AAOS
American Academy of Orthopaedic Surgeons
American Association of Orthopaedic Surgeons

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www.aaos.org

August 1, 2014

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, in partnership with American Association of Hip and Knee Surgeons, American Association of Neurological Surgeons, American Orthopaedic Foot & Ankle Society, American Orthopaedic Society for Sports Medicine, Congress of Neurological Surgeons, The Knee Society, Musculoskeletal Tumor Society, North American Spine Society, Orthopaedic Trauma Association, and Pediatric Orthopaedic Society of North America, wish to share with the FDA concerns related to the implementation of the Unique Device Identification System (UDI). The concerns reflect our dedication to the development of sound federal health care policy that fosters patient access to the highest quality surgical care.

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, 2009, and 2012 comments on this issue. In the months since the final rule was released, several implementation issues have come to our attention that have the potential to compromise the safety of and access to high quality surgical care.

It is understandable that as this rule moves from theory to practical application that unintended consequences will arise. Many of these issues relate to the requirement of labeling individual components of surgical trays and convenience kits and impact safety, accessibility, and flexibility in the operating room (OR). We have summarized these concerns below and ask that the FDA consider alternative implementation strategies to minimize the effect of unintended consequences on the provision of safe, effective surgical care.

<u>Safety</u>

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In the draft rule, the FDA identified 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. While we find that most of these objectives are covered by the final rule, there is significant concern that the objective of reducing medical errors may not be met. Rather, we believe that some aspects of UDI implementation may increase the risk of medical errors and compromise patient safety in other ways.

Labeling changes that alter how devices and instruments are packaged have the potential to increase the length of the procedure and interrupt the workflow in the operating room. OR staff must adapt to the packaging changes and the learning curve will, naturally, delay procedures. It is expected that the new labeling and data capture will also affect OR workflow. Such disruptions create the potential for wrong devices to make their way to the operative field.

An increase in the length of a procedure may require additional anesthesia time for the patient and longer wound exposure. There are inherent risks in the anesthesia and extending the time a patient is subjected to anesthesia may significantly increase these risks. The risk of infection also rises with the amount of time the operative site is exposed.

We encourage the FDA to work with manufacturers to study how label and packaging changes may modify the OR environment and make any necessary amendments to mitigate threats to patient safety. New methods of labeling devices should be evaluated in a pilot study, prior to widespread adoption, to gauge the effect of the method on safety (patient, device, and OR), workflow, and access.

Access

Surgeons have heard from individual industry representatives and AdvaMed about modifications to trays and convenience kits for UDI compliance. These changes include increased tray size to accommodate labeling, increased reprocessing time, and reduced availability of trays due to the time and resources necessary to produce and service trays for use. When added to the possibility of longer cases, as discussed above, reductions in the availability of devices may have a decidedly negative effect on access to surgical care. Longer procedure times, resulting in fewer cases performed in a given OR on any one day and fewer available trays may substantially diminish surgical volume.

Flexibility

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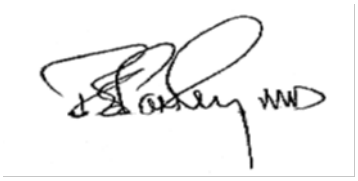
Innovation outstrips regulation in nearly every regulated industry in the United States. Surgical devices are no exception and, as such, necessitate a flexible and responsive regulatory scheme to best serve patients. We believe that a fluid labeling process will best serve surgical device access, enabling manufacturers to respond to real-world use of their products by our surgeon members. It is possible that more than one labeling method may be appropriate for various components of a convenience kit or future packaging and the regulations governing those choices should be amenable to those possibilities.

Conclusion

We acknowledge the fundamental challenges of creating and implementing a program of UDI's scope and complexity and hope, that by sharing our concerns with you, to promote the realization of the program's fullest potential. The societies thank 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. We look forward to working with the FDA in its efforts to regulate unique identification systems for medical devices that contribute to the delivery of quality patient care.

Sincerely,

Frederick M. Azar, MD
President, American Academy of Orthopaedic Surgeons



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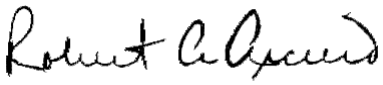

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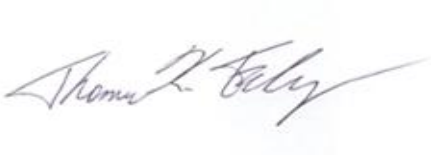

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