



DEPARTMENT OF HEALTH & HUMAN SERVICES

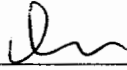
MEMORANDUM

Food and Drug Administration
Rockville MD 20857

DATE: January 26, 2006

TO: Jason D. Brodsky
Acting Associate Commissioner
Office of 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 Jeffrey S. Borer,
M.D.

I am writing to request a waiver for Jeffrey S. Borer, 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 18 U.S.C. §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. You are the appointing official for purposes of section 208; therefore, you have the authority to grant Dr. Borer a waiver under section 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. Borer 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 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. Borer has been asked to participate in official matters regarding New Drug Application (NDA) 21-572/S-008, Cubicin (daptomycin for injection 500 mg/vial), sponsored by Cubist Pharmaceuticals, for the treatment of *Staphylococcus aureus* bacteremia, including those with known or suspected endocarditis caused by methicillin-susceptible and methicillin-resistant strains.

Dr. Borer 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. Borer, a Professor of Cardiovascular Medicine at Cornell University, Weill Medical College, has been asked by the ~~_____~~ to serve on the Executive Committee of a ~~_____~~ funded study to examine the cardiovascular safety of an unrelated product, ~~_____~~ in patients with ~~_____~~. As a member of the Executive Committee, Dr. Borer's involvement in the study will be limited to that of an advisor to study investigators and steering committees. In addition, Executive Committee members may also take the lead in writing and submitting papers on the study for publication after it has ended. The study began enrolling patients in 2006 and is expected to end in 2009. Dr. Borer does not expect to be compensated for his services to the Executive Committee but if he is, it will come from the ~~_____~~ and not ~~_____~~. In order to avoid potential conflict of interest issues, the ~~_____~~ is requiring that members of its Executive Committee refrain from accepting speaking fees or other compensation from pharmaceutical companies who may be affected by results from the study. Consequently, Dr. Borer will sever all consulting and speaking relationships with

pharmaceutical companies once he begins serving on the study's Executive Committee.

Dr. Borer serves as a consultant to _____
_____. Dr. Borer is also a member of a Speaker's Bureau for _____. According to Dr. Borer, these activities are unrelated to the product coming before the committee for consideration, and the competing products. _____ make competing products to Cubicin®.

As a consultant advising the Anti-Infective Drugs Advisory Committee, Dr. Borer could potentially become involved in matters that could affect his financial interests. Under section 208, 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. Jeffrey S. Borer 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 limited waiver that would allow him to participate in the committee's discussions concerning Cubist Pharmaceuticals' Cubicin®, without voting.

First, arguably, Dr. Borer's interests in _____ do not constitute financial interests in the particular matter within the meaning of 18 U.S.C. §208(b)(3), since his consulting and speaking interests are unrelated to the products at issue, and the competing products. Nevertheless, I recommend that this waiver be granted.

Second, it is not clear that any current or future financial support from _____ to Dr. Borer would be directly and predictably affected by his participation in the issues at hand.

Third, there are ten competing products on the market for the treatment of *Staphylococcus aureus* bacteremia.

Fourth, Dr. Borer will be participating solely in an advisory capacity in which appropriate disclosure will be made of his interests. The FDA is not bound by the discussions and recommendations of the advisory committee or any votes taken and may take into account Dr. Borer's financial interests in assessing the advice he renders. In addition, any conflict or appearance of a conflict will be mitigated further by the fact that FDA has decided to limit Dr. Borer's participation. Under the terms of this limited waiver, Dr. Borer will be permitted to participate in the committee's discussions concerning Cubist Pharmaceuticals' Cubicin® but will be excluded from voting.

Moreover, the Agency has found it difficult to obtain the services of qualified cardiologists who do not have similar, or even worse, conflict of interest. Given the large number of competing products and their sponsors, most qualified cardiologist have or have had some involvement with Cubicin (daptomycin for injection), the competing products, and/or their sponsors. Dr. Borer is the only cardiologist participating in 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 various advisory committee members. 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. Jeffrey S. Borer, M.D., is the Gladys and Roland Harriman Professor of Cardiovascular Medicine, Professor of Cardiovascular Medicine in Radiology and in Cardiothoracic Surgery; and, Chief, Division of Cardiovascular Pathophysiology, Weill Medical College, Cornell University. Dr. Borer is also Past Chairman of the FDA's Cardiovascular and Renal Drugs Advisory Committee (1981-1982; 1983-1987), the author of more than 300 scientific papers and book chapters, and a member of numerous professional societies, such as the American Heart Association, the American Society for Clinical Investigation, the Society of Cardiac Angiography, and the American Society of Nuclear Cardiology. He is an expert in the diagnosis and management of cardiovascular

disease and cardiovascular clinic pharmacology. Cubist Pharmaceuticals is seeking approval of Cubicin (daptomycin for injection) for the treatment of *Staphylococcus aureus* bacteremia, including those with known or suspected endocarditis caused by methicillin-susceptible and methicillin-resistant strains. Endocarditis is an inflammation of the inside lining of the heart chambers and heart valves. Most people who develop endocarditis have underlying heart disease and bacterial infection is a common source of endocarditis. Dr. Borer's expertise in coronary artery disease and cardiovascular clinical pharmacology is essential to the committee's discussions of whether the data submitted demonstrates that Cubicin (daptomycin for injection) is safe and effective for its proposed indication. I believe that Dr. Borer's participation will bring an enormous amount of experience, knowledge, and expertise that is essential to the committee's discussions concerning Cubicin and will help to provide a foundation for developing advice and recommendations that are fair and comprehensive.

Accordingly, I recommend that you grant Jeffrey Borer, M.D., a limited waiver that would allow him to participate in the committee's discussions, without voting, concerning New Drug Application (NDA) 21-572/S-008, Cubicin (daptomycin for injection 500 mg/vial), sponsored by Cubist Pharmaceuticals, for the treatment of *Staphylococcus aureus* bacteremia, including those with known or suspected endocarditis caused by methicillin-susceptible and methicillin-resistant strains. I believe that such a waiver is appropriate because in this case, the need for the services of Dr. Borer outweighs the potential for a

conflict of interest created by the financial interests attributable to him.

CONCURRENCE: Jenny Slaughter 2/1/06
Date
Jenny Slaughter
Director, Ethics and Integrity Staff
Office of Management Programs
Office of Management

DECISION:

✓ 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.

Jason D. Brodsky 2.6.06
Date
Jason D. Brodsky
Acting Associate Commissioner
Office of External Relations
Food and Drug Administration