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November 7, 2012

Margaret A. Hamburg, MD, Commissioner
U.S. Food and Drug Administration
Division of Dockets Management
10903 New Hampshire Ave.
Silver Spring, MD 20993

RE: Unique Device Identification System, Docket FDA-2011-N-0090

Dear Dr. Hamburg,

On behalf of the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS), we appreciate the opportunity to submit comments regarding the above referenced FDA proposed rule on the Unique Device Identification (UDI) System. Neurosurgeons are intensely interested in the safety, availability, and efficiency of medical devices they provide to their patients. The scope of devices used to treat neurosurgical diseases of the brain and spine is vast and varied and we appreciate the difficult task before the FDA to create a UDI system that enhances patient protection.

Summary of AANS/CNS Comments on UDI

- **Date Format**—If the FDA were to finalize the proposal for a standardized date format for device labels and packages, we hope FDA will make a concerted effort educate all stakeholders on the format.
- **Direct Marking of Implantable Devices**—We appreciate the FDA's acknowledgement of the need for exceptions from direct marking for very small devices, such as screws used in spine surgery, and we ask the FDA to seriously consider the expense versus benefit of direct marking for other implantable devices.
- **Timeline/Effective Dates**—We do not support earlier implementation dates, as the UDI system is an expensive and ambitious undertaking that should be carefully crafted and a shorter timeline seems infeasible. In fact, the process may need additional time.
- **Global UDI Database (GUDID)** – The GUDID is a monumental enterprise that allows for key information but could become unwieldy if too much data is required and we urge the agency to weigh data element carefully to reduce the burden on reporters, while including items of most benefit to patients, clinical staff, and researchers
- **Combination Products/Convenience Kits**—As with other issues in the rule, FDA should consider the practical balance between expense and benefit in developing UDI for products that are packaged together in kits and devices that may be typically sold in along with a drug or biologic.

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Date Format

The AANS and CNS are aware that the proposal by FDA to create a standardized date for packaging and labels has met with controversy, as currently there are many formats and the American and European styles are different. While we do not have a preferred date format, we would hope whatever uniform system FDA ultimately decides to implement for dates is clear and that a concerted effort is made to all educate stakeholders on the format.

Direct Marking of Implantable Devices

We were pleased to see that FDA will permit applications for exceptions to direct marking for devices for which the marking is not achievable due to technical issues or if the marking would interfere with the structural integrity of the device. We agree that there are devices, such as aneurysm clips, intravascular stents, pedicle screws and other bone screws, neurostimulator electrodes, and cranial plate fixation screws, which are likely too small to be marked effectively. In addition, absorbable implanted devices such as chemotherapy wafers and devices with amorphous structures such as bone cement would be infeasible for marking.

The AANS and CNS also note that some groups have objected to the direct marking for any implantable devices. While these devices should be assigned UDIs, which would be entered into the patient's electronic medical record and included on the device packaging, we share the skepticism about whether direct marking is necessary if the device will be implanted. Once a device is implanted, the marking could only be read with technology allowing a scanner to pick up the marking from outside the body or if the device were surgically removed. Assigning a UDI to the device without directly marking would still help further the goal of more targeted recalls and better data, assuming it was correctly entered in to the patient record, registries, and other databases. Given the cost and burden of marking implantable devices, we recommend that FDA require the UDI for these devices on the packaging and not on the device itself.

Timeline/Effective Dates

We do not support earlier effective dates, as the UDI system is an expensive and ambitious undertaking that should be carefully implemented and a shorter timeline seems infeasible. In fact, we feel the process may need additional time. The immense scope of developing a UDI system requires time to adequately phase in the change and we support the agency's proposal to allow sufficient time to implement the provisions. We realize that FDA is constrained by some statuary deadlines but, to the extent possible, we urge FDA to take the time necessary to assure that the UDI system is practical and useful, as electronic medical records (EMRs) and information technology in medical centers is evolving and patients will ultimately be better served with an excellent system, even if it requires an additional year or more.

Global UDI Database

The AANS and CNS believe that the GUDID will be useful but appreciate the enormous complexity in developing and updating a database for devices. We would like to see data on MRI compatibility in the GUDID. However, patients would still need education and a card to carry with them explaining the adverse risks of the device with MRI use, as often receive now. Even with the most advanced and integrated EMR and database, patients must be alerted to potential risks associated with devices, some of which may remain in place for decades.

Combination Products/Convenience Kits

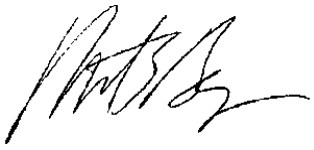
As with other issues in the rule, FDA should consider the practical balance between expense and benefit in developing UDI for products that are packaged together in kits. For example, a deep brain stimulator (DBS) lead anchoring ring comes in a kit of numerous other components (ring, clip, cap, and multiple anchoring screws). They are used simultaneously and one UDI would be sufficient for the unit of items. The multiple items in the kit would not require marking. In addition, some devices are typically sold along with a drug or biologic, such as bone morphogenetic protein (BMP) kits that include sponges to soak in the BMP and careful consideration should be given to whether marking all the items is useful. Finally, we question the need for the UDI to be included on packaging for multiple boxes of a device, if the UDI is on the containers for each individual device.

Conclusion

The AANS and CNS are eager to provide expertise to the FDA regarding the practicalities of device use in the clinical setting. The scope of devices used by neurosurgeons may well be the most varied of any surgical specialty. The list of implantable devices used by neurosurgeons is long and includes neuro-stimulators, pain pumps, brain shunts, spinal instrumentation, intravascular devices, artificial spinal discs, stereotactic radiosurgery equipment, and more. In addition, neurosurgery has developed a neurosurgical clinical outcomes data registry, the NeuroPoint Alliance (NPA), a national repository for important data on surgical care for the most common neurosurgical procedures, and UDIs may be useful in our efforts to track real-world experience with devices in our patients.

Finally, we want to thank FDA staff for their expertise, outreach to stakeholders, and dedication to the development of a reasonable UDI System. The agency has spent many years consulting with manufactures, patient groups, physician specialty societies, and others to craft the proposed rule. We particularly appreciate the clarity in the proposed rule and the specific list of questions for which FDA is especially interested in comments.

Sincerely,



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