



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 Robert A. Harrington, M.D.

I am writing to request a waiver for Robert A. Harrington, M.D., serving as a consultant to the Center for Drug Evaluation and Research, and in this capacity, serving as a consultant to the Circulatory System 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. Harrington 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. Harrington 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. Harrington 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. Harrington has advised the FDA that he and his employer have financial interests which could potentially be affected by his participation in this matter. He reported two consulting arrangements with [-----], the manufacturer of [----]. Regarding the first arrangement, he will be [-----] of an upcoming symposium conducted at an [-----] meeting. This continuing medical education course on [-----] is sponsored by [-----]. The symposium topic is not related to the Panel agenda topic. He will receive [----] for this arrangement in [-----]. For the second unrelated consulting arrangement, he serves on a [-----]. His work includes [-----] for which he expects [--] for each meeting he attends. Currently he has received [----] and expects another [----] for the meetings he attended.

Additionally, Dr. Harrington reports that his employer, the Duke Clinical Research Institute (DCRI) has been awarded a grant from [-----] for the [-----], which is unrelated to the Panel agenda topic. Dr. Harrington is the [-----] for this grant that will run from [-----]. The total amount of funding the institute anticipates is [-----] of which [-----] goes toward Dr. Harrington's salary support. Relevant to this meeting, [-----] has an agreement with [-----], manufacturer of [----].

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. Harrington potentially could become involved in matters that affect [-----] and [-----]. Under section 208, Dr. Harrington 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. Harrington allowing him 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 mitigated.

Second, given the nature of Dr. Harrington's unrelated consulting arrangements with [-----], it is unlikely that recommendations of the Panel will impact the viability of this firm or his ongoing relationships with it. Therefore, potential concern that Dr. Harrington's 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, given the unrelated nature of the grant from [-----] to the Panel deliberations, there is little likelihood the Panel recommendations would impact the SGE or his employer's continued relationship with the firm. Therefore, the potential concern that his impartiality might be called into question during deliberations should be diminished.

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. Harrington is a faculty member in the Duke Clinical Research Institute of Duke University Medical Center, where he is the Director of Cardiovascular Clinical Trials. His main research interests are in evaluating antithrombotic therapies to treat acute ischemic heart disease and to minimize the acute complications of percutaneous coronary procedures. He is actively involved in studying the mechanism of disease of the acute coronary syndromes, in understanding the issues of risk stratification in the care of patients with acute ischemic coronary syndromes and in trying to better understand and improve upon the methodology of large clinical trials. Dr. Harrington is not only an interventional cardiologist, but an expert in drug issues and clinical trial design and conduct. His research and work directly coincides with the issues which will be discussed at this Panel meeting making him a valuable participant. He has extensive experience in interventional cardiology, ischemic heart disease, acute coronary care and cardiovascular clinical trials. His views on stent thrombosis and possible mitigation of this devastating complication will be extremely valuable due to his recognized expertise in the field of antithrombotic therapy. The Duke Clinical Research Institute has conducted numerous trials of both drugs and devices in the US, Europe and Japan. The Center anticipates having presentations of clinical trial data from each of these geographic areas. Dr. Harrington's expertise will be crucial to the interpretation of foreign data and its applicability to the US patient population.

