DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MEMORANDUM

DATE: January 3, 2006

TO: Sheila Dearybury Walcoff, Esq.
Associate Commissioner 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 Thomas Fleming, Ph.D.

I am writing to request a waiver for Thomas Fleming, Ph.D., a consultant to the Center for Drug Evaluation and Research, 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 Thomas Fleming, Ph.D., 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. Fleming 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 as an arrangement concerning, prospective employment.

The function of the Drug Safety and Risk Management Advisory Committee, as stated in its Charter, is to advise the Commissioner of Food and Drugs on risk management, risk communication, and quantitative evaluation of spontaneous reports for drugs for human use and for any other product for which the Food and Drug Administration has regulatory responsibility. The committee also advises the Commissioner of Food and Drugs regarding the scientific and medical evaluation of all information gathered by the Department of Health and Human Services and the Department of Justice with regard to safety, efficacy, and abuse potential of drugs or other substances, and recommends actions to be taken by the Department of Health and Human Services with regard to the marketing, investigation, and control of such drugs or other substances.

Dr. Fleming has been asked to participate in all official matters concerning approaches that could be used to study whether Attention Deficit Hyperactivity Disorder (ADHD) products increase the risk of adverse cardiovascular outcomes. This matter is coming before the Drug Safety and Risk Management Advisory Committee on February 9, 2005.

Dr. Fleming has advised the Food and Drug Administration (FDA) that he has financial interests that could potentially be affected by his participation in the matter described above. Dr. Fleming serves as a member of two [redacted] Data Monitoring Committees for two trials on matters unrelated to the issue coming before the committee for consideration. The primary focus of his role is to safeguarding the interests of trial participants.

Dr. Fleming receives moderate compensation. [redacted] a division of [redacted], a subsidiary of [redacted] is the co-marketer of one of the products which could be impacted by the committee's discussions.

As a consultant advising the Drug Safety and Risk Management Advisory Committee, Dr. Fleming 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. Fleming 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 Thomas Fleming, Ph.D., that would permit him to participation in the matter previously described.

First, and foremost, this waiver is justified because Dr. Fleming's interests arguably do not constitute financial interests in the particular matter within the meaning of 18 U.S.C. §208(a) since his Data Monitoring Committee activities are unrelated to the issue coming before the committee for consideration. Nevertheless, I recommend that this waiver be granted.

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

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. Fleming's

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. Thomas Fleming, Ph.D., is Chair of the Department of Biostatistics at the University of Washington's School of Public Health and Community Medicine; Co-Director, Statistical and Clinical Coordinating Center, HIVNET; Director of the Biostatistics/Epidemiology Core, Center for AIDS Research, University of Washington; and, Professor of Biostatistics. Dr. Fleming is a highly regarded biostatistician who specializes in the statistical analysis of clinical trials and research studies. He has published numerous articles, book chapters and policy papers concerning surrogate endpoints and health outcomes in clinical trials, and design considerations for clinical trials. Dr. Fleming has extensive research expertise in survival analysis, cancer clinical trials, AIDS research, and sequential analysis. He has been a member of numerous professional societies, such as the Institute of Mathematical Statistics, the American Mathematical Society, the Biometric Society, and the Society for Clinical Trials. I believe that Dr. Fleming's expertise in biostatistics is essential to the committee's discussions and deliberations and will help provide a foundation for developing advice and recommendations that are fair and comprehensive.

Accordingly, I recommend that you grant Thomas Fleming, Ph.D., a waiver that will permit him to participate in all official matter concerning discussion of approaches that could be used to study whether Attention Deficit Hyperactivity Disorder (ADHD) products increase the risk of adverse cardiovascular outcomes. I believe that such a waiver is

appropriate because in this case, the need for the services of Dr. Fleming outweighs the potential for a conflict of interest created by the financial interest attributable to him.

CONCURRENCE: Mary Ann Williams for 1-6-06

Jenny Slaughter
Director, Ethics and
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.

1.6.06

Sheila Dearybury Walcoff, Esq.
Associate Commissioner for
External Relations
Food and Drug Administration

Date