AAOS
American Academy of Orthopaedic Surgeons
American Association of Orthopaedic Surgeons

6300 North River Road
Rosemont, Illinois 60018

P. 847.823.7186
F. 847.823.8125

www.aaos.org

November 7, 2012

Margaret A. Hamburg, MD
FDA Commissioner
Food and Drug Administration (FDA)
10903 New Hampshire Ave.
Silver Spring, MD 20993

Dear Dr. Hamburg:

On behalf of more than 18,000 board-certified orthopaedic surgeons, the American Academy of Orthopaedic Surgeons (AAOS/Academy) thanks the FDA for the opportunity to comment on the proposed rule for the Unique Device Identification System (UDI), as published in the July 10, 2012 *Federal Register*. We are dedicated to the development of sound federal health care policy that fosters patient access to the highest quality orthopaedic care.

General Comments

AAOS appreciates the FDA's efforts to solicit input from and provide feedback to stakeholders through public meetings and presentations in other venues. We have long supported the implementation of a unique device identification system with the potential to improve patient safety and reduce medical errors, as established in our 2006 and 2009 comments on this issue. In this comment, the Academy will respond to the stated public health objectives outlined in the announcement and offer feedback on questions of relevance to our patients and their care.

Public Health Objectives

The FDA identifies nine public health objectives that would be served by the ability to identify medical devices throughout the supply chain and during their use in the care and treatment of patients.

1. *Reduce Medical Errors*. AAOS agrees with the FDA's assessment that the ability to link device information from the UDI to the Global Unique Device Identification Database (GUDID) will aid in the identification of a device and the communication of such information may prevent inappropriate use.

2. *Simplify the Integration of Device Use Information Into Data Systems*. We believe there is tremendous potential for this utility, provided that the

AAOS
American Academy of Orthopaedic Surgeons
American Association of Orthopaedic Surgeons

6300 North River Road
Rosemont, Illinois 60018

P. 847.823.7186
F. 847.823.8125

www.aaos.org

automatic identification and data capture (AIDC) technology used is compatible with the myriad electronic medical record and computerized physician order entry systems in use throughout the United States.

3. *Provide for More Rapid Identification of Medical Devices With Adverse Events*.
4. *Provide for More Rapid Development of Solutions to Reported Problems.*
5. *Provide for More Rapid, More Efficient Resolution of Device Recalls.*
6. *Better-Focused and More Effective FDA Safety Communication*

   AAOS concurs that "an essential prerequisite to resolving adverse events is the timely and precise identification of the particular device or devices that may have a connection with an adverse event." However, we strongly encourage the FDA to complement this function of the UDI by improving the associated adverse event databases, specifically to facilitate searches for previous adverse event reports. AAOS has frequently advocated for greater functionality in the Manufacturer and User Facility Device Experience (MAUDE) database and the FDA Adverse Event Reporting System (FAERS) which could lead to an increase in their use by orthopaedic surgeons.

   AAOS also agrees with the FDA's premise that UDI technology will improve the identification of devices for the purposes of addressing reported problems, resolving recalls, enhancing safety communications. We appreciate the work of the FDA in identifying opportunities to use the UDI system to augment the Agency's existing safety and communication products

7. *Provide an Easily-Accessible Source of Definitive Device Identification Information*. Patient access to device information is an essential element of shared decision making. Orthopaedic patients will benefit greatly from the ability to look up their device in GUDID, as well as from the option of receiving simplified educational materials.

8. *Additional Benefits*. We are pleased by the capacity of the UDI system to assist in the identification of difficult to find devices and components. A 2006 survey of AAOS Fellows found that of those that had replaced a worn or failing device in the previous 5 years, replacement parts were not available for 12.3% of hip cases and 11.0% of knee cases. Most often joints were entirely revised when replacement parts were unavailable, however a small number of hip replacement parts were retrofitted or custom-ordered. Technology that could aid in the identification of the implanted device and help locate needed

AAOS
American Academy of Orthopaedic Surgeons
American Association of Orthopaedic Surgeons

6300 North River Road
Rosemont, Illinois 60018

P. 847.823.7186
F. 847.823.8125

www.aaos.org

replacement parts could significantly reduce the need for full revisions in the case of worn components.

9. *Standard Format for Dates Provided on a Device Label or Package*. The inclusion of packaging information promoting the safe use of devices is a significant benefit. Further, we support the development of an ASTM standard seeking consistency for arthroplasty device labels and our members are working to guarantee its compatibility with UDI requirements.

Comments on Questions Related to the Objectives of the UDI System and Potential Uses of UDIs

1. Which of the objectives and potential uses of the UDI system are most important to you?
   AAOS prioritizes the ability to link UDI data back to orthopaedic patients, facilitating patient monitoring and enabling early identification of those patients who may require follow-up. We strongly believe that, while UDI will allow patient to access their device information, recall activities should still involve the surgeon communicating with patients to provide accurate clinical information and treatment options.

6. If a combination product's primary mode of action is that of a device, is it appropriate to require each device constituent part of the combination product to bear its own UDI; and

7. If a combination product's primary mode of action is *not* that of a device, is it appropriate to require each device constituent part of the combination product to bear its own UDI; and

8. Should the FDA require a UDI on the label and package of every combination product that has a device constituent part, regardless of its primary mode of action, except when the primary mode of action is *not* that of a device, *and* the combination product is labeled with an NDC?

   Each component should bear its own UDI, regardless of the primary mode of action. This is particularly important if, for example, products which are to be used together may be used independent of each other. The possibility of

AAOS
American Academy of Orthopaedic Surgeons
American Association of Orthopaedic Surgeons

6300 North River Road
Rosemont, Illinois 60018

P. 847.823.7186
F. 847.823.8125

www.aaos.org

physician-directed usage necessitates treating each device component of a combination product as a stand-alone product, bearing its own UDI.

12. Is it appropriate to require direct marking for all implantable devices? Should the requirement be limited to certain types of implants? If so, how should we define which *implantable devices* meet that requirement?

There are serious safety and privacy concerns related to the direct marking of devices. Devices that may be reprocessed for use in multiple patients present a substantial challenge to patient safety. Material on the FDA website points to many of the barriers to appropriate reprocessing devices to prevent the retention of debris that may lead to infection. Frequently, these problems are related to the difficulty of removing debris from crevices and other textured surfaces. Direct marking of these devices may increase the areas that could potentially retain debris and inhibit reprocessing, and therefore diminish the safety the UDI is intended to enhance.

The AAOS is aware that some companies have used 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[1], necessitating revision surgery for the patient. The AAOS finds this situation to be untenable and strongly recommends against the use of unique identification on the implants themselves unless the device integrity is maintained. This information should be contained in the packaging of devices, and not on the implantable device itself if any concern arises about the mechanical integrity of the device due to the labeling process.

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 the directly applied identifier would be left on such devices if the identification system were incorporated on the device. If a patient was a multiple user of devices, systems would need to accommodate data from multiple devices, including, for example, dissolving sutures. AAOS is

AAOS
American Academy of Orthopaedic Surgeons
American Association of Orthopaedic Surgeons

6300 North River Road
Rosemont, Illinois 60018

P. 847.823.7186
F. 847.823.8125

www.aaos.org

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, 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 AAOS strongly recommends that implantable devices are uniquely identified on the packaging and not the devices themselves.

21. Should FDA require the use of specific AIDC technologies or have a role in approving the use of new AIDC technologies that are used to provide a UDI, or should we leave this decision to the healthcare community and issuing agencies?

These decisions are best left to the healthcare community and issuing agencies to determine. UDI should be technology neutral in order to accommodate all methods of labeling, marking, identifying products and software (one-dimensional linear barcode, two dimensional barcode, RFID or other Automatic Identification and data capture media). AAOS believes that the interaction between the healthcare community and issuing agencies will lead to the development of the most cost-effective and efficient AIDC technologies.

28. If you believe *additional* information should be required to assure the adequate identification of a medical device, please identify the information you believe is necessary and provide an explanation of your views.

AAOS strongly encourages the FDA to consider including separate designations for processing and manufacturing dates, when these dates differ, as the processing may affect material properties of the device. We believe that this step will increase the potential of UDI to optimally serve the interests of patient safety. Many device components, such as polyethylene inserts for total joint systems, have a shorter shelf life than the devices with which they are implanted. Inclusion of the equivalent of a 'use by date' would reduce the risk of implanting a device that has exceeded its functional life, thereby reducing the risk of component failures.

32. Will a specified format for dates on medical device labels reduce confusion concerning expiration dates; and
33. Which format would patients better understand, the "U.S." format (e.g., SEP 30, 2011) or the "international" format (e.g., 30 SEP 2011); and

AAOS
American Academy of Orthopaedic Surgeons
American Association of Orthopaedic Surgeons

6300 North River Road
Rosemont, Illinois 60018

P. 847.823.7186
F. 847.823.8125

www.aaos.org

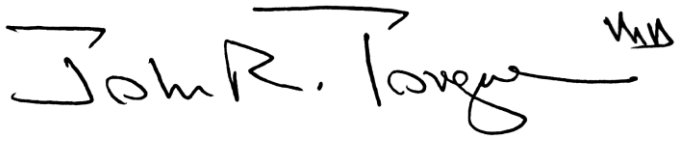
34. Which format would health care professionals better understand, the "U.S." format (e.g., SEP 30, 2011) or the "international" format (e.g., 30 SEP 2011); and
35. Is there a strong reason to favor one format over the other?

Standardizing the format for dates on medical device labels, including the location of the expiration dates, will reduce confusion regarding those dates. Patients and health care providers are increasingly exposed to products originating from around the world and are accustomed to seeing expiration dates expressed in a range of formats, including those cited in the proposed rule. AAOS has previously advocated for the UDI system to be internationally harmonized and continues to support that goal. To this end, we believe the "international" format, as described in question 35, best adheres to an internationally harmonized standard.

Conclusion

The AAOS thanks the FDA for their efforts to meet with stakeholders and provide thoughtful consideration of the issues involved in the development of the UDI proposed rule. The Academy applauds the prioritization of critical public health objectives driving this rule-making process. The AAOS looks forward to working with the FDA in its efforts to regulate unique identification systems for medical devices that will aid in quality patient care.

Sincerely,



John R. Tongue, MD
President, American Academy of Orthopaedic Surgeons

[1] Lee EW, Kim HT, 2001, Early fatigue failures of cemented, forged, cobalt-chromium femoral stems at the neck-shoulder junction, *J Arthroplasty*, Feb;16 (2):236-8.