AAOS
American Academy of Orthopaedic Surgeons
American Association of Orthopaedic Surgeons

317 Massachusetts Avenue NE
Suite 100
Washington, D.C. 20002-5701

P. 202.546.4430
F. 202.546.5051

www.aaos.org/dc

April 19, 2012

The Honorable Tom Coburn, MD
172 Russell Senate Office Bldg.
Washington, DC 20510

Dear Senator Coburn:

On behalf of the American Association of Orthopaedic Surgeons (AAOS), I would like to thank you for introducing the Promoting Accountability, Transparency, Innovation, Efficiency, and Timeliness at FDA Act of 2012 ("PATIENTS' FDA" Act). This legislation will ensure greater transparency and accountability in U.S. Food and Drug Administration (FDA) decision-making, reduce unnecessary delays and regulatory burdens, and provide patients timely access to innovative devices.

The AAOS, which represents over 18,000 board-certified orthopaedic surgeons, has been a committed partner to the FDA and other agencies in patient safety, cultural competency, and the provision of high-quality, affordable healthcare. We commend you and your colleagues for working to reauthorize the Medical Device User Fee Act (MDUFA), and we appreciate the opportunity to offer our support for the Patients' FDA Act, which complements the proposed agreements between the FDA and the drug and device industries.

The AAOS believes the Patients' FDA act, which requires greater transparency and accountability in the FDA's review and decision process will improve regulatory certainty and ensure that patients receive innovative products when they need them. Orthopaedic patients are daily benefactors of a successful and timely review process of medical devices by the FDA. The AAOS' overarching interest is patient benefit, and our comments are directed toward a singular goal of access to safe, effective products for our patients. As surgeons, we witness the benefits of safe, effective, and innovative products and the tragedy of untreated medical problems.

The AAOS supports the Patients' FDA Act's medical device regulatory improvements, which strengthen tracking and review of applications for investigational device exemptions, and include modification of the custom device exemption to meet the device needs of individual patients. Custom devices are medical devices that deviate from those under an approved premarket application (PMA), or 510(k) clearance, and are manufactured in response to a specific

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request from a physician to meet the unique needs of an individual patient. Congress intended custom devices to be available for patients whose anatomy does not suit a standard device, but the AAOS believes that current statutes and regulations do not allow enough flexibility to serve the patient populations requiring such devices.

Currently, only one unique device for a specific patient can be manufactured under the exemption. If a second patient requires a similar device, that device can no longer be considered a custom device, and the manufacturer must have FDA clearance or approval or be evaluating the device in a clinical study. The clinical use of these devices, however, is so limited that it is unreasonable and/or overly burdensome to apply for 510(k) clearance or premarket approval.

When Congress created the exemption, it was aware of the practice of creating devices for unusual needs of patients and health care practitioners and intended to create a statutory provision that would allow a limited number of custom devices to be produced for these cases. Unfortunately, the FDA's current interpretation of the exemption does not afford patients and providers this flexibility.

There is clearly a need for custom implants and devices for patients suffering from rare orthopaedic disorders. Treatment of these patients require devices that are either existing products with modifications or new products manufactured to fit the unique anatomy of a particular patient.

Several groups of patients are particularly disadvantaged by the current exemption. For example, children with juvenile inflammatory arthritis (JIA) and skeletal dysplasia often have challenges fitting devices to their smaller anatomy. Standard implants will not fit, so it is necessary to make implants that are based on current designs or smaller versions of regular implants which may have unusual features. For orthopaedic oncology patients, the custom device exemption provides the only timely method of obtaining an appropriate device; this time element is critical when treating these patients because there is often only a limited time window between cancer treatments when the white blood cell count is high enough to do a procedure.

Accordingly, the AAOS supports broadening the custom device exemption to include devices that are modifications of existing devices and to allow for a limited production of more than a single unit of a particular device. While we understand the need for the exemption to be applied narrowly, it also must

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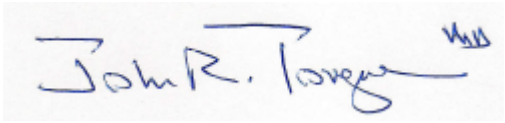
provide flexibility for patients to receive the best care in a timely fashion.

The AAOS also applauds the Patients' FDA Act's provisions to modify the advisory committee process and strengthen it for the benefit of patients. The AAOS supports removal of section 712 (21 U.S.C. §379d-1). Researchers with broad-based conflicts of interest provide the FDA with a wealth of knowledge and expertise. Conflicts of interest for candidate and FDA panel members must be mitigated in a rational and balanced process. Material conflicts are inherent in orthopaedic medical research and must be addressed appropriately. Certain panel members or potential panel members may be conflicted with interests representing an entire medical specialty. For instance, the AAOS is aware of several orthopaedic laboratories which conduct research on biomaterial standard specifications, cellular biological applications, and orthopaedic joint mechanics. Each researcher receives funding from virtually every orthopaedic manufacturer in the U.S. to support the operational and research needs of their laboratories. The material conflicts may run into the hundreds and the orthopaedic community considers these personnel to have such broad-based material conflicts so as not to be conflicted.

The AAOS supports the Patients' FDA Act because we believe that patients will benefit from its provisions. We thank you for your work on this legislation.

Sincerely,



John R. Tongue, MD
President, American Academy of Orthopaedic Surgeons