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Andrew C. von Eschenbach, M.D.
FDA Commissioner
Division of Dockets Management (HFA-305)
Food and Drug Administration (FDA)
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Dear Dr. von Eschenbach:

The American Association of Orthopaedic Surgeons (AAOS/Association), representing over 17,000 Board certified orthopaedic surgeons, welcomes the opportunity to comment on the Food and Drug Administration's Draft Guidance on Procedures for Determining Conflict of Interest and Eligibility for Participation in FDA Advisory Committees [Docket 2007D-0101].

The Association has taken a leadership role in defining and adhering to principles of ethics and professionalism with regard to conflicts of interest. Disclosure is required of annual and continuing medical education meeting presenters to identify research and institutional support, royalties, stock or stock options, consulting or employment relationships, and miscellaneous non-income support. Committee members must disclose conflicts of interest at each meeting and sign an attestation form annually. Furthermore, the AAOS generated the following statements which serve as guiding principles: *Opinions on Ethics and Professionalism*, *Principles of Medical Ethics and Professionalism in Orthopaedic Surgery*, and *Codes of Ethics and Professionalism for Orthopaedic Surgeons*.

The AAOS recognizes that the FDA has endured intense pressure from Congress and the public, following the February 2005 joint meeting of the FDA's Arthritis Advisory and Drug Safety and Risk Management committees on nonsteroidal anti-inflammatory drugs (NSAIDs). Several measures in the Senate and the House are pending and the Association appreciates the FDA's attempt to proactively pre-empt legislative remedies. Nevertheless, the draft guidance is entirely too restrictive to enable FDA panel participation from a majority of experienced physicians. The AAOS suggests that the FDA maintain the FDA Waiver Criteria 2000 with perhaps some minor refinements including providing more training for new panel members.

The agency's investigatory process is sufficiently rigorous to assess current conflicts of interest. The 2007 draft suggests a one size fits all approach to the FDA centers. Our experience with the FDA proves otherwise- the drug, biologics, and device centers all have different cultures and different needs. While the 2007 draft guidance,

if implemented, may enhance public trust, the American people will not be served by appointing FDA panel members without sufficient expertise and knowledge. The goal of any conflict of interest process is to mitigate risks and assure that safe and effective drugs, devices, and biologics are approved in a timely manner for the benefit of American consumers. It is the patients who ultimately benefit from receiving new medical therapies, perhaps in saving or extending their lives. The FDA must strike the proper balance in mitigating the potential for conflict of interests with the broader goal of enhancing and promoting the best interests of public health.

Waivers

The Association expects that the application of waivers under the 2007 guidance will be nonexistent. Under the FDA Waiver Criteria 2000, FDA panel members could be granted a waiver when performing "homework" assignments when the appointing official determined that the financial interest was deemed not so substantial as to likely affect the integrity of the services that the government may expect.

Also under the 2000 guidance, a waiver could be granted when the need for the individual's services outweighed the potential for conflict of interest. The agency was given latitude to decide on the appropriate application of their criteria. Unfortunately, if the 2007 draft guidance becomes finalized, waivers will not be granted in either of these two circumstances.

Orthopaedic and Rehabilitative Devices Panel

The AAOS appreciates the hard work of the dedicated volunteers participating in the advisory committee process, and the FDA staff who are tasked with facilitating this process. The Orthopaedic and Rehabilitative Devices Panel is successful due to the exemplary reviews prepared by FDA staff and the outstanding quality of experts on the panel. Panel members are commonly experienced surgeons or other professionals from academic centers. Especially with new technologies, these experts have personal experience in treating the diseases and conditions for which the investigational device has an intended use. Oftentimes, these experts may have participated in the clinical trials of a particular device or a competing product's study, having hands-on experience with these new technologies. Many of these same experts are sought after by manufacturers as consultants.

Broad-based conflicts

Researchers with broad-based conflicts of interest provide the FDA with a wealth of knowledge and expertise. The 2007 conflict of interest guidance will disallow those individuals whereas those conflicts were appropriately managed under the 2000 guidance. 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 personnel such as this to have such broad-based material conflicts so as not to be conflicted. In the orthopaedic community, researchers with multiple conflicts are important resources for the FDA Orthopaedic and Rehabilitative Devices Panel. One researcher served as a former panel chair person and another served over a decade on the panel. The AAOS is very concerned that the 2007 guidance will not allow extremely qualified participants of this nature to serve on FDA panels preventing a wealth of expertise and experience to be utilized by the federal government.

Disqualification Limits

The AAOS finds sufficient inconsistency in defining a limit of $50,000 for disqualification from panel participation. The type and size of each manufacturer can be quite variable. As the 2007 conflict of interest draft is currently written, there would be no difference in distinguishing holdings of a multinational company with a broad range of products from that of a single product company. The product approval of a new medical device for a large, diversified company will ultimately have a negligible effect on the share's value, whereas a FDA approval for a company's only product may have huge implications on the value of that particular stock.

Least burdensome concept

Conflict of interest investigatory processes for FDA panel nominees must be least burdensome. Potential panel nominees currently undergo sufficient rigor during the disclosure and investigation processes. Increasing the burden on potential candidates will substantially decrease the pool of candidates.

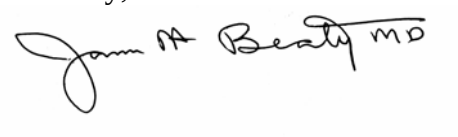
Exclusions

The AAOS finds few salvageable portions of the 2007 draft guidance with rare notable exceptions. The Association notes that the exclusion the following financial interests: pensions, employment benefits, diversified mutual funds, investment trusts, retirement accounts, financial interests from leave of absence at academic institutions, Social Security and Veterans' benefits are necessary and appropriate. The exclusion of grants and contracts with the employee's university to conduct research on a product not under FDA panel review or that of a competitor are also reasonable.

Conclusion

The AAOS appreciates the opportunity to comment on this critically important guidance. We encourage the FDA to immediately withdraw the 2007 guidance and continue to utilize the FDA Waiver Criteria 2000, with minor modifications. The Association looks forward to working with the FDA on future efforts to bring safe and effective medical products to patients more quickly.

Sincerely,



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