

# CENTRAL BAPTIST HOSPITAL

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November 8, 2006

**Docket No. 2006N-0292**

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 Central Baptist Hospital, 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, Central Baptist Hospital 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. Specific examples of recalled medical devices we have received at Central Baptist Hospital include:

1. BTS-Human Tissue Allografts. Biomedical Tissue Services LTD.
2. Gore Tag Thoracic Endoprosthesis System. W.L. Gore and Assoc., Inc.
3. Spinal Graft Technologies recall on human tissue where donors may not have been screened appropriately for last 3 years.
4. Peritoneal Dialysis Unit Tubing Sets; Transfer Sets, Continuous Ambulatory Peritoneal Dialysis (CAPD)
5. Baxter—COLLEAGUE Infusion Pumps : Harness Available to Prevent Battery Swelling

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and Overheating

6. LifeScan—OneTouch SureStep Blood Glucose Meters :  
Display Problems May Develop
7. Boston Scientific/Guidant—Various Cardiac Pacemakers :  
Manufacturer Has Received 5 Additional Reports of Device Failure

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 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. Specific examples of device corrections we have received at Central Baptist Hospital include:

1. Gambro Prisma Continuous Renal Replacement Systems. Gambro Renal Products.
2. Tyco/Mallinckrodt-Model CT 9000 ADV Liebel-Florsheim Power Injectors. Mallinckrodt Inc. Div Tyco Healthcare Group LP..
3. Siemens patient table for Magnetom Avanto and Espree system
4. Medtronic—LIFEPAK 500 AEDs ; Component Leads May Have Intermittent Connection to Printed Circuit Board Assembly Pads

**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. Specific examples of recent adverse event reports submitted to the FDA include:

1. One report was filed on PRISMA machine of Gambro Renal Care Products for alarm malfunctions (FDA report filed on 6/30/06). No patient harm.
2. One report was filed on Ethicon ETS-Flex 35 mm GIA, Ethicon Inc. for dislodging from the stapler and breaking into several pieces in a patient’s abdomen (FDA report filed on 7/17/06). All broken pieces retrieved from patient abdomen, no patient harm.
3. One report was filed on disposable Novasure device that malfunctioned during endometrial ablation, Cytoc Surgical Products (FDA report filed on 7/13/06). Patient

suffered a partial uterine perforation.

### **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:**

Central Baptist Hospital 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, Central Baptist Hospital 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 by our hospital and has the potential to generate errors by adding another layer to the process of tracking medical devices.

Currently Central Baptist Hospital maintains a database of all devices and products through our Engineering/Biomedical Department and Materials Management Department when they are received on site. All medical devices are evaluated, tested, and tagged internally prior to use in the organization. When a recall occurs, a work order is generated and the device is manually tracked down based on serial, lot, or model numbers. If staff provides the organization tag number, the device is tracked down using that. Recalled products distributed through our Materials Management Department are tracked by serial, lot, or model numbers from our inventory database. A UDI would improve our processes significantly and decrease, if not eliminate, the majority of the time our Biomedical Engineers take to track down equipment and devices throughout the organization. Bar coding medical devices would be a cornerstone in improving patient safety; improving quality of care; and encouraging cost effectiveness.

### **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.

Central Baptist has used EHRs for approximately 10 years now in most areas, but key areas such as the Operating Room do not document electronically. When evaluating a surgery or procedure it is currently impossible to have all of the information of the supplies and devices utilized during the surgery or procedure. A UDI for medical devices would facilitate the reporting of medical devices involved in adverse events and having that information readily available in the electronic medical record would make obtaining the essential information for reporting to the FDA and manufacturer less burdensome.

The FDA should regulate that manufacturers barcode medical devices on a mandatory basis. The incentives for establishing a uniform, standardized system of UDI's are cost reduction, better control of routine maintenance, and less non-use of medical devices with radiofrequency identification. Barriers for establishing UDI's would be in the cost to the manufacturers and to the organizations to purchase the appropriate software for proper tracking. Currently we have an internal tagging system for all of our medical devices, but small movable equipment can be difficult to track down quickly because it changes locations so often. All devices should have UDI's to allow organizations an improved ability to identify and track recalls more quickly. UDI's should also be placed on packages of disposable items.

UDI's should at a minimum contain the manufacturer name, model number and/or serial number, lot number, year made, and expiration date. The UDI data set should be obtained and maintained by the FDA on the national level and at the organizational level it should be maintained by the Risk Management and/or Patient Safety, Biomedical, and Materials Management departments. UDI's should be made publicly available through the FDA recall system and other recall agencies such as ECRI, NRAC, and MD buyline, etc. Both human readable and encoded automated technology should be available and the UDI should be lasered or etched onto the device itself. The UDI should be based on nonspecific technology. Bar codes should be placed on all devices so they are scan able and the bar codes should be compatible with those used for the drug bar code rule.

The public health and patient safety benefits of having a standardized UDI system is the consistency it offers in locating devices efficiently and timely. The UDI system would assist with adverse event reporting requirements in that the needed information would always be readily available to the reporter and investigator of the event. Currently, if an adverse event occurs with a device, the package is discarded along with vital

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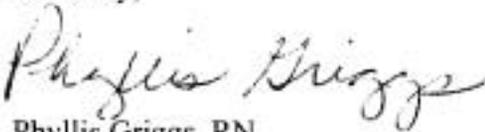
identification information, which leaves the submitted FDA reports inadequate. Medical errors would be reduced because we would be able to locate the recalled devices much more quickly, hopefully before they had a chance to negatively impact patients. This form of technology would be widely supported in our organization. The primary obstacles would be that we are in an older facility and the potential cost of supporting software systems.

Central Baptist Hospital has already implemented EHRs and bedside barcoding for pharmaceutical dispensing and is working on developing computerized physician order entry. Central Baptist Hospital would consider a device recalls technology system to be a top priority for our organization to invest in to continue our commitment to quality care and patient safety. Infrastructure or technological advancements needed for hospitals and other device user facilities to be able to capture and use UDI for basic inventory control and recall completion purposes would be to make it a legal requirement among manufacturers regulated through the FDA and installing the appropriate software in facilities.

Implementing a UDI system in our organization would allow us the ability to complete medical device recalls, especially Class I and Class II recalls within the internal time guidelines we have set for such recalls. It would greatly decrease having to rely on so many individuals in service areas to respond to an urgent recall or alert. The information could be accessed very quickly through a software data bank and locating the effected product could take hours instead of days.

In closing, I thank you for the opportunity to provide comments on a UDI and reiterate Central Baptist Hospital's 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,



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