AAOS
American Academy of Orthopaedic Surgeons
American Association of Orthopaedic Surgeons

August 12, 2015

Stephen Ostroff, MD
Acting FDA Commissioner
Food and Drug Administration (FDA)
10903 New Hampshire Ave.
Silver Spring, MD 20993

RE: Docket No. FDA-2010-N-0389-0034

Dear Dr. Ostroff,

On behalf of more than 18,000 board-certified orthopaedic surgeons and orthopaedic researchers, the American Academy of Orthopaedic Surgeons (AAOS/Academy), in partnership with the American Association for Hand Surgery, American Orthopaedic Foot and Ankle Society, American Orthopaedic Society for Sports Medicine, American Society for Surgery of the Hand, Arthroscopy Association of North America, Musculoskeletal Tumor Society, Orthopaedic Research Society, Orthopaedic Trauma Association, Pediatric Orthopaedic Society of North America, and the Scoliosis Research Society, welcomes the opportunity to comment on the Medical Device User Fee Amendments Public Meeting. The Academy and societies champion the interests of patients by improving treatment options through education and research. We are dedicated to the development of sound federal health care policy that fosters patient access to the highest quality orthopaedic care. AAOS and the societies are committed to keeping the world in motion through the prevention and treatment of musculoskeletal conditions.

## Overall Performance

The overall performance of the medical device user fee program under MDUFA III has been highly effective. In our interactions with industry, we have heard mostly favorable feedback about review times, communication, and predictability of the review process. Data from the Agency's scheduled reports supports these evaluations. However, issues still exist and more could be done to minimize the impact of reviewer assignments on variability of the review process. Each delay in moving a product to market subsequently delays patient access to novel therapies. For this reason, we encourage FDA to take steps to stabilize the reviewer workforce.

Reports from our members indicate that further progress is needed to improve the transparency of regulatory pathways. Programs designed to expedite access for patients with unique diagnoses, anatomies, and combinations thereof are not functioning optimally for these groups. Barriers still exist in accessing the custom device exemption, humanitarian device exemption, and compassionate use exemption pathways. Clinicians report confusion among administrators and institutional review boards (IRBs) regarding the regulations and review requirements, producing delays in submitting requests and acquiring approval to use devices.

Determining the availability of currently marketed options prior to requesting exemptions is overly burdensome for clinicians, particularly as no readily searchable database exists for this purpose. Surgeons often have a very brief window

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for identifying a need for an exemption, preparing the request, and planning the procedure. A delay of 1-2 days can have dire consequences. FDA does respond quickly to these requests but more can be done to provide procedural support throughout the process and to clarify the role of IRBs in governing the use of these exemptions at the local level.

### Changes to the Medical Device User Fee Program

There are aspects of the medical device user fee program that should be changed or discontinued to further strengthen and improve the program. First and foremost, we would like to see a shift toward device-specific guidance as opposed to the process-focused guidance documents that have been the product of the Congressionally-mandated performance goals. The rapid advances in technology consistently outpace regulation, as illustrated by a speaker who described diabetics "hacking" their pumps to derive additional utility from the device through the data it collects, but is not readily accessible to the patient. In orthopaedics, despite innovations in materials, designs, and bearing surface combinations, no new orthopaedic-specific guidance documents have been released since 2007.

FDA should allocate additional dollars toward staff travel to relevant meetings and symposia. Participation of FDA personnel in research programs is mutually beneficial. Research and scientific meetings provide educational opportunities to FDA staff that are not available elsewhere. FDA participation also fosters productive working relationships between Agency staff and clinicians, researchers, and industry. As demonstrated by meetings such as the Orthopedic Device Forum, regular interaction promotes an environment of open communication among the scientific community, government, and related industry on orthopaedic issues of mutual interest.

### Other Pertinent Information

Comments from the "Science, Academia, and Innovation" session at the meeting included a notable push for transitioning device regulation emphasis from premarket to postmarket. There are benefits and risks inherent in both models. We urge FDA to thoughtfully consider the required infrastructure necessary to successfully make the transition as well as the consequences of such a change, both intentional and unintentional. We are particularly concerned with the additional burden on clinicians attendant to capturing postmarket (i.e., postoperative) data. In a healthcare delivery environment that continually strives to do more with less and whose electronic health records lack interoperability, even between institutions, the additional administrative burden further reduces the time surgeons have to provide quality care for their patients.

Speakers across multiple sessions noted the importance of programs for special populations and those with unmet needs. Compelling stories were shared, at this meeting and during sessions FDA has held to discuss patient preferences, requesting a change in the determination of risks and benefits to reflect the differences in patient populations. Those who have few or no existing diagnostic or treatment options are often more willing to accept a ratio weighted more heavily toward risk than patients with access to multiple therapeutic options. We support the incorporation of a risk

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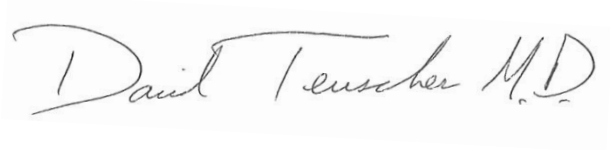
tolerance spectrum throughout the review process. We also strongly advocate for increased incentives for manufacturers who develop products to address unmet needs and special populations.

**Conclusion**

We thank the FDA for convening this public meeting, 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,



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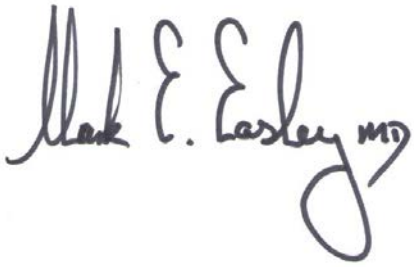

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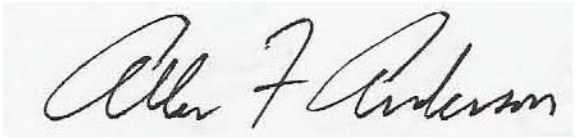

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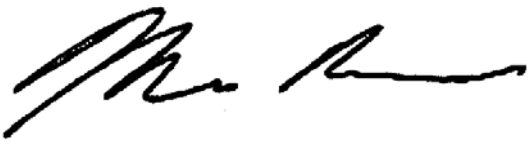

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