



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. /s/
Director, Advisors and Consultants Staff
Center for Drug Evaluation and Research

SUBJECT: Conflict of Interest Waiver for John G. Bartlett, M.D.

I am writing to request a waiver for John G. Bartlett, 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. Bartlett 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. Bartlett 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. Bartlett has been asked to give a presentation at the joint meeting of the Anti-Infective Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee. At this meeting, the committees' will discuss 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 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. Bartlett has advised the Food and Drug Administration that he has financial interests that could potentially be affected by his participation in the meeting. Dr. Bartlett is a member of advisory boards for _____, _____, _____, and _____. Dr. Bartlett receives minimal compensation for his participation.

Moreover, in September 2006, Dr. Bartlett gave a presentation on Human Immunodeficiency Virus. He is awaiting payment of his honorarium from _____.

As a consultant, Dr. Bartlett 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. Bartlett 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. Bartlett, which would permit him to give a presentation and answer questions

related to his presentation at the joint meeting of the Anti-Infective Drugs and Drug Safety and Risk Management Advisory Committees meeting.

First, Dr. Bartlett's interests are not so substantial as to preclude his participation in this matter. He receives minimal compensation for his activities.

Second, Dr. Bartlett's interests are unrelated to the product at issue, the competing products, and the issues coming before the committees. _____, _____, and _____ advisory boards discuss matters related to the Human Immunodeficiency Virus and the _____ advisory board discusses matters that affect the entire corporation.

Third, it is highly unlikely that Dr. Bartlett's limited participation at this meeting will affect his receiving final payment from _____ for work that has already been completed.

Moreover, the uniqueness of Dr. Bartlett's qualifications justifies granting this waiver. Dr. Bartlett was invited to present at this meeting, specifically because of his vast knowledge of antibiotics and considered experience in the management of patients with community-acquired pneumonia, an infection for which Ketek is approved. In particular, Dr. Bartlett was one of the authors of the latest practice guidelines for the management of community-acquired pneumonia, including those due to resistant pathogens, endorsed by the Infectious Diseases Society of America. Dr. Bartlett's breadth of knowledge of antibiotics and his recognized expertise in community-acquired pneumonia make him an essential contributor at this meeting.

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. Bartlett is Professor of Medicine and Chief of the Division of Infectious Diseases at the Johns Hopkins University School of

