



MEMORANDUM

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

THROUGH: Vincent Tolino /S/ 11/7/06
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 JoAnn Lindenfeld, M.D.

I am writing to request a waiver for JoAnn Lindenfeld, M.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. Lindenfeld 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 her employer has a financial interest. Since Dr. Lindenfeld 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 her or her employer.

Dr. Lindenfeld 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 [-----].

Thirty-three firms are currently identified as manufacturers of stent, drug or delivery components, and 18 firms produce devices that are alternative technologies to drug-eluting stents. These matters are coming before the Circulatory System Devices Panel for consideration and are particular matters of general applicability.

Dr. Lindenfeld has advised the FDA that she has financial interests which could potentially be affected by her participation in this matter. She reported two consulting arrangements with [-----], a stent manufacturer as well as a manufacturer of alternative technologies. She serves on the [-----] for a device unrelated to DES. At this time, she has only attended an organizational meeting; and the anticipated amount of fees expected is [-----]. No additional detail is available at this time. She serves on the [-----] for [-----]. Total fees expected for this ongoing arrangement is [-----]; amount received thus far is [----].

In addition, she has participated in various speaking engagements for [-----], a manufacturer of [-----]. These lectures focus on [-----] and are unrelated to the Panel issues. Total honorarium received for these talks 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 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. Lindenfeld potentially could become involved in matters that affect [-----] and [-----] and its subsidiaries). Under section 208, Dr. Lindenfeld 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. Lindenfeld allowing her to participate in matters identified below.

First, the issues to be addressed by the Panel are particular 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 lessened.

Second, given the nature of Dr. Lindenfeld's unrelated consulting arrangements with [-----], it is unlikely that recommendations of the Panel will impact the viability of this firm or her ongoing relationships with the firm. Therefore, potential concern that her impartiality might be called into question during Panel deliberations should be diminished.

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 SGE's interests when making a final decision.

Fourth, Dr. Lindenfeld's past speaking engagements were unrelated to the Panel issues and she is currently unaware of any future speaking engagements.

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. Lindenfeld is board certified in internal medicine, cardiovascular disease and critical care medicine. She is Professor of Medicine in the Division of Cardiology, at the University of Colorado Health Sciences Center in Denver. She is also Medical Director of the Cardiac Transplantation Program, Director of the Women's Health Center and Director of the Medical and Continuing Education Program at the University of Colorado Hospital. Dr. Lindenfeld is universally recognized as an expert noninvasive cardiologist and heart failure expert and has traditionally served as a useful and thoughtful counterweight to the interventional cardiology perspective. Therefore her participation at the Panel meeting should promote a balanced and productive discussion. Also, several of the key questions to be addressed at the Panel meeting relate to whether the pharmacology regimens should be changed, which new pharmacology trials should be done, and are there new agents in development that may address some of the concerns. Her expertise in these areas will be critical to this discussion.

