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Division of Dockets Management (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane RM 1061
Rockville, MD 20852

Thank you for the opportunity to comment on the Draft Guidance on Determining Conflict of Interest (docket number 2007D-0101). As a recent advisory panel chair, I wanted to raise a few concerns related to the ability to find panel members with the experience and knowledge fundamental to the success of the advisory panel process.

The Orthopaedic and Rehabilitative Devices Panel succeeds based upon the excellent reviews prepared by the FDA staff and the outstanding quality of experts on the panel. It is already a challenge to find panel members with knowledge and experience that are willing and able to take time from their normal activities to serve the FDA. The panel members are commonly experienced surgeons or other professionals from academic centers. What makes them valuable to the panel, especially in new technologies, is their personal experience with the disorders for which a new device is indicated. This means these experts often have experience through clinical studies of the device being reviewed or a competing device. In addition, these same experts are frequently the same individuals sought after by industry as consultants. In addition, many are advanced in their careers and have stock holdings in companies that may be involved in products in their area of interest.

Please reconsider the absolute value of \$50,000. There are several problems with this limit. First, the type of company and product can make a huge difference. As written, there would be no distinguishing holdings in a multinational company with a broad range of products from a single product company. The approval of a new device for a large diversified company will have negligible effect on the shares value, but an approval for a company's only product can have huge implications on the value. I think we all agree that a potential panel member in the latter situation should be excluded, but should the former?

Please reconsider the member with a previous consulting arrangement. Many potential panel members have been consultants on a variety of issues. Again, panel members are sought for their experience and knowledge by the panel and by industry. Previous arrangements need to be considered on an individual basis.

2007D-0101

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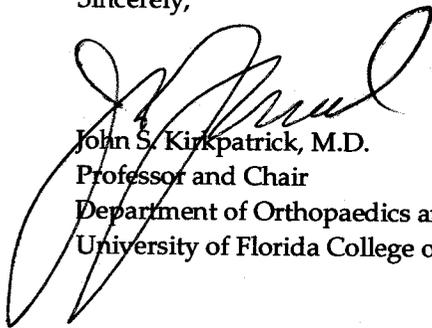
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Please reconsider the scope of effect including general partners, employers and organizations in which the member serves as an officer. Many potential panel members are employed by universities which have as part of their mission research. Industry funded research frequently exceeds the \$50,000 limit and as such may eliminate many more potential panel members. In addition, many panel members may be investigators in such research projects. This makes them very experienced in the devices and the experience may outweigh the conflict.

I agree with the concept of trying to develop better guidelines for conflict of interest. I have even been quoted as saying "it is a good idea, but maybe not a realistic one" in response to the draft guidance. Such stringent guidelines as proposed may result in panel members being only inexperienced younger professionals. I am hopeful that you can find an appropriate compromise between the public health need for the best possible panel members and the need to minimize the potential for conflict of interest.

Thank you once again for the opportunity to comment and for your partnership in the health of our patients by ensuring the safety and effectiveness of devices available.

Sincerely,



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