

November 9, 2006

The Honorable Andrew C. von Eschenbach, M.D.
Acting Commissioner
U.S. Food and Drug Administration
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20857

Re: Unique Device Identification; Request for Comments; 71 Fed. Reg. 155; [Docket No. 20006N-0292]

Dear Dr. von Eschenbach:

On behalf of McKesson Corporation, I am pleased to respond to your request for comments on a potential Unique Device Identification system for medical devices.

For over 170 years, McKesson has led the industry in the delivery of medicines and healthcare products to pharmacies, hospitals and other healthcare entities. Today, as the largest distributor of pharmaceuticals in North America and the largest health information technology (IT) company in the world, we deliver vital pharmaceuticals, medical supplies, and health information technology and automation solutions that touch the lives of more than 100 million patients in every healthcare setting. McKesson was the first drug distributor to fully automate our distribution process by implementing radio frequency and scanning technology throughout our entire warehouse and distribution network. This automation technology promotes cost-efficiencies, streamlines inventory management and, ultimately, enhances patient safety.

McKesson also distributes medical-surgical supplies and equipment and provides innovative materials management solutions and services to more than 65,000 hospitals, physicians, surgery centers, clinics, home health care providers and nursing homes nationwide. Through our health IT business, we provide clinical, administrative and financial systems to over 60% of all large hospitals to improve the quality and delivery of healthcare.

As an early proponent of barcodes on all pharmaceutical products, we support the FDA's efforts to examine the feasibility of establishing a UDI system for medical devices that will improve patient safety and increase distribution efficiencies. Based on our long

history and expertise in supply chain distribution, automation technology and healthcare information systems, we welcome the opportunity to share our insights regarding the development of a UDI system.

Developing a System of Unique Device Identifiers

1. How should a unique device identification system be developed? What attributes or elements of a device should be used to create the UDI?

We suggest that the FDA select a global standard setting organization, such as GS1 (Global Standard 1), that has extensive experience in developing industry-driven standards for the Electronic Product Code (EPC) and the Global Product Classification (GPC) systems, to design a UDI system. As a part of this process, we recommend the FDA create healthcare industry work groups to establish symbology, key format components, level of identification and recommended UDI technologies for the appropriate device classification or category.

On a broad level, a UDI system should have the following elements:

- a GS1 or similar numbering schema that include attributes such as the manufacturer ID, packaging unit and, where appropriate, serialization; and
- a central database to house and make available UDI data as a cross-referencing tool among supply chain partners for recalls and adverse event reporting.

Similar to the NDC code database for pharmaceuticals, a central database or data repository for UDI data for medical devices should be developed. The database should include elements such as standard class (equipment, instrument, implant, supply), device type (patient monitor, wound closure, garment) and other characteristics indexed by the manufacturer ID code.

2. What should be the role, if any, of FDA in the development and implementation of a system for the use of UDIs for medical devices? Should a system be voluntary or mandatory?

The FDA should establish the development and implementation schedule with recommendations from the healthcare industry and sponsorship from a global standard setting organization such as GS1. We also recommend that the FDA identify the data schema to be used to uniquely identify the device to the unit of packaging or the unit of use, where possible.

Just as the NDC process used to identify specific pharmaceuticals begins with the manufacturer, we recommend that a UDI system begin with the manufacturer and be mandatory for the highest priority medical devices, such as implants.

3. *What are the incentives for establishing a uniform, standardized system of unique device identifiers?*

Incentives for establishing a UDI system include greater efficiencies in inventory management, improved patient safety and reduced healthcare supply chain costs. Unique identifiers for medical devices will streamline inventory management processes and reduce the potential for errors. Additionally, the implementation of an effective UDI system will improve product recall and adverse event reporting processes, thereby enhancing patient safety.

4. *What are the barriers for establishing unique device identifiers? What suggestions would you have for overcoming these barriers?*

Barriers to establishing a UDI system include the cost for manufacturers, distributors and providers to implement and comply with a UDI system.

Most barriers can be overcome if there is widespread recognition within the industry of the efficiencies and the patient safety benefits associated with a UDI system. In conjunction with healthcare industry work groups, a uniform classification system should be developed, preferably by a global standard setting organization that has had extensive experience in this area. The financial burden to industry for the adoption of a UDI system can be mitigated if implementation is gradually phased in over a number of years.

6. *Should unique device identifiers be considered for all devices? If yes, why? If not, what devices should be considered for labeling with a UDI and why?*

McKesson recommends that a UDI should be considered for all products classified as medical devices. The highest priority for a unique identifier should be given to devices such as implants due to their significant inventory cost as well as major implications for patient safety.

Items that have a general use outside of healthcare, such as off-the-shelf computer software, cotton balls or latex gloves, should not be required to have an UDI. These items would be difficult to track and their impact on patient safety is relatively low.

7. *At what level of packaging (that is, unit of use) should UDIs be considered? Should UDIs be considered for different levels of packaging? If yes, should the level of packaging be based on the type of device? Why or why not?*

In conjunction with a standard setting organization, healthcare industry groups should determine, by category of medical device, the appropriate level of packaging that should require a UDI.

Implementing Unique Device Identifiers

9. What is the minimum data set that should be associated with a unique device identifier? Would this minimum data set differ for different devices? If so, how? How would the data in the minimum data set improve patient safety? What other data would improve patient safety?

In conjunction with a standard setting organization, healthcare industry groups should determine, by category of medical device, the minimum data set that should be associated with a UDI.

10. How should the UDI and its associated minimum data set be obtained and maintained? How and by whom should the UDI with its associated minimum data set be made publicly available?

The FDA should bear the responsibility for publicizing UDI data as they now do with NDC data. Online services could facilitate submission of new devices and changes to existing devices by manufacturers. In conjunction with a standard setting organization, healthcare industry groups should determine how and by whom a minimum data set for UDI is made publicly available.

11. Should the UDI be both human readable and encoded in an automatic technology? Should the UDI be on the device itself (e.g., laser-etched) for certain devices?

Similar to UPC codes used in food distribution and other industries, we believe UDIs should be both human and machine-readable. The UDI could be etched on the device itself for high priority medical devices, where applicable. We recommend that the FDA, potentially in conjunction with a global standard setting organization, undertake a study on the benefits and need for product serialization in appropriate medical device categories.

12. Should a UDI be based on the use of a specific technology (e.g., linear bar code) or be nonspecific? Please explain your response. If a bar code is recommended, is a specific type of symbology preferred, and if so, what type and why? Should the bar code be “compatible” with those used for the drug bar code rule? If yes, why? If not, why not?

The recommendation of a specific technology at this time would limit the adoption of newer, potentially more effective technologies that are continually emerging.

UDI Benefits and Costs

13. From your perspective, what public health and patient safety benefits could be gained from having a standardized unique device identifier system? How would such a system contribute to meeting device recall and adverse event reporting requirements, and to reducing medical error? Please submit detailed data to support benefits you identify.

By establishing uniform identification standards for medical device identification across the healthcare industry, a UDI system will not only reduce administration costs but enhance patient safety. Currently, most medical devices lack a unique, readable item identifier or uniform product number (UPN) on the packaging or on the device. The UDI could be incorporated into current scanning technology already used throughout the supply chain to manage inventory levels, medical device recalls and adverse event reporting. Universal codes that are visible on the packaging will facilitate product recalls and adverse event reporting, thereby enhancing patient safety.

17. From your perspective, what are the obstacles to implementing or using a UDI system in your location?

Potential obstacles include the following:

- modification of relevant systems needed to incorporate item attributes into UDIs; these systems include accounts payable, accounts receivable, customer/vendor contracts, and warehouse scanning systems; and
- the relative priority of UDI to other higher priority initiatives, including medication reconciliation, healthcare record interoperability and other safety initiatives.

Conclusion

We applaud the FDA's efforts to examine the potential benefits for a unique device identification system for medical devices. As a major device distributor and healthcare information technology company, we believe that significant benefits can be obtained in patient safety and improved distribution efficiencies through the use of a unique device identification system. Development of such a system should include the following steps:

- utilize a global standard setting organization such as GS1 to establish a recognized and universally used classification schema for FDA-regulated medical devices;
- create focused healthcare industry work groups sponsored by the standard setting organization to establish minimum data sets, prioritization of device categories and appropriate UDI technologies;
- undertake a study on the benefits and need for product serialization;
- develop a central data repository to maintain and make available UDI data on FDA-regulated medical devices; and
- determine a realistic implementation timeline after UDI standards and a central repository are established.

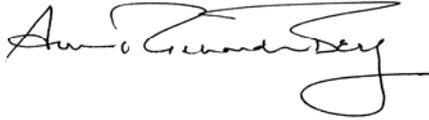
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Ann Richardson Berkey
Vice President
Public Affairs

McKesson appreciates the opportunity to share its views on unique device identification. We look forward to working with the FDA and the Administration as you consider important issues that must be resolved to establish a UDI system.

Please do not hesitate to contact me with any questions. I can be reached at (415) 983-8494 or ann.berkey@mckesson.com.

Sincerely,

A handwritten signature in black ink, appearing to read "Ann Richardson Berkey". The signature is fluid and cursive, with a large loop at the end of the last name.

Ann Richardson Berkey
Vice President, Public Affairs