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 John Flack, M.D.

I am writing to request a waiver for John Flack, M.D., a consultant to the Center for Drug Evaluation and Research, from the conflict of interest prohibitions of 18 U.S.C. §208(a). The appointing official may grant waivers under section 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. Flack, a waiver under 18 U.S.C. §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 any other person whose interests are imputed to the employee under 18 U.S.C. §208, has a financial interest. Since Dr. Flack is a special Government employee, he is under a statutory obligation to refrain from participating in an official capacity in any particular matter having a direct and predictable effect on a financial interest attributable to him, his spouse, minor child, or general

partner; an organization or entity for which he serves as an officer, director, trustee, general partner, or employee; and, a person with whom he is negotiating for, or has an arrangement concerning, prospective employment.

Dr. Flack has been asked to participate in all official matters to discuss 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. This matter is coming before the Cardiovascular and Renal Drugs Advisory Committee.

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. Flack has advised the Food and Drug Administration that he has financial interests that could potentially be affected by his participation in the matters at issue. Dr. Flack is on the Speaker's Bureau for [redacted] regarding hypertension dyslipaemia. In addition, Dr. Flack serves as a consultant to [redacted] on hypertension and lipids. These interest are unrelated to the product coming before the committee and the competing products. He receives moderate compensation. [redacted] makes [redacted] a competing product to aprotinin injection (trade name, Trasylol).

As a consultant participating in the Cardiovascular and Renal Drugs Advisory Committee meeting, Dr. Flack potentially could become involved in matters that could affect his financial interests. Under 18 U.S.C. §208(a), 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. Flack 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. Flack, which would permit him to participate in the matter previously described.

First, this waiver is justified because arguably, Dr. Flack's interests do not constitute financial interests in the particular matter within the meaning of 18 U.S.C. §208(a) since these interests are unrelated to aprotinin injection (trade name,Trasylol) and the competing products. Nevertheless, I recommend that this waiver be granted.

Second, Dr. Flack's financial interests are not so substantial as to preclude his participation in this matter. He receives minimal compensation for his services.

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. Flack's participation in 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. John Flack is the Interim Chairman in the Department of Internal Medicine and Chief of the Division of Clinical Epidemiology and Translational Research at Wayne State University. Dr. Flack was selected as one of the "Best Doctors in America" in 1998, 2002, 2003, and 2005 by Woodward/White, Inc. He was awarded Pillar of Excellence for Reducing Health Disparities from the Michigan Peer Review Organization in 2005. Dr. Flack was selected as a Health Care Hero by Crain' Detroit Business in August 2005, for leading multidisciplinary and cutting edge research into root causes of obesity and lifestyle related diseases that lead to excessive disease burdens in African Americans. He has also received the Distinguished Research Award in 1993 from the International Society of Hypertension in Blacks. Dr. Flack received the 1998 Daniel J. Savage Distinguished

Research Award from the Association of Black Cardiologist. He serves on several national advisory boards, including the International Society on Hypertension in Blacks (ISHIB) board where he was Vice President from January 1998 through 2001, and President of ISHIB from 2002 through 2004. Dr. Flack is a manuscript reviewer for several prominent medical journals including the Circulation, Ethnicity and Disease, Hypertension, and JAMA. Dr. Flack was also the former member of the Health Care Quality Effectiveness Research study section at the Agency for Health Care Policy Research. I believe his participation will contribute to the diversity of opinions and expertise represented on the committee and will provide a foundation for developing advice and recommendations that are fair and comprehensive.

Accordingly, I recommend that you grant John Flack, M.D., a waiver that will permit him to participate in all official matters to discuss 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. Flack outweighs the potential for a conflict of interest created by the financial interests 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 18 U.S.C. §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/ 8/17/06

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

Date