



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DATE: September 19, 2007

TO: Randall W. Lutter, Ph.D.
Deputy Commissioner for Policy
Food and Drug Administration

THROUGH: Vincent Tolino /S/ 09/20/07
Director, Ethics and Integrity Staff
Office of Management Programs
Office of Management

FROM: Kathleen L. Walker /S/ 09/19/07
Chief, Integrity, Committee and Conference Management Branch
Division of Ethics and Management Operations, OMO
Center for Devices and Radiological Health

SUBJECT: 208(b)(3) Conflict of Interest Waiver for Edwin C. Gravereaux, M.D.

I am writing to request a waiver for Edwin C. Gravereaux, M.D., a temporary voting member of 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. Gravereaux 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. Gravereaux is a special Government employee, he 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. Gravereaux has been asked to participate in Panel discussions on clinical trial designs for carotid artery stenting in patients not at high risk for adverse events from surgical revascularization.

This matter is coming before a meeting of the Circulatory System Devices Panel of FDA's Medical Devices Advisory Committee. This issue is a particular matter of general applicability.

The function of the Committee, as stated in its Charter, is 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.

Dr. Gravereaux has advised the FDA that he has a financial interest which could potentially be affected by his participation in the matter described above. He serves as an adjudicator for Harvard Clinical Research Institute, which has an affiliation with his employer, Brigham and Women's Hospital. As an adjudicator, he was selected to review [-----] captured in two of [-----] [-----], a matter related to the agenda topic. He examines extracted data from [-----]. He is compensated by [-----] and has received a total of [-----] for 4 meetings for this ongoing arrangement.

In addition, Dr. Gravereaux reported a related consulting relationship with [-----], a [-----] and subsidiary of [-----]. As a [-----], he provides [-----] for [-----] designated trainees. This open-ended agreement commenced in 2005. Dr. Gravereaux received [-----] for training he conducted in 2006 [-----]; at this time he has not done any work for 2007.

As a temporary voting member to the Circulatory System Devices Panel of FDA's Medical Devices Advisory Committee, Dr. Gravereaux potentially could become involved in matters that could affect his financial interests. Under section 208, he 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 Dr. Gravereaux to participate in such matters as you deem appropriate.

For the following reasons, I believe that it would be appropriate for you to grant a waiver to Dr. Gravereaux that would allow him to participate fully in the matter described because the need for his services greatly outweighs the conflict of interest created by this financial interest.

First, the discussion of clinical trial designs is a particular matter of general applicability, granting no individual or firm an advantage.

Second, the amount of compensation received by the SGE for his consulting services is not so significant that it would outweigh the need for his participation.

Moreover, 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 interests and affiliations they may have acquired as a result of their demonstrated abilities.

For this meeting the Agency believes it is crucial to have vascular surgery expertise to balance the cardiology expertise and acknowledges that a major difference of opinion currently exists between vascular surgeons and cardiologists regarding the optimal trial design for showing safety and effectiveness of carotid stenting. Dr. Gravereaux is Director of Endovascular Surgery and Interventional Therapy, and Associate Surgeon, Department of Surgery, Division of Vascular and Endovascular Surgery at Brigham and Women's Hospital, Boston, MA. He is a board certified vascular surgeon with extensive vascular surgery experience that includes carotid stent trials and trials for minimally invasive treatment of arterial occlusive disease and aortic aneurysms. At this time, the Circulatory System Devices Panel is in need of vascular surgeons and the Center for Devices and Radiological Health conducted a search. Of the 12 vascular surgeons contacted to participate in this meeting, eight were not available, leaving Dr. Gravereaux one of the four remaining vascular surgeons. Dr. Gravereaux brings an extensive surgical perspective, which will enhance the discussion of the carotid stent trial designs.

I believe that participation by Dr. Gravereaux in the committee's deliberations will contribute to the diversity of opinions and expertise represented on the committee.

