



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DATE: November 6, 2006

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

THROUGH: Vince Tolino
Director, Ethics and Integrity Staff
Office of Management Programs
Office of Management

FROM: Igor Cerny, Pharm.D. 15/
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 voting 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. 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 the overall benefit to risk considerations for the approved product, Ketek (telithromycin), new drug application (NDA) 21-144, manufactured by Sanofi-Aventis with the current indications of acute bacterial exacerbations of chronic bronchitis, acute bacterial sinusitis, and community acquired pneumonia. This issue is coming before a joint meeting of the Anti-Infective Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee and is considered a particular matter involving specific parties.

The committees' functions, as stated in their Charters, are as follows: 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. The Drug Safety and Risk Management Advisory Committee 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 committees make their appropriate recommendations to the Commissioner of Food and Drugs.

Dr. Bradley has advised the Food and Drug Administration that he has financial interests that could potentially be affected by his participation in the matter at issue. Dr. Bradley is a consultant for _____ regarding _____ for otitis media and community acquired pneumonia in children. All fees associated with this consulting activity go directly to Dr. Bradley's employer, the Children's Hospital at San Diego. Dr. Bradley does not receive any personal remuneration for his work. _____ is a competing product to Ketek (telithromycin). However, the joint committee will not address the pediatric program under Investigational New Drug (IND) for Ketek, rather the discussion will focus on clinical studies and use in adults.

Dr. Bradley's employer, the Children's Hospital at San Diego, is currently involved in a long-term, multi-centered, safety study of _____ in children. The study began in 2003, at the Food and Drug Administration's request, and is expected to end in 2007. There is only one patient enrolled in the study. The Children's Hospital receives \$ _____ per year from _____ for an annual visit with the patient. Dr. Bradley is the principal site investigator but he

does not receive any personal remuneration or salary support for his role in the study.

As a voting consultant to the Center for Drug Evaluation and Research, 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. 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 matter described above.

First, although Dr. Bradley's employer currently has a financial interest in _____, he himself has no personal financial interest in the firm. Generally there is less likelihood that the judgment of the individual will be affected by an imputed interest of an employer than by a personal financial interest.

Second, with respect to the current _____ sponsored safety study of _____ in children, it is important to note that the Children's Hospital is one of several sites for the study and that Levaquin is already approved in the U.S. for the treatment of community acquired pneumonia in adults.

Third, there are more than five competing products on the market that compete with Ketek for the treatment of community acquired pneumonia in adults.

Fourth, the uniqueness of Dr. Bradley's qualification justifies granting this waiver. Dr. John Bradley is the only pediatric infectious disease physician on the Committee who participated in several prior advisory committee meetings on Ketek. His experience and participation in both public and closed sessions involved extensive open discussion of benefit/risk considerations for Ketek, as well as mention in closed session of a _____ finding of _____ in a large _____ study. It is highly desirable to have at least one member at the December Committee meeting who is intimately familiar with the long history of Ketek development, discussion of benefit/risk considerations, and _____ issues known _____

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. In addition, the committees' 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 because 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. I believe Dr. Bradley's participation will contribute to the diversity of opinions and expertise represented on at this meeting and will provide a foundation for developing advice and recommendations that are fair and comprehensive.

**APPEARS THIS WAY
ON ORIGINAL**

