



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. Igor Cerny
Director, Advisors and Consultants Staff
Center for Drug Evaluation and Research

SUBJECT: Conflict of Interest Waiver for Steven Ebert,
Pharm.D.

I am writing to request a waiver for Steven Ebert, Pharm.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. Ebert 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 his employer has a financial interest. Since Dr. Ebert is a special Government employee, he is under a statutory obligation to refrain from participating in any deliberations that involve a particular matter having a direct and predictable effect on a financial interest attributable to him or his employer.

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. Ebert has been asked to participate in all 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. Ebert 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. Ebert is a member of the Speakers Bureau's for _____
_____ a competing product, _____.

In addition, Dr. Ebert consulted for _____ on _____ and although his consulting has ended, he may still technically be under contract as a consultant to them. _____ is a competing product to Cubicin.

As a consultant advising the Anti-Infective Drugs Advisory Committee, Dr. Ebert 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. Steven Ebert 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 Steven Ebert, Pharm.D., that would permit him to participate in the matters previously described.

First, arguably, Dr. Ebert's interests in [REDACTED] do not constitute financial interests in the particular matters within the meaning of 18 U.S.C. §208(b)(3), since his speaking interests are unrelated to the product at issue, and the competing products. Dr. Ebert has attended the annual Speakers Bureau's training for each of these companies but was never asked to give a lecture and he does not anticipate giving any talks this year.

Second, with regards to Dr. Ebert's consulting for [REDACTED] a competing product, it is important to consider that although this is a competing product, Dr. Ebert's consulting focused on the marketing of [REDACTED]. In May 2005, he was asked to participate in a panel meeting which took place in December 2005. The panel was asked how likely it was that hospitals would add [REDACTED] to their formularies and for which approved indications it would most likely be used. He has not been asked for any further consulting. However, he is unsure whether he signed a consulting agreement which would technically make him a consultant for [REDACTED] for a 12 month period.

Third, Dr. Ebert's financial interests are not so substantial as to preclude his participation in this meeting. He received nominal compensation from each firm 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 various advisory committee members and Dr. Ebert's participation will contribute to the balance of views represented and the diversity of opinions and expertise. The Committee's intended purpose would be

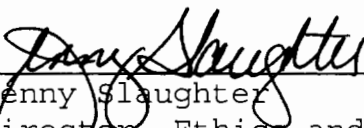
significantly impaired if the agency could not call upon experts who have become eminent in their fields, notwithstanding the financial interests and affiliations they may have acquired as a result of their demonstrated abilities. Dr. Ebert is a Clinical Specialist in Infectious Diseases at Meriter Hospital. He has worked in the field of anti-infective pharmacology, and has years of experience as both a clinical practitioner and researcher in infectious disease. He serves as a reviewer for a number of scientific journals. In addition, Dr. Ebert is a member of various professional societies including, the Infectious Disease Society of America, the Pharmacology Society of Wisconsin and the American Society of Microbiology. I believe that Dr. Ebert's participation will bring an enormous amount of experience, knowledge and expertise that is essential to the committee's discussions concerning this issue and will provide a foundation for developing advice and recommendations that are fair and comprehensive.

Accordingly, I recommend that you grant Steven Ebert, Pharm.D., a waiver that will permit him to participate in all official matters 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

**APPEARS THIS WAY
ON ORIGINAL**

case, the need for the services of Dr. Ebert outweighs the potential for a conflict of interest created by the financial interests attributable to him.

CONCURRENCE:



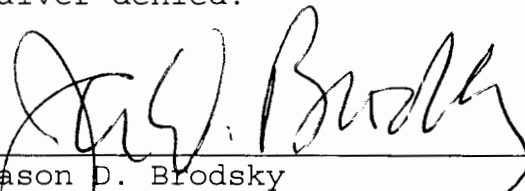
Jenny Slaughter
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DECISION:

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
Acting Associate Commissioner
Office for External Relations
Food and Drug Administration

2.7.06
Date