



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 2085

MEMORANDUM

DATE: July 19, 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. ISI
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). 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. Fleming, 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,

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a person with whom he is negotiating for, or has an arrangement concerning, prospective employment.

Dr. Fleming has been asked to participate in all official matters concerning new drug application (NDA) 21-158/S-006, Factive (gemifloxacin mesylate) tablets, Licensed from LG Life Sciences, Ltd., marketed by Oscient Pharmaceuticals Corporation, for the proposed treatment of acute bacterial sinusitis.

The function of the Anti-Infective Drugs Advisory Committee 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 infectious diseases and disorders and to make appropriate recommendations to the Commissioner of Food and Drugs.

Dr. Fleming 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. Fleming is a member of [REDACTED] s and [REDACTED] s Data Monitoring Committees (DMC). The DMC's are overseeing trials of drugs unrelated to the issue before the committee or the products that could potentially be affected. [REDACTED] and [REDACTED] make competing products.

As a consultant participating in the Anti-Infective Drugs 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.

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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 Dr. Fleming, which would permit him to participate in the matters previously described.

First, this waiver is justified because arguably, Dr. Fleming'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 the matters at issue; nevertheless, I recommend that this waiver be granted.

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

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 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. Thomas R. 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,

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 participation 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 matters concerning new drug application (NDA) 21-158/S-006, Factive (gemifloxacin mesylate) tablets, Licensed from LG Life Sciences, Ltd., marketed by Oscient Pharmaceuticals Corporation, for the proposed treatment of acute bacterial sinusitis. 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 interests attributable to him.

CONCURRENCE: _____ 151 _____ 8/16/06
Jenny Slaughter Date
Director, Ethics and Integrity Staff
Office of Management Programs
Office of Management

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. _____ 151 _____ 8/17/06
Randall Lutter, Ph.D. Date
Associate Commissioner for
Policy and Planning
Food and Drug Administration