



AMERICAN SOCIETY OF
PLASTIC SURGEONS



PLASTIC SURGERY
EDUCATIONAL FOUNDATION

Executive Office

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November 9, 2006

Andrew C. Von Eschenbach, MD
Acting Commissioner
Division of Dockets Management (HFA-305)
Food and Drug Administration
5360 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Comments re. Unique Device Identification (UDI) for Medical Devices
Submitted Electronically: <http://www.fda.gov/dockets/ecomments>

Dear Dr. Von Eschenbach:

The American Society of Plastic Surgeons (ASPS) appreciates the opportunity to offer comments on the Food and Drug Administration (FDA) “Unique Device Identifier; Request for Comments” [Docket No. 2006N-0292]. ASPS is the largest association of plastic surgeons in the world, representing surgeons certified by the American Board of Plastic Surgery. Plastic surgeons provide highly skilled surgical services that improve both the functional capacity and quality of life of patients. These services include the treatment of congenital deformities, burn injuries, traumatic injuries, cancer, and aesthetic surgery. ASPS promotes the highest quality patient care, professional, and ethical standards and supports the education, research, and public service activities of plastic surgeons.

We appreciate the significant effort that the FDA has made in holding its recent open public hearing for wide-ranging stakeholders as well as the open comment period. We believe that a carefully designed unique device identification system, once implemented, will improve patient safety and quality of care for American patients and ultimately, the greater international community. Furthermore, use of such a system would greatly assist current collaborative efforts between manufacturers, clinicians, patients, and the FDA to better support post-market surveillance of medical devices.

Basis for Unique Device Identifier (UDI) System

ASPS believes that a UDI system will have broad utility in the delivery of quality healthcare. Most stakeholders, including device distributors, hospitals, manufacturing trade associations, and

federal agencies including the Agency for Healthcare Research and Quality, Department of Defense, and Department of Veterans Affairs are generally supportive of efforts to develop UDIs. Aside from implementation issues, the case for development of a UDI system is significant. While scientific literature supporting the use of UDI is documented predominantly in relation to pharmaceutical usage, evidence exists for its patient safety role for medical devices.

A UDI would likely have a positive impact foremost on patient safety through increased medical accuracy and the reduction of medical errors. For instance, it would provide an additional patient safeguard against implantation or use of a wrong medical device. It would also further patient-centered care through optimizing patient outcomes as well as facilitating post-market surveillance through improved capture of adverse events and enhanced capabilities for product recalls and market withdrawals.

A key benefit may be the ability to associate use of a device with a specific patient user. While this concept has been used for tracked devices under FDA regulation, it is generally not in use in the greater device market. Furthermore, tracking itself could be enhanced by UDI development. Ultimately, use of a UDI system would improve current recall efforts where painstaking efforts are often necessary in the review of largely paper medical records and other documentation, which can produce delays in relaying information to the public. As is often the case, physicians, hospitals, and other healthcare providers would not have to rely on paper searching to identify and locate products. UDI could also be invaluable into the future as electronic health records proliferate.

Improved adverse event reporting, through increased device identification, could also facilitate gradual incorporation in electronic medical records and other clinical databases. This enhanced information could serve as a foundational resource in the event new health questions arise in actual clinical practice. As physician and patient advocates, we feel such enhancements for post-market surveillance would help foster a more transparent “culture” for the reporting adverse events and where the reported information would help to continuously improve patient outcomes.

Implementation of Unique Device Identifier (UDI) System

With all its advantages, a UDI must still be carefully developed in light of the diversity of medical devices. The system must allow flexibility in the type of technology to allow for differing device characteristics. There are a number of technologies currently available, including bar coding and radiofrequency identification (RFID), and all would support a UDI system. However, without more research and evidence on newer technologies, such as RFID, it may be premature to require this particular technology over others. Furthermore, costs must be weighed in relation with its benefits to assure its practicality for use in the healthcare market.

Many manufacturers currently use bar codes or other identifying information on their packaging. Due to the varying nature of medical devices, particularly implantable devices, we would not suggest requiring UDI on the device itself. There is too much variation in medical device makeup. For instance, there are safety concerns with damage or decreased effectiveness of a device due to marking of some implantable or other devices. We would however encourage, but

not mandate, such reasonable use on the package at the unit of use. Information might include basic information including manufacturer/product name, make/model, lot number, and device-specific serial number. We would also advise continued work towards international harmonization to prevent a myriad of conflicting UDI systems.

In our view, a national UDI system should be voluntary as these benefits do not exist for all devices (for example, a bandage). For those devices where patient safety would be enhanced, however, patients would be best-served by use of a UDI system.

ASPS appreciates your consideration of these comments. We applaud the FDA for its efforts to improve patient safety through unique device identification systems for devices. We would be happy to answer any questions that you may have. Please do not hesitate to contact Khatereh Calleja, ASPS Manager of Federal Affairs, at kcalleja@plasticsurgery.org or 202-672-1518.

Sincerely,

A handwritten signature in cursive script, appearing to read "Roxanne J. Guy".

Roxanne Guy, MD, FACS

ASPS President