



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DATE: October 18, 2007

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

THROUGH: Vincent Tolino /S/ 10/22/07
Director, Ethics and Integrity Staff
Office of Management Programs
Office of Management

Michael F. Ortwerth, Ph.D. /S/ 10/30/07
Deputy Director, Advisory Committee Oversight and Management Staff
Office of Policy, Planning, and Preparedness

FROM: Kathleen L. Walker /S/ 10/18/07
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 John C. Somberg, M.D.

I am writing to request a waiver for John C. Somberg M.D., a 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 John C. Somberg, M.D., 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. Somberg 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.

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. Somberg has been asked to participate in the Panel's discussion regarding a premarket approval application (PMA) submitted by Abbott Vascular (a subsidiary of Abbott Laboratories) for the *XIENCETM V Everolimus Eluting Coronary Stent System*. This system is indicated for improving coronary luminal diameter in patients with symptomatic heart disease due to de novo native coronary artery lesions (length \leq 28 mm) with reference vessel diameter of 2.5mm to 4.0mm.

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 involving specific parties.

Dr. Somberg has advised the FDA that his employer has a financial interest that could potentially be affected by his participation in the matter described above. His institute, Rush University Medical Center (RUMC), has been identified as a clinical site for the *XIENCETM V* study. Dr. Somberg works in the Pharmacology Department and had no involvement in the study. [-----
---], the principal investigator, works in the Cardiology Department. There is no managerial relationship between the two physicians.

The Office of Device Evaluation within the Center for Devices and Radiological Health provided the following relevant study data:

- Total number of sites involved with *XIENCETM V* study: [--]
- Total number of patients enrolled in the trial: [----]
- Total number of patients enrolled at RUMC: [-]
- Percentage of patients treated at RUMC: [----]
- Date of first study enrollment: [-----]
- Date of last study enrollment: [-----]
- Amount to institute: [-----]
[-----]

As a member of the Circulatory System Devices Panel, Dr. Somberg 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. Somberg 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. Somberg 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, although Dr. Somberg's institution was involved in the sponsor's trial, he had no direct, personal involvement and received no compensation. The fact that this financial interest is imputed to him from his employer should lessen any potential conflict the interest may present.

Second, Dr. Somberg's institution contributed a statistically insignificant portion of the trial data with only [----] of the total patient enrollment. This limitation should help to mitigate any concern that the SGE's impartiality might be called into question during Panel deliberations.

Third, there are over 20 firms that manufacture, market or plan to develop competing products or technologies for the same indication as the subject PMA device. The need for this individual's expertise outweighs the large market availability of similar products being considered.

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.

Dr. Somberg is Chief, Division of Clinical Pharmacology and Professor of Medicine and Pharmacology, Rush University Medical College. He brings to the Panel unique expertise in cardiovascular pharmacology that is unmatched on the Panel and a distinct perspective on potential pharmacologic issues related to drug-eluting stents (DES). Dr. Somberg is the only panelist with this background to have participated in several Panel meetings discussing DES applications. He brought to those discussions a thorough understanding of the mechanisms by which drug-eluting stents achieve their intended effect, which is a critical issue when evaluating a new DES that incorporates a drug that has not been used previously on a stent.

Dr. Somberg also maintains a practice in clinical cardiovascular medicine where he deals with the concerns of his patients on a daily basis. As a practicing cardiologist, he can speak from the perspective of patients who have received DES. One such issue that is expected to arise at this meeting is the topic of antithrombotic drug therapy and the need for patients to be on this therapy for an extended period of time, and to potentially delay or avoid certain invasive surgical procedures. Dr. Somberg's experience in working with patients will allow him to speak directly to this issue.

In addition to his participation in previous Panel meetings in which DES applications were reviewed, Dr. Somberg was an active member in the December, 2006 Panel meeting discussing general issues of drug-eluting stents. His perspective will assist the Panel in determining how to approach not only the data contained in the PMA, but also recent data concerning DES. The Center notes that he was a significant contributor to the DES discussions in the October, 2007 Panel meeting and will bring a critical consistency to the deliberations on the current application. The Center conducted a thorough evaluation of the 82 SGEs assigned to the Circulatory System

Devices Panel and could not identify any current SGEs with a similar background in cardiovascular pharmacology. I believe that participation by Dr. Somberg in the Panel's deliberations will contribute to the diversity of opinions and expertise represented on the Panel.

Accordingly, I recommend that you grant John C. Somberg M.D., a waiver that would allow him to participate in all official matters concerning the *XIENCE™ V Everolimus Eluting Coronary Stent System* PMA, sponsored by Abbott Vascular. I believe that such a waiver is appropriate because in this case, the need for the services of Dr. Somberg outweighs the potential for a conflict of interest created by the financial interest attributed to him.

DECISION:

Waiver granted based on my determination, made in accordance with section 208(b)(3), that the need for the individual's services outweighs the potential for a conflict of interest created by the financial interest attributable to the individual.

Waiver denied.

/S/

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

11/08/07
Date