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Senator Herb Kohl

330 Senate Hart Building

Washington, D.C. 20510

Senator Bob Corker

185 Senate Dirksen Building

Washington, D.C. 20510

Dear Chairman Kohl and Ranking Member Corker:

On behalf of over 18,000 orthopaedic surgeons, the American Association of Orthopaedic Surgeons (AAOS) commends you for convening the hearing, "A Delicate Balance: FDA and the Reform of the Medical Device Approval Process." The AAOS concurs that a delicate balance exists between patient safety and innovation in FDA approval and clearance processes. We will limit our remarks to the issues of device registries, recalls, FDA's unique device identification (UDI), metal-on-metal hips, conflicts-of-interest, and 510(k) vs. PMA issues.

Device Registries

The AAOS supports the written and verbal statements made by Dr. Frederick Resnic regarding the need for national medical registries to serve the public good. Dr. Resnic stated that, "*the best such registries in the U.S. are currently initiated, funded and maintained by non-profit professional medical societies or large healthcare provider systems. Aligning resources and incentives in a public-private partnership, such as the INTERMACS registry of cardiac support devices may serve as a template for future medical device registries.*"

The American Joint Replacement Registry (AJRR) was incorporated in 2009 to develop a uniform collection of data that will define the epidemiology of total joint replacement for outcomes research to improve the quality of orthopaedic patient care. The pilot project is currently underway in 15 hospitals. The AJRR's goal is to achieve a 90% capture rate of all hip and knee replacements done in the U.S. by 2014. Public-private partnerships in medical registries can be

of great benefit to the U.S. public by identifying sub-optimal performance of a device in the early or mid-term, as well as to help to bring the costs of health care down considerably.

Device Recalls

Patient safety is the highest priority in cases of recalled implanted devices. The risks of revision surgery must be carefully weighed and discussed with the patient[i] before a course of treatment is decided upon. Medical device recalls can be a serious matter, but it is important to note that not all devices that are recalled, even in the case of Class I recalls, may be defective or cause patient harm. Devices are recalled for many reasons. Re-operation may be the best option for patients with implants that have failed, are in chronic pain as a result of the faulty implant, and/or whose function has been negatively affected by the failure. Revision surgery in the absence of evidence of clinical failure, as a preventative measure against possible implant device malfunction, is rarely recommended.

Unique Device Identification (UDI)

The AAOS requested that the FDA implement a UDI system for medical devices well before it was added to the Food and Drug Administration Amendments Act (FDAAA) of 2007. UDI will assist in protecting patients by improving processes for device recalls and corrections, strengthen the ability of the FDA, manufacturers, and registries to monitor adverse events, and will aid in reducing medical errors. We look forward to UDI implementation and are pleased to hear that the FDA will issue a proposed rule soon and a final rule before the end of 2011. While the FDA's UDI system has been delayed longer than anticipated, the AAOS appreciates the thoughtful approach to UDI global harmonization and realizes that the global nature of this initiative has played a part in the time-consuming aspect of developing the proposed rule.

Metal-on-Metal Hips

While the majority of metal-on-metal (MoM) hip cases are without incident, it is extremely disappointing for surgeons to find that some of their patients have poor outcomes. Surgeons regret when any patient must undergo a revision surgery for any reason, as did Ms. Korgaokar.

It is important to note that initial problems with MoM hip replacement systems were signaled by data generated from foreign registries in Australia and the United Kingdom. While the AJRR is underway with a pilot program, a national orthopaedic registry is not yet operational in the U.S.

The AAOS continues to communicate with the FDA on any new MoM developments or research findings as they become available.

Conflicts-of-Interest

The AAOS instituted a mandatory disclosure program for governance groups and continuing medical education contributors in 2009. The database is publicly searchable, all orthopaedic surgeons are encouraged to participate in the AAOS Orthopaedic Disclosure Program, and we remind our Fellows to update their conflicts-of-interest information twice a year.

AAOS Orthopaedist-Industry Conflicts of Interests Mandatory Standards of Professionalism require that an orthopaedic surgeon shall disclose to the patient any financial arrangements with industry that relate to the patient's treatment. These standards were adopted on April 18, 2007 and effective for acts occurring on or after January 1, 2008. Ms. Korgaokar's surgeon's relationships with DePuy are publically available.

510(k) vs. PMAs

The AAOS supports the FDA's rigorous and thorough examination of the 510(k) process. We agree with the Government Accountability Office's assessment that the FDA should move swiftly to make determinations on the remaining 26 pre-amendment device types and to either require premarket approval applications or to reclassify the device type.

The Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act established the FDA's authority to regulate devices on a risk-based scheme. The classification scheme established three regulatory classes of devices and includes implantable devices into Class II and Class III, depending on their risk to the patient. As a science-based agency, the FDA has routinely down-classified implantable devices (from Class III to Class II) if they demonstrate excellent safety records over many years.

Metal plates and screws have been used for decades in orthopaedic care and demonstrate stellar safety records. These types of Class II devices are implantable devices. Moreover, the results of Dr. Maisel's and Mr. Hall's studies corroborate an overarching exceptional safety profile for orthopaedic devices.

As such, AAOS profoundly disagrees with statements calling for all implantable devices to go through the PMA process. We believe that some of these statements are founded on anecdotes and case reports, and are not based on scientific data. As the premier science-based agency, the FDA has carefully examined safety data and taken definitive action on problematic device types such as infusion pumps and automatic external defibrillators (AED), neither of which are implantable devices. As discussed at the hearing, the FDA has taken a number of positive steps to bolster their postmarket surveillance efforts during the last year thereby increasing patient safety.

Conclusion

In closing, we again thank you for your leadership and efforts to improve the health care of seniors and look forward to working with you to that end. If you have any questions, or if we can be of assistance, please contact Jeanie Kennedy, Manager of Regulatory and Government Relations for the AAOS at 202/548-4148 or kennedy@aaos.org.

Daniel J. Berry, MD

AAOS President

Cc: Senate Special Aging Committee

[i] AAOS Information Statement on Implant Device Recalls: http://www.aaos.org/about/papers/advistmt/1019.asp