AAOS
American Academy of Orthopaedic Surgeons
American Association of Orthopaedic Surgeons

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www.aaos.org

July 31, 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 for Hand Surgery, American Orthopaedic Foot & Ankle Society, American Orthopaedic Society for Sports Medicine, American Shoulder and Elbow Surgeons, Arthroscopy Association of North America, The Knee Society, Orthopaedic Rehabilitation Association, Orthopaedic Research Society, and Pediatric Orthopaedic Society of North America, wish to share feedback with the FDA on the agency's 2014-2018 Strategic Priorities. These comments reflect our dedication to the development of sound federal health care policy that fosters patient access to the highest quality orthopaedic care.

We appreciate FDA's ongoing efforts to communicate strategic priorities to stakeholders. The five areas identified as cross-cutting strategic priorities align with areas that we similarly consider of great importance for assuring the safety and effectiveness of orthopaedic devices. We also recognize that the proposed priorities are intended to be global in nature and, therefore, do not reflect specific areas in need of increased effort within the centers. While products with established safety profiles and predictable performance pose few regulatory challenges, cutting technologies and therapies pose greater uncertainties and, therefore, should not be regulated in the same manner. We strongly encourage FDA to revisit the strategic priorities and refine them to reflect this reality.

Cross-Cutting Strategic Priorities

Regulatory Science

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Regulation of emerging technologies and therapies, such as new materials, new combinations of materials, and biologics, substantially lags behind the innovation, potentially stifling important advancements. Surgeons lament the lack of clarity regarding when and how these products may be safely used. Further, the absence of this information hampers shared decision-making with patients. We look forward to enhanced clinical trial quality and new tools and models for the assessment of orthopaedic products.

Globalization

Orthopaedics has long enjoyed the long-term data available from registries such as the Swedish Knee Arthroplasty Register. However, the utility of that data is limited, as it is not universally applicable to the diversity of U.S. orthopaedic patients. FDA's intention to "… develop a global data information system and network in which regulators worldwide can regularly and proactively share real-time information and resources across markets" is laudable. Many factors hinder the creation of such a system in the U.S., including, but not limited to, the lack of registry infrastructure, the medical liability environment, substantially greater patient volumes, and challenges in following patients across multiple medical systems throughout their lifetime. We encourage the FDA to work with medical specialties to develop these systems, including the creation of uniform reporting requirements, and to assist in efforts to obtain clarification and guidance on applicability of the *Common Rule* to clinical data registries.

Safety & Quality

FDA's activities in this area appear to be focused almost exclusively on industry and manufacturing processes. This focus is disappointing, as it excludes two key stakeholders that determine the safety and quality of the outcomes derived from the use of products. It is critical that the FDA reevaluate this section and identify mechanisms for incorporating the experiential and empirical data that physicians and their patients may contribute.

Smart Regulation

We agree with FDA's intent to protect the public health while promoting innovation, however, the balance of the language almost exclusively addresses food and tobacco. While these may be some of the most widely used products regulated by the FDA, drugs, biologics, and devices have as great an impact on people's lives. FDA should make a concerted effort to discuss how smart regulation will benefit the millions of patients that look to them to provide reasonable assurances of safety and effectiveness

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in the drugs, devices, and other therapies that they must use on a daily basis to survive and thrive.

Core Mission Goals and Objectives

Enhance Oversight of FDA-Regulated Products

We support the capture of data to further patient safety, device effectiveness, and outcomes studies to inform future innovation and use. It is critical to acknowledge the considerable investment in infrastructure, both within and outside of FDA, coupled with changes to existing laws governing data collection and dissemination, that will be necessary to achieve goals of strengthening detection and surveillance of problems with FDA-regulated products. FDA is limited in its ability to require post-market data for products and many factors constrain physician participation in voluntary reporting via registries. Further, registries are not compelled to share their data with FDA. We urge careful consideration of how the objectives to reach this goal will be achieved and the role stakeholders will play.

Regarding the use of adverse event reporting (AER) to support this goal, FDA should improve the AER interface to facilitate reporting. The current system is not easily located on the FDA website and little to no feedback is furnished to reporters. We also recommend enhanced communication of recalls and notices, targeting outlets frequented by physicians, to increase awareness of these issues.

Improve and Safeguard Access to FDA-Regulated Products to Benefit Health

FDA should set realistic timelines for responses to requests for information and expert input. Inquiries from the Network of Experts program have consistently asked for the identification, vetting, and participation of surgeons in as few as 5 days. Another example is the request for feedback on this document. The draft was published in the *Federal Register* on July 1, 2014, ahead of an extended holiday weekend, with just 30 calendar days to respond. Such short timelines are not respectful of the time commitments of our surgeon members – patients should not be inconvenienced by rescheduling to accommodate the FDA's need for feedback and surgeons should not be put in the position of choosing between their patients' immediate needs and issues critical to the provision of orthopaedic care. We strongly encourage the FDA to be aware of the burden their requests may represent and to allow sufficient time for the provision of thoughtful feedback, as these issues deserve.

Promote Better Informed Decisions About the use of FDA-Regulated Products

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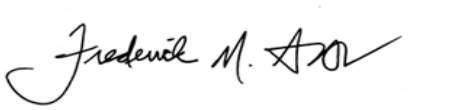
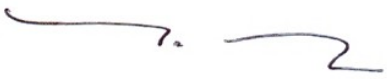
We support all the objectives related to this goal and look forward to the production of functional tools to facilitate risk-benefit conversations between patients and physicians.

Strengthen Organizational Excellence and Accountability
The achievement of these objectives will greatly enhance the predictability of FDA regulation. The addition of a fourth objective related to increased transparency regarding the actions needed to achieve objective 4.2 would be welcome and boost confidence in the FDA's commitment to improving its effectiveness.
The societies thank the FDA for sharing their organizational goals and objectives. We trust our feedback and recommendations will be given serious consideration in the context of our established history of cooperation and collaboration with the agency. Any questions should be directed to Will Shaffer, MD, AAOS Medical Director (Shaffer@aaos.org, 202-548-4145).

Sincerely,



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



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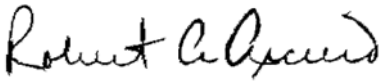

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Thomas K. Fehring, MD
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EB Marsolais, MD, PhD
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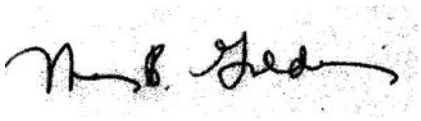

Mary B. Goldring, PhD
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