in black ink, appearing to read 'Bill Bumgarner', with a stylized, cursive-like flow.

Bill Bumgarner  
CEO & President  
Avera Holy Family Health