

Food and Drug Administration  
Rockville MD 20857MEMORANDUM

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 Stuart B. Goodman, M.D., Ph.D.

I am writing to request a waiver for Stuart B. Goodman, M.D., Ph.D., a member on the Orthopaedic and Rehabilitation Devices Panel of FDA's Medical Devices Advisory Committee, 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. Goodman 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. Goodman 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. Goodman has been asked to participate in the Panel discussions on a premarket approval application (PMA) from 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. Goodman has advised the FDA that he has financial interests which could potentially be affected by his participation in this matter. He reported an ongoing consulting arrangement with [-----] on their [-----] products, a matter unrelated to the agenda topic. Dr. Goodman expects to receive \$[-----] for 2007. The total amount received for his services in 2006 was \$[-----]. Relevant to this meeting, [-----] is an unaffected unit of the parent of competing firms.

Dr. Goodman also reported that his institute, the Stanford University School of Medicine, was an awardee of two grants from [-----] for their [-----], which is unrelated to the agenda item to be discussed at the meeting. He is the principal investigator for both grants. For the grant that commenced in 2000 and ended in 2005; the total amount the institute received was [-----] of which [-----] went toward Dr. Goodman's salary support. All monies for this grant were disbursed in 2006. The second grant will run from September 2004 until August 2009 and the total support his institute anticipates is [-----] of which [-----] will go toward Dr. Goodman's salary. Relevant to the Panel meeting, [-----] is not a firm at issue. Its sister companies, [-----] and [-----], are competing firms to the PMA sponsor. Dr. Goodman's interests in [-----] are unrelated to the issues to be discussed and the affected products. Arguably, his interests do not constitute a financial interest in the matter under 18 USC § 208(a). Nevertheless, in the utmost of caution, I recommend that this waiver be granted.

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 the premarket approval 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 specific issues or problems concerning the safety and effectiveness of devices. As a member of the Orthopaedic and Rehabilitation Devices Panel, Dr. Goodman potentially could become involved in matters that affect [-----]. Under section 208, Dr. Goodman is 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. Goodman allowing him to participate in matters identified below.

First, given the nature of the unrelated consulting Dr. Goodman provides to [-----], and the unrelated grants his employer has with the company, it is unlikely that Panel recommendations will impact either the economic stability of the company, or his and his employer's continued relationship with the firm. The possibility that the SGE's impartiality will be called into question should be minimal.

Second, there are more than 50 firms actively pursuing development or marketing various types of devices to treat degenerative disc disease of the cervical spine. The existence of multiple products/firms should help mitigate any appearance of bias on the part of the SGE.

Third, the Panel's role is advisory in nature and the Agency officials making the decisions are not bound by the recommendations of the Panel. Therefore, the Agency will take into consideration the involvement of the SGE when making a final decision.

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

