



Food and Drug Administration
Rockville MD 20857

MEMORANDUM

TO: Randall W. Lutter, Ph.D.
Deputy Commissioner for Policy

THROUGH: Vincent Tolino
Director, Ethics and Integrity Staff
Office of Management Programs
Office of Management

FROM: Kathleen L. Walker /S/ 06/20/07
Chief, Integrity, Committee and Conference Management Branch
Division of Ethics and Management Operations, OMO
Center for Devices and Radiological Health

SUBJECT: Conflict of Interest Waiver for John S. Kirkpatrick, M.D.

I am writing to request a waiver for John S. Kirkpatrick, M.D., serving on the Orthopaedic and Rehabilitation Devices Panel of FDA's Medical Devices Advisory Committee as a consultant, from the conflict of interest prohibitions of 18 U.S.C. §208(a). Waivers under section 208(b)(3) may be granted by the appointing official where "the need for the individual's services outweighs the potential for a conflict of interest created by the financial interest involved" and where the individual has made a disclosure of the financial interests at issue. We have determined that you are the appointing official for purposes of section 208. Therefore, you have the authority to grant Dr. Kirkpatrick a waiver under section 208(b)(3).

Section 208(a) prohibits Federal executive branch employees, including special Government employees, from participating personally and substantially in matters in which the employee or his employer has a financial interest. Since Dr. Kirkpatrick is a special Government employee, this individual is under a statutory obligation to refrain from participating in any deliberations that involve a particular matter having a direct and predictable effect on a financial interest attributable to him or his employer.

Dr. Kirkpatrick has been asked to participate in the Panel discussions on a premarket approval application (PMA), sponsored by Medtronic Sofamor Danek (a unit of Medtronic, Inc.), for the Bryan Cervical Disc Prosthesis. This system is a non-fusion artificial disc device that is to be implanted via an open anterior approach. It is indicated in skeletally mature patients with cervical degenerative disc disease at one level from C3-C7. This matter is coming before the Orthopaedic and Rehabilitation Devices Panel for consideration and is a particular matter involving specific parties.

Dr. Kirkpatrick has advised the FDA that he has financial interests that could potentially be affected by his participation in these matters. He reported owning [---] shares in [-----], currently valued at \$[----], which represents [-----] of his net worth. [-----] is the parent of a similar device and competing technology competitors to the PMA sponsor. He also reported owning [---] shares in [-----], parent of several competing technology competitors. The stock is currently valued at \$[-----] and represents [-----] of his family's net worth. The total value of his combined stockholdings is \$[-----].

The functions of the Committee, as stated in its Charter, are to review and evaluate available data concerning the safety and effectiveness of marketed and investigational devices and advise the Commissioner of Food and Drugs regarding recommended classification of these devices into one of three regulatory categories; recommend the assignment of a priority for the application of regulatory requirements for devices classified in the standards or premarket approval category; advise on any possible risks to health associated with the use of devices; advise on formulation of product development protocols and review premarket approval applications for those devices classified in this category; review classification as appropriate; recommend exemption to certain devices from the application of portions of the Act; advise on the necessity to ban a device; and respond to requests from the Agency to review and make recommendations on the specific issues or problems concerning the safety and effectiveness of devices. As a consultant to the Orthopaedic and Rehabilitation Devices Panel, Dr. Kirkpatrick potentially could become involved in matters that affect [-----] and [-----]. Under section 208, Dr. Kirkpatrick is arguably prohibited from participating in such matters. However, as noted above, you have the authority under 18 U.S.C. § 208(b)(3) to grant a waiver permitting this individual to participate in such matters as you deem appropriate.

For the following reasons, I believe it would be appropriate for you to grant a waiver to Dr. Kirkpatrick allowing this SGE to participate in the matter identified below:

First, the values of Dr. Kirkpatrick's stocks represent [-----] of his total net worth. Therefore it is unlikely that his judgment will be influenced by these interests.

Second, Panel recommendations would not be expected to affect the viability of [-----] and [-----] or significantly alter their stock value since they are both very large, well-established organizations with highly diversified product lines and a global presence.

Third, [-----] are two of more than 50 firms marketing or pursuing development of a device to treat degenerative disc disease of the cervical spine. The availability of multiple firms/products should mitigate the potential perception of bias on the part of this SGE.

Lastly, the Federal Advisory Committee Act requires that committee memberships be fairly balanced in terms of the points of view represented and the functions to be performed by the advisory committee. Also, the committee's intended purpose would be significantly impaired if the Agency could not call upon experts who have become eminent in their fields, notwithstanding the financial interest and affiliations they may have acquired as a result of their demonstrated abilities. Dr. Kirkpatrick is the Professor and Chair, Department of Orthopaedics and Rehabilitation at the

