DEPARTMENT OF HEALTH & HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Rockville MD 20857

DATE: March 20, 2006

TO: Jason D. Brodsky
Acting Associate Commissioner
Office for External Relations
Food and Drug Administration

THROUGH: Jenny Slaughter
Director, Ethics and Integrity Staff
Office of Management Programs
Office of Management

FROM: Igor Cerny, Pharm.D.
Director, Advisors and Consultants Staff
Center for Drug Evaluation and Research

SUBJECT: Conflict of Interest Waiver for David DeMets, Ph.D.

I am writing to request a waiver for David DeMets, Ph.D., a member of the Cardiovascular and Renal Drugs Advisory Committee, from the conflict of interest prohibitions of 18 U.S.C. §208(a). The appointing official may grant waivers under 18 U.S.C. §208(b)(3) 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. DeMets 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. DeMets 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 Cardiovascular and Renal Drugs Advisory Committee, as stated in its Charter, is to review and evaluate available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cardiovascular and renal disorders and to make

appropriate recommendations to the Commissioner of Food and Drugs.

Dr. DeMets has been asked to participate in all official matters concerning the discussion of the Agency's draft recommendations for re-labeling of anti-hypertensive drugs for outcome claims, as a follow-up to the committee's meeting on June 15, 2005, where the committee discussed class labeling of antihypertensive drugs based on the proximity of their data to outcome trials. The discussion will not focus on any particular product or firm and is a particular matter of general applicability.

Dr. DeMets has advised the Food and Drug Administration (FDA) that he has financial interests that could potentially be affected by his participation in this matter. Dr. DeMets is a statistical advisor for [redacted] and [redacted] and a member of [redacted], [redacted], [redacted], and [redacted]' Data Safety Monitoring Boards on matters unrelated to the products or issues coming before the committee.

As a member of the Cardiovascular and Renal Drugs Advisory Committee, Dr. DeMets could potentially 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. DeMets 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. DeMets that would allow him to participate fully in the matter described above.

First, arguably Dr. DeMets' interests do not constitute a financial interest in the particular matter of general applicability within the meaning of 18 U.S.C. §208(b)(3), since his consulting and Data Safety Monitoring Boards are unrelated to the affected antihypertensive drugs or the matter at issue. Nevertheless, we recommend that this waiver be granted.

Second, Dr. DeMets' interests are not so substantial as to be deemed likely to impact his impartiality. He receives moderate compensation.

Moreover, it is important to consider that the matter in which Dr. DeMets is participating is a particular matter of general applicability. The committee's discussions will not focus on any particular product or firm. Rather, the committee's recommendations and the Agency's action on this issue could impact all firms that market or are developing antihypertensive drugs to the same extent.

Further, 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 various advisory committee members and Dr. DeMets' participation will contribute to the balance of views represented and the diversity of opinions and expertise. 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. DeMets is Chairman and Professor, Department of Biostatistics, University of Wisconsin. He is a highly regarded biostatistician who specializes in the statistical analysis of clinical trials and research studies. Dr. DeMets has published numerous articles, book chapters and policy papers on such topics as "Discrete Sequential Boundaries for Clinical Trials," "An Aid to Data Monitoring in Long-term Clinical Trials," and "Practical Aspects in Data Monitoring." He is a member of numerous professional societies, such as the American Mathematical Society, the American Statistical Association, and the Society for Controlled Clinical Trials. We believe that Dr. DeMets' participation will contribute to the diversity of expertise and viewpoints represented and will provide a foundation for developing advice and recommendations that will be fair and comprehensive.

Accordingly, I recommend that you grant Dr. DeMets a waiver that would allow him to participate in all official matters concerning the Agency's draft recommendations for re-labeling of anti-hypertensive drugs for outcome claims, as a follow-up to the committee's meeting on June 15, 2005, where the committee discussed class labeling of antihypertensive drugs based on the proximity of their data to outcome trials. I believe that such a waiver is appropriate because in this case, the need for the services of Dr. DeMets outweighs the potential for a conflict of interest created by the financial interests attributable to him.

CONCURRENCE: _____ 3/21/06

Jenny Slaughter
Director, Ethics and
Integrity Staff
Office of Management Programs
Office of Management

Date

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.

_____ 3.27.06

Jason D. Brodsky
Acting Associate Commissioner
Office for External Relations
Food and Drug Administration

Date