



## 200,000 Physicians Strong

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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

Dear Dr. Von Eschenbach:

Founded in 2001, the Alliance of Specialty Medicine (the Alliance) represents over 200,000 physicians in 11 medical specialty organizations and serves as a strong voice for specialty medicine. The Alliance is composed of a diverse mixture of organizations that represent non-surgical and surgical specialties, as well as hospital and office-based physicians. The Alliance welcomes the opportunity to comment on the Food and Drug Administration's Unique Device Identification open public meeting and request for comments [Docket No. 2006N-0292]. We appreciate the efforts of the FDA to facilitate this meeting in a transparent manner in which stakeholders were invited to present their perspectives in a public forum.

### RATIONALE FOR A SYSTEM

While the Alliance is cognizant of the FDA's regulatory authority, FDA's collaboration and communication on UDI systems with other federal agencies including but not limited to the Agency for Healthcare Research and Quality, the Centers for Medicare and Medicaid Services, the Veteran's Administration, and the Department of Defense is laudable and of great benefit to the global healthcare community.

Many arguments exist to support the development of a UDI. Of foremost concern to the healthcare community are patient safety and the reduction of medical errors. While the peer-reviewed patient safety scientific literature is certainly not as robust for medical devices as exists for pharmaceutical drugs, evidence continues to increase to create a rationale for device identification leading to safer patient care.

Patient safety, through better human factors design, is a critical device safety problem. Gathering more data in post-market surveillance may provide information on sub-optimal device design that could be a cause of medical errors, such as buttons on an infusion pump control pad located too closely together. Human factors engineering is a critical element in the use of medical devices. Device design is often a dynamic in adverse event causation, not just human error. By implementing a UDI system, early device problems will be captured more quickly and will prevent multiple events from occurring.

2006N-0292

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American Academy of Dermatology Association • American Association of Neurological Surgeons •  
American Association of Orthopaedic Surgeons • American College of Emergency Physicians • American College of Obstetricians and  
Gynecologists • American Gastroenterological Association • American Society for Therapeutic Radiology and Oncology  
American Society of Cataract & Refractive Surgery • American Urological Association • Congress of Neurological Surgeons  
National Association of Spine Specialists

### **DEVELOPMENT OF A SYSTEM OF UNIQUE DEVICE IDENTIFIERS**

The Alliance wholeheartedly endorses the development of a national UDI system. As the U.S. is the largest manufacturer of medical devices, the implementation of such a system could and may well prove to be a global initiative. This system must be mandatory to be effective as voluntary collection is random and inefficient for all stakeholders.

Notwithstanding the initial expense, the health care industry stands to benefit significantly. The Alliance will reserve advocating for a specific type of technology identification system. Several different types of technologies are currently in use including radiofrequency, bar coding, optical systems, and others. Many factors will need to be quantified in the Agency's decision-making process for a UDI. We are pleased at the FDA's thoughtful deliberation on UDI to date by holding stakeholder's meetings and commissioning white papers.

Identification should be placed on devices at the unit of use level. UDI could occur at more than one level but is necessary at the unit of use level for health care utility. A UDI could occur on the devices themselves with the noted exception of implantable devices. The Association of Medical Device Reprocessors has implemented such a marking and tracking system for reprocessed devices including very small devices, such as drill bits. The FDA should use a reasonableness test with regard to patient safety in determining the unit of use for devices. For instance, items such as gloves, cotton balls, cotton swabs, and many Class I devices sold over the counter, do not require identification of every single item. Efforts to identify the box should be sufficient to accomplish appropriate patient safety, with these low risk devices.

### ***Use of International Harmonization/Standards***

As codified in the Food and Drug Administration Modernization Act (FDAMA) in 1997, FDA officials were directed to meet with representatives of foreign countries to reduce the burdens of global regulation and harmonize regulatory requirements. Additionally, officials were directed to engage in efforts to accept mutual recognition agreements relevant to the regulation of devices and good manufacturing practices between the European Union and the United States. FDAMA recognized national and international standards in the review of medical devices. The Alliance thanks the FDA for its leadership on global harmonization task forces and the advances in standardization accomplished over the past few years.

### **IMPLEMENTING UNIQUE DEVICE IDENTIFIERS**

#### ***Privacy/ Informed consent issues***

The Alliance is aware that some companies are using laser etching as an identification marker on implantable devices, specifically hip stems. Some of the etchings on the devices led to early weakening and failure, necessitating revision surgery for the patient. The Alliance finds this situation to be untenable and strongly recommends against the use of unique identification on the implants themselves. This information should be contained in the packaging of devices, not on the implantable device itself.

A UDI etched or marked on an implantable device also raises many privacy issues. News reports have questioned the security of smart cards used with radio frequency identification (RFID) systems. Engineers have been able to break the codes and accessed confidential information. RFID systems currently can be read within a distance of forty feet. Ultimately, the goal of the UDI system is to be linked to an electronic health record. As smart card systems are insufficiently encrypted, a UDI system on implantable devices would not be HIPAA compliant.

Furthermore, some devices are resorbable and are incorporated into a patient's anatomy. Presumably only an identification chip would be left on such devices. If a patient were a multiple user of devices, systems would need to accommodate data from multiple devices, including for instance, dissolving sutures. The Alliance is aware that devices are currently marketed to contain a patient's entire medical record and are percutaneously implanted below the skin. Reading such a system with RFID if not properly encrypted would provide access to confidential information of a medical and financial nature. Patients could choose to change their informed consent policy necessitating an operation to remove an implantable device. For all of these reasons, the Alliance strongly recommends that implantable devices are uniquely identified on the packaging, not on the devices themselves.

### ***Hospital Interface***

As with other initiatives, the UDI system will have little utility if it is not incorporated at the hospital level. Bar-codes are currently required on pharmaceutical drugs and at present are systematically used at few hospitals. Similarly, though a 2005 JCAHO requirement, hospitals are required to track allograft tissue. The Alliance is aware that tissue processors could identify and track tissue immediately following the Biomedical Tissue Services and Donor Referral Services recalls. However, hospitals did not immediately notify surgeons (and patients) due to lengthy hospital chart abstractions. Most hospitals track their recalls manually by a lengthy chart review. Some hospitals manage their own bar-coding systems and synchronize their data with manufacturers, distributors, or others in the supply chain. This additional layer adds the possibility of medical error and is expensive to maintain.

Hospitals must implement tracking and identification of drugs, devices, and biologicals to increase safety for patients. The Alliance strongly encourages the FDA to coordinate efforts on UDI systems with the American Hospital Association and the Joint Commission on Accreditation of Healthcare Organizations.

### ***Guidance Document Development***

The Alliance strongly advocates that the FDA to streamline their internal processes. While it is important to provide a solid legal foundation for regulatory actions, the FDA has become encumbered in its legal review of documents. Internal processes should be more efficient with only the most important matters designated for the review of Chief Counsel. Guidance documents are critically important toward the functioning of the Agency and establishing a least burdensome pathway.

Progress is being significantly hampered at the agency by the lack of guidance document development and subsequent guidance publishing. Manufacturers report receiving increased questions during product reviews when guidance is not clear to both industry and the FDA review staff. The slower review times directly impact the amount of work the Agency is able to accomplish.

The Alliance acknowledges the success of the utilization and development of FDA guidance documents. These documents assist in predictability and transparency for manufacturers in the development of pre-market device submissions as well as expediting the review process. Manufacturers often cite receiving different interpretations of product reviews. Guidance documents assist in the standardization of FDA policy and interpretation. Additionally, guidance documents are often used as special control documents to support a downclassification. The Alliance stands ready to assist the FDA in revising and creating guidance documents to address critically important, clinical information.

#### **UDI BENEFITS AND COSTS**

The Alliance acknowledges an increased cost to manufacturers but believes the benefits outweigh the risks. The use of a UDI will lead to efficient reimbursement when used in tandem with an EHR. As one-third of every healthcare dollar is wasted, the implementation of a UDI system will save needed resources. A UDI system will encourage cost-effectiveness in the supply chain efficiency of the manufacturing community. Such a system would ultimately decrease healthcare costs by standardizing inventory and associated costs through the hospital system.

Recalls of devices would be more readily and thoroughly accomplished. Manufacturers report that they do not always locate all recalled devices as some are lost in the system. Depending on the framework of the UDI regulation, the FDA could capture device denominator data. With such data, the FDA would be more informed as to the extent of the risk/benefit ratio and have more data to determine a public health risk. The Agency could feasibly capture lot and model numbers which are not usually provided by voluntary reporters to MedWatch adverse event reporting system.

Device interoperability could be programmed into an electronic health record (EHR). Additionally, a UDI system would significantly prevent the counterfeiting of devices by allowing purchasers to assess the pedigree of their shipment.

Equipment could be easily and more quickly located in a hospital setting with UDI. Moreover, in tandem with an EHR, a UDI system could identify devices that are incompatible with MRIs in addition to identifying a patient's allergies to certain metals.

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Again, we appreciate the opportunity to comment on unique identification systems for devices. We strongly encourage the FDA to mandate UDI for medical devices to aid in patient safety, to decrease medical errors and to decrease healthcare costs for our nation.

The Alliance welcomes the opportunity to work with the Agency as you progress on the development of unique identification systems. We encourage you to contact us with any specialty specific issues. Should you have any questions, or would like to assist one of our member organizations, please contact Emily L. Graham, CCS-P, CPC, ASCRS Manager of Regulatory Affairs at [egraham@ascrs.org](mailto:egraham@ascrs.org) or 703-591-2220 or Robin Hudson, MPA, AUA Manger of Regulatory Affairs at [rhudson@auanet.org](mailto:rhudson@auanet.org) or 410-689-3762.

Sincerely,

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American Association of Orthopaedic Surgeons  
American College of Obstetricians and Gynecologists  
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