



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 John Bradley, M.D.

I am writing to request a waiver for John Bradley, M.D., a member of the Anti-Infective Drugs Advisory Committee, 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. Bradley, 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. Bradley 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. Bradley 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. Bradley has advised the Food and Drug Administration that he has a financial interest that could potentially be affected by his participation in the matters at issue. Dr. Bradley is a consultant for [REDACTED] regarding [REDACTED] for pediatric community-acquired pneumonia and [REDACTED] for pediatric hospital-acquired pneumonia. Dr. Bradley's employer, Children's Hospital at San Diego, receives minimal fees for his services. Dr. Bradley does not receive any personal remuneration for his involvement. The treatment of pediatric community-acquired pneumonia is not part of the agenda for the upcoming Anti-Infective Drugs Advisory Committee meeting. [REDACTED] makes [REDACTED] a competing product.

As member of the Anti-Infective Drugs Advisory Committee, Dr. Bradley potentially could become involved in matters that could affect his financial interest. 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. Bradley 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. Bradley, which would permit him to participate in the matters described above.

First, this waiver is justified because arguably, Dr. Bradley's interest does not constitute financial interest in the particular matter within the meaning of 18 U.S.C. §208(a) since this interest is unrelated to the matters at issue; nevertheless, I recommend that this waiver be granted.

Second, Dr. Bradley's interest is not so substantial as to preclude his participation in this matter. Dr. Bradley's employer, Children's Hospital at San Diego, will receive minimal compensation from _____, while he himself will receive no personal remuneration 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 advisory committee. Also, 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. Bradley is Director, Division of Infectious Diseases, Children's Hospital and Health Center, and Associate Clinical Professor of Pediatrics, University of California, San Diego. He is board certified in pediatrics and pediatric infectious diseases. His memberships in professional societies include the Infectious Diseases Society of America, the American Academy of Pediatrics, and the Pediatric Infectious Diseases Society. He has written extensively on topics such as the management of community-acquired pediatric pneumonia, old and new antibiotics for pneumonia, otitis media, and bacterial meningitis. 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 Bradley, M.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. Bradley 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