



November 9, 2006

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Lewis S. "Mike" Eidson
President

Re: Unique Device Identification [Docket No. 2006N-0292]

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Dear Secretary:

The Association of Trial Lawyers of America ("ATLA") hereby submits comments in response to the Food and Drug Administration's ("FDA") Notice requesting information about how the use of a unique device identification ("UDI") system for medical devices may improve patient safety. *See* 71 Fed. Reg. 46233.

ATLA, with 55,000 members in the United States, Canada and abroad, is the world's largest trial bar. It was established in 1946 to safeguard victims' rights, strengthen the civil justice system, promote injury prevention, and foster the disclosure of information critical to public health and safety. ATLA supports the use of a mandatory UDI system for medical devices and suggests the FDA should play a major role in implementing the system. ATLA believes a mandatory UDI system will improve public health and safety by enhancing the current recall and adverse event reporting processes and reducing the number of medical errors caused by medical devices.

I. The FDA Should Play a Primary Role in the Development and Implementation of a Mandatory UDI System for Medical Devices

Every year more than 8,000 new medical devices are marketed in the United States.¹ The FDA is the federal agency charged with ensuring the safety of medical devices and does so, in part, by regulating both the labeling and reporting requirements for all approved medical devices. 21 C.F.R. Pts. 801, 803. A mandatory, standardized UDI system for medical devices will assist the FDA in executing the agency's labeling and tracking authority.

A mandatory, rather than voluntary, UDI system also will improve device safety. Currently, manufacturers, importers, distributors, and device user facilities all utilize different methods to identify and track medical devices, and their use of such methods is sporadic at best. Sometimes the same device is tracked by different entities in different ways. A mandatory UDI system for medical devices will allow all the parties involved with medical devices, including the FDA, to use the same

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¹ David W. Feigal, M.D., M.P.H., Susan N. Gardner, Ph.D., and Mark McClellan, M.D., Ph.D., *Ensuring Safe and Effective Medical Devices*, 348 *New Eng. J. Med.* 191-92 (2003).

methods to identify and track medical devices. A voluntary system would only recreate the variation and inconsistency in medical device identification that currently exists in the health care arena.

ATLA believes the FDA's active involvement in the development and implementation of a mandatory UDI system for medical devices is crucial. A neutral party must closely monitor health practitioners' compliance with the UDI system. As the FDA currently retains authority regarding medical devices, it is the logical agency to oversee the program. ATLA suggests that the FDA adopt specific policies including strict enforcement mechanisms in order to execute such a system.

II. Mandatory UDIs for Medical Devices Will Offer Significant Contributions to Recalls and Adverse Event Reporting and Will Reduce Medical Errors

A. Mandatory UDIs Will Streamline the Recall Process

More than 1,000 medical devices are recalled every year.² While the majority of recalls are issued voluntarily by device manufacturers and distributors, the FDA also has authority to issue recalls of medical devices. If a device "would cause serious, adverse health consequences or death," the FDA may issue a cease distribution and notification order under certain circumstances, as well as order a mandatory recall of medical devices. 21 C.F.R. §§ 810.10, 810.13.

Currently, manufacturers, importers, and distributors are responsible for identifying and tracking all the devices subject to a recall and developing their own recall strategies. As a result, their recall strategies and identification systems are wide-ranging and complicated and involve numerous parties, making oversight of recalls a complex process. The lack of a uniform identification system to pinpoint medical devices subject to a recall produces inconsistent and often dangerous results.

Mandatory UDIs for medical devices will streamline the recall process by establishing standardized information sets to effectively identify medical devices. However, the magnitude of potential benefits a mandatory UDI system can provide will largely depend upon other factors. For example, UDIs could simplify recalls if hospitals and doctors' offices obtain the capabilities to electronically enter medical device information into a database. Hospital staff using electronic databases could quickly identify current hospital inventory, as well as those patients who have received or used recalled devices. Further, mandatory UDIs will facilitate recalls by providing all of the parties affected by a recall – the FDA, device users, doctors, device user facilities, manufacturers, and importers – access to uniform information.

² David W. Feigal, M.D., M.P.H., Susan N. Gardner, Ph.D., and Mark McClellan, M.D., Ph.D., *Ensuring Safe and Effective Medical Devices*, 348 *New Eng. J. Med.* 191-92 (2003).

Access to standardized identification information will expedite the discovery process needed to locate devices subject to a recall.

The potential benefits of mandatory UDIs are illustrated by a massive recall of Guidant devices. Dr. Barry Maron testified about the circumstances surrounding the recall before the Senate Judiciary Committee.³ Dr. Maron discussed the story of a 21-year-old patient, Joshua Oukrup, who received a Guidant Prizm 2DR 1861 defibrillator to treat his hypertrophic cardiomyopathy. Approximately three and a half years after receiving his device, Joshua died suddenly as a result of a short-circuiting defect. At the time of Joshua's death, Guidant had already documented twenty-five (25) other similar short-circuited defibrillators. In addition, Guidant had already begun manufacturing adjustments to new defibrillators of the same model several years prior to Joshua's incident yet had continued to sell the defective devices. These circumstances eventually lead to the largest recall of these devices in the twenty-five year history of the industry. Mandatory UDIs could have facilitated the complicated recall of the approximately 200,000 affected devices.

While mandatory UDIs will improve the recall process, the FDA also must institute new policies to improve communications regarding recalled devices. Effective communication to medical device users is a consistent problem with device recalls. Device users affected by a recall often are not notified of the recall until long after any action by the manufacturer and/or the FDA. Sometimes, patients are never notified of the device recall. The case of Zina Lewis documents such an instance.⁴ In 2002, Zina Lewis had a Guidant Pulsar Max II dual chamber pacemaker implanted. Throughout 2002 and 2003, her health inexplicably deteriorated. By July 2003, Zina's doctors urged her to have the device removed. After undergoing a complex open-heart surgery to have the Pulsar Max II removed, Zina received another Guidant implant device, the Insignia pacemaker.

Prior to undergoing the life-threatening surgery, Zina was never notified that between May and June 2003, Guidant, with the FDA's knowledge, issued safety advisories for both the Insignia and Pulsar Max II. Zina would never have received the Insignia implant had she been aware of the advisory. The Insignia was a faulty device that Zina lived with until several complications required its removal in 2005 – the same year that Guidant, with the FDA's knowledge, issued a recall of both the Pulsar Max II and Insignia. Zina, and the hundreds of other individuals implanted with the faulty devices, were never notified of the recalls. This haphazard process left Zina not only with immense physical and emotional trauma but also a future plagued with life-threatening medical complications. Thus, while a standardized identification system for medical devices would greatly improve the facilitation of

³ *Defective Products: Will Criminal Penalties Ensure Corporate Accountability?*, Senate Judiciary Committee, 109th Cong. (2006) (testimony of Dr. Barry Maron, Director, Hypertrophic Cardiomyopathy Center, Minneapolis Heart Institute Foundation).

⁴ *See Zina Lewis v. Guidant Corporation, et al.* MDL #05-1708 (DWF/AJB).

recalls, ATLA urges the FDA to implement policies to better notify patients of faulty devices.

B. Mandatory UDIs Will Improve Adverse Event Reporting

Medical device user facilities, manufacturers, and importers must report all deaths and serious injuries that may have been caused, in whole or in part, by a faulty medical device. 21 C.F.R. Pt. 803. They also must establish and maintain adverse event files and submit annual summary reports to the FDA. *Id.* In 2004 alone, the FDA received approximately 47,000 manufacturer reports and more than 3,000 user facility reports of adverse medical device events.⁵ Given the magnitude of reports the FDA receives every year, a mandatory UDI system for medical devices could help to organize and track the devices included in such reports. This, in turn, will lead to better oversight and improved safety.

C. Mandatory UDIs, Used in Connection With Other Technologies, Will Lead to a Reduction of Medical Errors

Mandatory UDIs for medical devices have the potential to greatly reduce some commonly occurring preventable medical errors, but the extent of the benefits derived from UDIs will depend on its use in conjunction with innovative technologies such as bar codes and electronic medical records.

ATLA believes the placement of bar codes onto medical devices will revolutionize the current methods used to identify and track medical devices. Bar codes will eliminate the privacy issues associated with Radio Frequency Identification (“RFID”) technologies and will create consistency with the FDA’s 2004 final bar code rule for human drugs and biological products. 21 C.F.R. §§ 201.25, 610.67. The establishment of a consistent system that utilizes the same, or at the very least, complementary technologies to identify both drugs and medical devices may help decrease costs and institutional restructuring concerns voiced by hospitals, pharmacies, and doctors’ offices.

Further, a mandatory UDI system used in conjunction with electronic medical records may help to decrease the number of patients implanted with the wrong device, implanted with a device in the improper location, or treated with or touched by a device to which they are allergic. For example, some implantable devices are incompatible with magnetic resonance imaging (MRI) machines. A patient with such an implantable device is at risk of serious injury or death if he or she is exposed to an MRI machine. A UDI could provide detailed device information in a device user’s electronic medical record and allow for an easy assessment of the compatibility of the patient’s device with MRI machines.

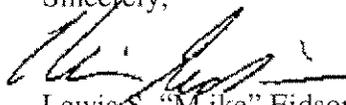
⁵ Marilyn J. Field and Hugh Tilson, *Safe Medical Devices for Children*, Institute of Medicine (2005) (prepublication copy).

The combined use of a UDI system and electronic medical records also may decrease the medical errors associated with reprocessed single use devices (“SUDs”). Reprocessed SUDs may present increased risks to patients because they have been previously used in other patients and typically have characteristics that make them extremely difficult to thoroughly clean and sterilize.⁶ A UDI will provide a patient’s physician with the knowledge that he or she has previously received a reprocessed SUD, which could aid in the diagnosis of the patient’s current problem.

The opponents of a mandatory UDI system cite cost as one of the main reasons to establish a voluntary system. Yet, medical errors cost between \$17 and \$29 billion dollars annually.⁷ These errors injure and kill thousands of patients every year and inflate the cost of healthcare. A mandatory UDI system for medicals devices will help to reduce the rate and cost of these errors. In several years, the health, safety, and financial benefits will outweigh the initial costs associated with implementing a mandatory UDI system.

ATLA appreciates this opportunity to submit comments on the Agency’s Notice regarding the use of a medical device UDI system. If you have any questions or comments, please contact Gerie Voss, ATLA’s Regulatory Counsel at (202) 965-3500 ext. 748.

Sincerely,



Lewis S. “Mike” Eidson
ATLA President

⁶ *Medical Device Safety: How FDA Regulates the Reprocessing of Supposedly Single-Use Devices*, House Government Reform Committee, 109th Cong. (2006) (statement of Stephen J. Ubl, President and CEO, Advanced Medical Technology Association).

⁷ Institute of Medicine, *To Err is Human: Building a Safer System 1* (1999).