



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration  
Rockville MD 20857

DATE: October 5, 2007

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

THROUGH: Vincent Tolino  
Director, Ethics and Integrity Staff  
Office of Management Programs  
Office of Management

FROM: Kathleen L. Walker /S/ 10/05/07  
Chief, Integrity, Committee and Conference Management Branch  
Division of Ethics and Management Operations, OMO  
Center for Devices and Radiological Health

SUBJECT: 712(c)(2)(B) 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 section 712(c)(2)(A) of the Federal Food, Drug, and Cosmetic Act. Waivers under section 712(c)(2)(B) may be granted by the appointing official where it is "necessary to afford the advisory committee essential expertise" and where the individual has made a disclosure to FDA of the financial interests at issue. We have determined that you are the appointing official for purposes of section 712(c)(2)(B). Therefore, you have the authority to grant Dr. Gravereaux a waiver under section 712(c)(2)(B).

Section 712(c)(2)(A) prohibits Federal executive branch employees, including special Government employees, from participating in any particular matter in which the employee or an immediate family member has a financial interest that could be affected by the advice given to the FDA with respect to the matter. Because 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.

The function of the Medical Devices Advisory 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 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.

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 712(c)(2)(A), he is prohibited from participating in such matters. However, as noted above, you have the authority under section 712(c)(2)(B) to grant a waiver permitting Dr. Gravereaux to participate in such matters if necessary to afford this Panel essential expertise.

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 his voting participation is necessary to afford the Panel essential expertise.



DECISION:

X Waiver granted based on my determination, made in accordance with section 712(c)(2)(B) of the Federal Food, Drug, and Cosmetic Act, that voting participation is necessary to afford the Panel essential expertise.

\_\_\_\_\_ Waiver granted based on my determination, made in accordance with section 712(c)(2)(B) of the Federal Food, Drug, and Cosmetic Act, that nonvoting participation is necessary to afford the Panel essential expertise

\_\_\_\_\_ Waiver denied.

<u>/S/</u>	<u>10/09/07</u>
_____	Date
Randall W. Lutter, Ph.D.	
Deputy Commissioner for Policy	
Food and Drug Administration	