



MEMORANDUM

TO: Randall Lutter, Ph.D.
Associate Commissioner for Policy and Planning

THROUGH: Jenny Slaughter _____ /S/ 08/15/06 _____
Director, Ethics and Integrity Staff
Office of Management Programs
Office of Management

FROM: Kathleen L. Walker _____ /S/ 08/11/06 _____
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 [-----] for the [-----]. This system is a two-piece articulating stainless steel device that is inserted into the intervertebral disc space at a single level using an open anterior approach. The device is indicated for skeletally mature patients with cervical degenerative disc disease (DDD) at one level from C3-C7.

Dr. Goodman has advised the FDA that he has financial interests which could potentially be affected by his participation in this matter. He reported consulting, on an ad hoc basis, with [-----] regarding their [-----], an issue unrelated to the agenda topic. [-----] is an unaffected unit of the parent of competing firms. Dr. Goodman anticipates receiving less than [----] for

2006; the total amount received for 2005 was [----]. He also consults for [-----] on their [-----], a matter unrelated to the agenda topic. Dr. Goodman expects to receive less than [----] for 2006. The total amount received for his services in 2005 was [----]. Relevant to this meeting, [-----] is an unaffected unit of the parent of competing firms. Both of these arrangements are ongoing.

Dr. Goodman also reported that his institute, 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. Dr. Goodman is the principal investigator for both grants. For the grant that commenced in 2000 and ended in 2005; the total amount the institute anticipates is [-----] of which [-----] will go toward Dr. Goodman's salary support. This grant is a continuation of a previous 5-year grant. All monies have not been disbursed; Dr. Goodman expects payment should be forthcoming in 2006 for 2005. The second grant will run from September 2004 until August 2009 and the total support his institute anticipates is [-----] of which [-----] goes toward Dr. Goodman's salary.

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 [-----] and [-----]. 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, Dr. Goodman's services as a consultant to [-----] and [-----] are unrelated to the issues before the Panel; therefore, the contractual relationships arguably are not covered by section 208. However, a waiver for these interests is being sought out of an abundance of caution.

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, compensation that Dr. Goodman receives for the unrelated grants and the consulting fees are not so significant as to affect the integrity of the services the Agency may expect from him.

Fourth, given the nature of the unrelated grants from [-----] to the Panel deliberations, there is little likelihood the Panel recommendations would impact Dr. Goodman or his employer's continued relationship with the firm. Therefore, the potential concern that Dr. Goodman's impartiality might be called into question during deliberations should be diminished.

Fifth, 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 they may have acquired as a result of their demonstrated abilities. Dr. Goodman is a Professor, Department of Orthopaedic Surgery at Stanford University School of Medicine and Co-Director of the Surgical Arthritis Unit at Stanford University Medical Center. He is a recognized orthopaedic surgeon with experience in implants and materials. We believe that Dr. Goodman's participation in these panel deliberations is invaluable and will provide a foundation for developing advice and recommendations that are fair and comprehensive.

Accordingly, I recommend that you grant Dr. Goodman a waiver allowing him to participate fully in all official matters before the panel related to the discussion and recommendations for [-----] [-----]. I believe that such a waiver is appropriate because in this case, the need for the services of Dr. Goodman outweighs the potential for a conflict of interest created by the financial interest involved.

CONCURRENCE: /S/ 08/16/06
Jenny Slaughter Date
Director, Ethics and Integrity Staff
Office of Management Programs
Office of Management

DECISION:

 X Waiver granted based on my determination made in accordance with section 208(b)(3), that the need for the individual's services outweighs the potential for conflict of interest created by the financial interest attributable to the individual.

 Waiver denied.

 /S/ 08/23/06
Randall Lutter, Ph.D. Date
Associate Commissioner for
Policy and Planning