



MEMORANDUM

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

THROUGH: Vincent Tolino /S/ 11/21/06
Director, Ethics and Integrity Staff
Office of Management Programs
Office of Management

FROM: Kathleen L. Walker /S/ 10/27/06
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 Judah Z. Weinberger, M.D., Ph.D.

I am writing to request a waiver for Judah Z. Weinberger, M.D., Ph.D., serving on the Circulatory System 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. Weinberger 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. Weinberger 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. Weinberger has been asked to participate in the Panel's discussion of issues related to stent thrombosis in coronary drug-eluting stents (DES). These stents contain drugs that potentially reduce the chance the arteries will become blocked again. The discussion will also include issues regarding the association between DES thrombosis and the [-----]. These matters are coming before the Circulatory System Devices Panel for consideration and are particular matters of general applicability. Thirty-three firms are currently identified as manufacturers of the stent, drug or delivery components and 18 firms produce devices that are alternative technologies to drug-eluting stents.

Dr. Weinberger has advised the FDA that he has financial interests which could potentially be affected by his participation in this matter. He reported that his [-----] trust holds approximately [-----] of stock in [-----]. The current value of the stockholding is approximately [-----], which is [-----] of his net worth. The trust also holds approximately [--] shares of [-----] stock valued at [-----], which is [-----] of his net worth. Relevant to this meeting [-----] and [-----] product lines include DES and alternative technologies to treat the same patient population.

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 consultant to the Circulatory System Devices Panel, Dr. Weinberger potentially could become involved in matters that affect [-----] and [-----] and its subsidiaries. Under section 208, Dr. Weinberger 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. Weinberger allowing him to participate in matters identified below.

First, the issues to be addressed by the Panel are matters of general applicability, involving an entire class of products and granting no advantage to any individual manufacturer. Therefore, the Panel recommendations would not be expected to have a significant financial impact on any specific firm and the potential perception of bias on the part of the SGE should be mitigated.

Second, the [-----] and [-----] stockholdings represent [-----] of the SGE's net worth, therefore, the likelihood that his judgment will be influenced by these interests is minimized.

Third, [-----] and [-----] are very large, well-established firms with highly diversified product lines and global presence. Therefore, the SGE's recommendations would not be expected to affect the viability of these large firms or significantly alter their stock values.

Fourth, 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 SGE's reported interests when making a final decision.

