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April 25, 2013

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

RE: *Docket No. FDA–2011–N–0661*

Dear Dr. Hamburg:

On behalf of more than 18,000 board-certified orthopaedic surgeons, the American Academy of Orthopaedic Surgeons (AAOS/Academy) welcomes the opportunity to offer comments on the Food and Drug Administration's (FDA) proposed order to require the filing of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) for the following two class III preamendments devices: Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis; and hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis.

AAOS previously shared the concerns and opinions of our members regarding these devices at the June 27-28, 2012, Orthopaedic and Rehabilitative Devices panel meeting. Our comments focused on pre-clinical evaluation and post-implantation responses to metal/metal bearings, in the larger context of our commitment to the provision of safe and effective care for orthopaedic patients.

Proposed Findings With Respect to Risks and Benefits

The material presented at the June 2012 panel meeting, particularly reports from international total joint registries, and published research forms the basis of the Academy's position regarding the classification of metal/metal total hip replacement systems. While we acknowledge that the majority of these implants are functioning well in patients, we believe there is a need for additional research into the natural history of adverse local tissue responses in association with metal on metal bearings. There is also a need

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for further characterization of the diagnostic and predictive value of currently available tools to assist patients and surgeons in their evaluation of the potential risks associated with these devices.

AAOS recognizes that many of the risks described by the FDA are common to all total hip replacement systems, such as infection and loss or reduction of joint function. However, the distinctive risks, as outlined in the proposed order, are difficult to characterize and clinically evaluate. For example, there is no standard for the measurement of metal ion levels and there is no standard for the classification of adverse local tissue reactions. Access to screening tools, such as blood ion levels and metal artifact reduction sequence magnetic resonance imaging, is not widely available and further complicates post-operative care for patients experiencing adverse outcomes.

The benefits of these devices, as described by the FDA in the proposed order, are similar to those of other total hip replacement systems. The unique benefits are identified as "offer(ing) the potential to be especially beneficial in young, active patients." A 2011 technology overview, prepared by AAOS and referenced by the FDA, found that "patients who receive metal-on-metal total hip arthroplasty and hip resurfacing are at greater risk for revision than patients who receive total hip arthroplasty using a different bearing surface combination." The analysis also pointed out that "The U.K./Wales registry reported hip resurfacing patients in all age groups, except males <55 years of age, were at an increased revision risk compared to cemented total hip arthroplasty with an unspecified bearing surface."

Classification Determination

AAOS supports the FDA's determination that the existing data is not adequate to identify special controls sufficient to ensure safety and effectiveness and therefore not adequate to support reclassification of metal/metal hip systems. Current standards and guidance documents are not adequate to establish safety and efficacy of these devices in the absence of a premarket approval application and accompanying data. AAOS is committed to participating in the creation of these standards, through our involvement with ASTM International. We will continue to support

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surgeon input in the development of characterization, test method, and other standards to accurately reflect the clinical applications of metal/metal devices.

Conclusion

We thank the FDA for considering our suggestions and hearing our concerns. AAOS looks 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
President, American Academy of Orthopaedic Surgeons