



AMERICAN ACADEMY OF
ORTHOPAEDIC SURGEONS

AMERICAN ASSOCIATION OF
ORTHOPAEDIC SURGEONS

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March 17, 2014

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

RE: Docket No. FDA-2013-D-1601

Dear Dr. Hamburg,

On behalf of more than 18,000 board-certified orthopaedic surgeons, the American Academy of Orthopaedic Surgeons (AAOS/Academy) in partnership with the American Association for Hand Surgery, the American Orthopaedic Foot and Ankle Society, American Shoulder and Elbow Surgeons, American Society for Surgery of the Hand, Cervical Spine Research Society, Limb Lengthening and Reconstruction Society, North American Spine Society, Orthopaedic Rehabilitation Association, Orthopaedic Research Society, Scoliosis Research Society, and Society of Military Orthopaedic Surgeons, welcomes the opportunity to comment on the Custom Device Exemption Draft Guidance for Industry and Food and Drug Administration Staff.

As noted in our January 18, 2013 comments, AAOS members had concerns with the functionality of the previous custom device provision with respect to meeting orthopaedic patients' needs. In 2011, via meetings of the Orthopaedic Device Forum, AAOS members heard from surgeons and engineers about the challenges faced in securing custom device solutions. Staff from FDA's Office of Compliance in the Center for Devices and Radiological Health discussed the definition of a custom device and the regulations governing their production and use, emphasizing the difference between "custom" and "customizable." AAOS worked closely with stakeholders to develop legislative language to address the custom provision and offer the following comments in response to the FDA's draft guidance on the custom device exemption.

Overall, we find the document to be clear and concise. The definitions and examples provided describe and illustrate many of the questions our members have previously raised around this issue. We believe the flow chart at the end of the document is a useful tool in making the initial determination of the appropriate pathway for a given

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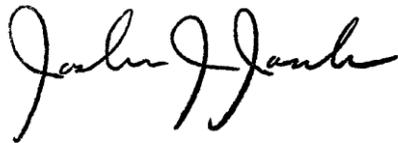
device need and that it will enhance communication between surgeons and manufacturers as they work together to address patients' needs.

We recognize that this pathway is inherently difficult to describe, owing to its relatively infrequent use, as compared to PMA or 510(k). For that reason, we feel that the reporting required by the draft guidance will add a great deal to the general understanding of the appropriate use and function of the custom device exemption. We are confident that the information gathered by the program will establish precedent, lay the groundwork for increased predictability, and assist in directing any future changes to the pathway that may be necessary.

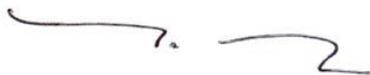
We acknowledge our responsibility to educate our members about the various pathways for medical device marketing. It is important that surgeons act within the confines of existing regulation when advocating for their patients' needs. We are committed to providing timely and accurate information to our members to facilitate the proper use of healthcare resources, including regulatory pathways that strive to address unmet needs.

We thank the FDA for considering our suggestions and hearing our concerns. We look forward to working with the FDA and other stakeholders to continue to advance the science of orthopaedic care and continuously improve patient safety and outcomes.

Sincerely,



Joshua J. Jacobs, MD
Immediate Past President, American Academy of Orthopaedic Surgeons



Mark Baratz, MD
President, American Association for Hand Surgery

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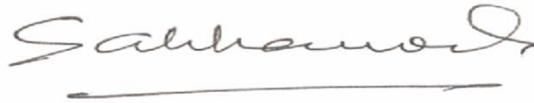
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