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November 9, 2006

Andrew C. Von Eschenbach, M.D.
Acting FDA Commissioner
Division of Dockets Management (HFA-305)
Food and Drug Administration (FDA)
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: [Docket No. 2006N-0292] Unique Device Identification; Request for Comments.

Dear Dr. Von Eschenbach:

The American College of Cardiology (ACC) appreciates the opportunity to provide input on the FDA's Request for Comments on Unique Device Identification (UDI), as published in the Federal Register on August 11th, 2006 (71 Fed. Reg. 46233). The ACC is a 34,000 member non-profit professional medical society and teaching institution whose mission is to advocate for quality cardiovascular care through education, research promotion, development and application of standards and guidelines, and to influence health care policy. The College represents more than 90 percent of the cardiologists practicing in the United States.

Generally speaking, the ACC strongly supports the prospect of developing a uniform system for introducing UDI to medical devices, as we share in the FDA's belief that doing so could significantly enhance patient safety. In particular, the College has already pursued the promise of improving patient safety with regard to cardiovascular care through our National Cardiovascular Data Registry (NCDR™) program which, as you are aware, is a collaborative effort with the Heart Rhythm Society (HRS) and the Society for Cardiovascular Angiography and Interventions (SCAI). The development of a uniform system for UDI will greatly augment the effectiveness of this program.

Given the unique position the College enjoys in collecting data on cardiovascular care for purposes of improving safety and research, we believe our recommendations carry the weight of experience in helping the FDA shape a UDI system. The ACC's comments are presented below in a format that corresponds to the questions provided in Section III of the FDA's Federal Register notice (71 Fed. Reg. 46235) of Request for Comments.

“Developing a System of Unique Device Identifiers”

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

As you are aware, the ACC’s NCDR™ collects information on implantable medical devices, including: implantable cardiac defibrillators; peripheral vascular devices (stents, balloons and distal protection devices); closure devices; and intracoronary devices (stents, balloons and diagnostic devices). A unique identification system should include these devices and information that is sufficiently detailed to allow NCDR™ to track individual devices. The data to identify devices at the individual unit level would make NCDR™ a much more powerful reporting tool for adverse events, and also allow NCDR™ data to be used in device efficacy studies. It is critical for the FDA to consider, during the ongoing process of developing the principles to guide this identifier and other data elements, input from parties that will be affected by the establishment of a standardized unique identification system.

The ACC recommends these principles include: an official nomenclature; an identification system open to users at all levels of technology; and recognition that the chief aim of this system is to improve patient safety. To achieve this, the UDI development process must include: the determination of what data is needed for such a system: identification of the technology needed to track devices; “data” definitions; and resolution of data repository or utility issues as discussed during the FDA public meeting on UDI held on October 10, 2006.

The NCDR™ will be significantly affected by the FDA’s proposed adoption of a UDI system. The ACC therefore offers its assistance and expertise to the FDA while it develops this system from the ground up. Specifically, criteria for including implantable devices and nomenclature definitions are the two most critical elements of a UDI system that would directly impact the NCDR™.

For example, the NCDR™ supports the ECRI nomenclature criteria outlined in the Task 4 White Paper - Automatic Identification of Medical Devices - Final Version, August 17, 2005 (FDA Contract 223-04-6051, Plymouth Meeting, PA), which includes:

- No redundancy;
- Internal consistency;
- No ambiguity;
- Mapping of elements across different nomenclatures;
- Multiple hierarchies of reference to devices;
- Context free identifiers; and
- Version control.

Further, the ACC recommends that any device definition:

- Include different implant types (i.e., permanent, temporary, active, and non-active);

- Permit tracing of a device to a patient, and have that information easily retrievable for monitoring or study;
 - Include those devices used for in-vitro diagnostics, sterile process information; and
 - Identify whether the devices are single-use, reprocessed, or reusable.
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 ACC recommends a mandatory system for the use of UDI be developed and implemented under the guidance and regulatory authority of the FDA, as it could require comprehensive, complete tracking of devices that can be used for analyzing adverse events. For example, under a mandatory system unique device data in the NCDR™ would allow complete analyses of all devices of a particular type if the efficacy of that device were to be studied. Under other alternatives for consideration, there would be no possibility of undertaking the kind of comprehensive analyses of safety and effectiveness that would be otherwise possible under a mandatory approach since not all devices would be tracked. Any clinical analysis of a voluntary or other non-mandatory system would always be suspect because there would be no information on excluded devices.

Responsibility for data management is another aspect to be considered by the FDA. As with the pharmaceutical tracking system, FDA should be the repository of the data and manufacturers should subscribe to gain access to the database, with fees perhaps proportional to manufacturer volume of sales. FDA would be responsible for assigning the unique identification in a chosen format, e.g., a UPN. NCDR™ would in all likelihood add the unique identification as a field to the respective registry for which the device information is being collected. The ACC believes it would have success in getting data on identifying aspects of medical devices from FDA, because the NCDR™ is dedicated to advancing patient safety and improved outcomes, which is consonant with the FDA mission. The NCDR™ could better track off-label use of these devices for patient safety reasons.

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?

The ACC recommends that any UDI system must, at a minimum, uniquely identify those devices that are critical to patient treatment (e.g. implantable devices). Devices that are incidental to treatment, such as disposable devices and equipment, could also be identified uniquely at the batch level. For purposes of the NCDR™, we would prefer unique identification for all implantable devices, and not just the implantable devices NCDR™ tracks or other devices it might track in future registries. In addition, the ACC echoes the recommendation found in the meeting summary on UDI held at the Food and Drug Law Institute on 10/27/2005: “Participants felt that implantable devices should have complete granularity, i.e., each item should be identified.” Mandating UDI would allow

for tracking of all devices so that analyses of efficacy could be done across all devices, instead of just some.

By way of example, the NCDR™ already collects unique identification information for defibrillators. The Centers for Medicare and Medicaid Services (CMS) has contracted with the NCDR™ for the Intracoronary Defibrillator (ICD) Registry, which collects unique ICD device data from all hospitals implanting ICDs. The NCDR™ maintains an ICD Master Device List which specifies the following:

- a. Effective Date (date first available for selection/implant);
- b. Expired Date (date no longer available for implant);
- c. Device ID (sequential number maintained by the ACC);
- d. Name of Manufacturer;
- e. Model Name; and
- f. Model Number.

The Device ID is a number assigned by NCDR™ and is unique to the particular implanted device. The Device ID is linked to the manufacturer name, the device model name and number given by the manufacturer. This permits analysis of tracked devices by manufacturer and model number, as well as linking with patient clinical data in order to differentiate adverse impacts of a device from other factors, such as patient characteristics, or participant factors.

Similarly, for reasons that ICDs are uniquely labeled, other cardiology and medical devices should be labeled uniquely as well. In addition, unique identification labeling should be required for devices used in cardiology procedures and for which data are collected in the NCDR™. Collecting information only at the “lot” level of detail would fail to provide the data necessary to adequately study efficacy of these devices.

The NCDR™ already collects specific manufacturer data (i.e. manufacturer, model, length, and diameter) on intracoronary devices. Due to the lack of standardized device identification, NCDR™ participants must code these devices manually, adding unnecessary time and resources to the data collection process, as well as introducing greater potential for error. Compared with the current method of manual data entry, integrating a standardized automatic identification system for devices would save untold hours of data collection effort and eliminate the chance for data capture error.

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?

For reasons stated in our response to the prior question, the ACC reiterates its recommendation that the unique device identification be mandated at the unit of use (i.e., for a particular individual medical device). Again, identifying medical devices at the lot level would be inappropriate, although it may be sufficient for general medical supplies such as surgical gloves.

“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? Is so, how? How would the data in the minimum data set improve patient safety? What other data would improve patient safety?

The ACC recommends a “number approach” for establishing a minimum data set that allows information for the device to be linked to a particular patient with the device. This includes a “smart number” or a random number approach with device information tied to that number. Following the format for the NCDR™ ICD Registry, the unique identification system should be set up so that the number can be used to identify manufacturer name, model name, model number, and a unique device number across all devices. Since manufacturers also change model names and other descriptors of their devices, it would be imperative that the FDA assign a unique ID at the time it provides approval for the device. By using this approach, changes in the model name would not affect the unique ID.

The ACC recommends that a minimum data set for a standardized UDI system be flexible enough to be specifically descriptive, allowing physical characteristics of the device to be included as part of the smart number approach. For example, because stents differ by diameter, a smart number would be able to differentiate between these diameter differences for stents from the same manufacturer, even if that manufacturer changes the name or model number for these different stents in the future.

Other data that can be analyzed to improve patient safety, including clinical, demographic and outcomes, are currently collected by the NCDR™, which can be linked to specific device numbers that are also to be collected by the Registry. With a unique device number, even more detailed analyses of device efficacy can be carried out.

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 ACC recommends that the FDA assume responsibility for assigning the unique device identification, as it currently does with biological and pharmaceutical products, or in much the same way that CMS assigns the unique provider number. The FDA would also collect the necessary information from manufacturers. The NCDR™, in its ICD Registry, would then track defibrillator data from a variety of sources produced by the manufacturers and from the FDA list of approved devices.

The ACC also recommends that the FDA serve as the data repository or utility for this system to uniquely identify devices, and subsequently make such datasets publicly available. With the ICD Registry, the unique identification numbers and related descriptive information for defibrillators are maintained by NCDR™ and are not made available to the public. Analysis of this information is done through research centers

under contract with NCDR™ to carry out special studies authorized and reviewed by ACC research committees. The ACC takes no position on whether unique numbers associated with particular device names and model numbers should be made publicly accessible, as it is not something that will affect NCDR™ operations or research.

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?

The ACC recommends that devices should be encoded for UDI in an automatic technology (e.g., readable by an optical scanner or a radio frequency receiver, etc.) that enables them to be both human and electronically readable. An additional consideration for choosing a particular UDI encoding method or technology should be to minimize any burden of implementation for stakeholders (such as participants in the NCDR™ program, which includes the approximately 800 hospitals participating in the CathPCI Registry and the nearly 1300 hospitals participating in the ICD Registry). The ACC recognizes that not all hospitals may currently have the technology for scanning a UDI number, and that acquisition and other administrative costs inevitably arising out of the implementation of a mandatory UDI system compels us to urge the FDA to keep these concerns in mind when choosing among coding systems. Ideally, the FDA would devise a system that relies on technology that is not too costly and can—at the same time—be coordinated or synchronized with hospitals' tracking systems to the extent possible. Further, an FDA system should consider human factor engineering in hospital labs or wherever used in the hospital.

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 ACC recommends that FDA adopt scanning for implantable devices with linear or other bar code technology. The data entry of UDI should be quick and fool-proof, as cardiac labs and operating rooms are typically crowded and busy, so data entry must therefore work well within these kinds of constraints. An automatic system would reduce the burden placed on participating hospitals for collecting data while also improving the accuracy of data collected.

As we stated earlier in this letter, for other devices (such as peripheral and intracoronary devices) we continue to recommend implementation of a coding scheme that provides a way to identify the manufacturer, make or model, length, diameter and the specific “batch” of a product.

The ACC's recommendations on the development of a uniform system for UDI are based on our knowledge of the most relevant and current clinical literature and practices available. Our goal in providing these comments is to assist the FDA in making

appropriate regulatory decisions based on scientific evidence. We remain eager to continue our assistance in the future on this and other FDA initiatives.

Again, the ACC appreciates the opportunity to comment on the FDA's Request for Comments on UDI. If you have any questions, or if we can be of assistance in these efforts, please contact Sergio Santiviago, Senior Specialist, Regulatory Affairs at 202.375.6392, or by e-mail at ssantivi@acc.org

Sincerely,

A handwritten signature in black ink that reads "Steven E. Nissen". The signature is written in a cursive style with a large, prominent "S" at the beginning.

Steven E. Nissen, M.D., F.A.C.C.
President