DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MEMORANDUM

DATE: August 15, 2006

TO: Randall Lutter, Ph.D.
Associate Commissioner for
Policy and Planning
Food and Drug Administration

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

FROM: Igor Cerny, Pharm.D. /S/
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 clinical data for aprotinin Injection (trade name, Trasylol), an approved product (New Drug Application 020-304), sponsored by Bayer Pharmaceuticals Corporation, a part of Bayer HealthCare AG, a subsidiary of Bayer AG, with the indication for prophylactic use to reduce perioperative blood loss and the need for blood transfusion in patients undergoing cardiopulmonary bypass in the course of coronary artery bypass graft (CABG) surgery.

Dr. DeMets has advised the Food and Drug Administration (FDA) that he has a financial interest that could potentially be affected by his participation in this matter. Dr. DeMets is a member of Data Safety Monitoring Board for [redacted]. The board advises on both upper and lower Gastrointestinal safety of [redacted] for at-risk Osteoarthritis and Rheumatoid arthritis patients. [redacted] makes [redacted] one of the competing product to Trasylol.

As a member of the Cardiovascular and Renal Drugs Advisory Committee, Dr. DeMets could potentially become involved in matters that could affect his financial interest. 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' interest in [redacted] does not constitute a financial interest in the particular matter within the meaning of 18 U.S.C. §208(b)(3), since the Data Safety Monitoring Board advises on matters unrelated to the product at issue and the competing products. Nevertheless, I recommend that this waiver be granted.

In addition, Dr. DeMets' interest is not so substantial as to preclude his participation in this matter. He receives minimal compensation for his service.

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 clinical data for aprotinin Injection (trade name, Trasylol), an approved product (New Drug Application 020-304), sponsored by Bayer Pharmaceuticals Corporation, a part of Bayer HealthCare AG, a subsidiary of Bayer AG, with the indication for prophylactic use to reduce perioperative blood loss and the need for blood transfusion in patients undergoing cardiopulmonary bypass in the course of coronary artery bypass graft (CABG) surgery. 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 interest attributable to him.

CONCURRENCE: /S/ 8/16/06

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

Date

DECISION:

X 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/ 9/1/06

Randall Lutter, Ph.D.
Associate Commissioner for
Policy and Planning
Food and Drug Administration

Date