



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 for 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 Jan Patterson, M.D.

I am writing to request a waiver for Jan Patterson, M.D., a member of the Anti-Infective Drugs Advisory Committee, from the conflict of interest prohibitions of 18 U.S.C. 208(a). Waivers under section 208(b)(1) may be granted by the appointing official where "the [financial] interest is not so substantial as to be deemed likely to affect the integrity of the services which the Government may expect from such employee" 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. Patterson a waiver under section 208(b)(1).

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. Patterson is a special Government employee, she 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 her, her spouse, minor child, or general partner; an organization or entity for which she serves as an officer, director, trustee, general partner, or employee; and, a person with whom she is negotiating for, or has an arrangement concerning, prospective employment.

Dr. Patterson 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.

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. Patterson has advised the Food and Drug Administration (FDA) that her spouse has financial interests that could potentially be affected by her participation in the matters described above. Dr. Patterson's spouse serves as a consultant to ~~_____~~ on ~~_____~~. He also serves on the Speaker's Bureau and Advisory Board for ~~_____~~ regarding ~~_____~~. He receives moderate fees for his role. ~~_____~~ make competing products to Cubicin (daptomycin).

As a member of Anti-Infective Drugs Advisory Committee, Dr. Patterson could potentially become involved in matters that could affect her spouse's financial interests. Under section 208, she is prohibited from participating in such matters. However, as noted above, you have the authority under 18 U.S.C. §208(b)(1) to grant a waiver permitting Dr. Patterson to participate in such matters, as you deem appropriate.

First and foremost, arguably Dr. Patterson's spouse's interests in ~~_____~~ do not constitute financial interests in the particular matter within the meaning of 18 U.S.C. §208(a) since his consulting/advisory board and speaking activities are all unrelated to the issue and product coming before the committee, and competing products. Nevertheless, in the utmost of caution, I recommend that this waiver be granted.

Second, Dr. Patterson and her spouse's interests are not so substantial as to preclude her participation in these matters. Dr. Patterson's spouse receives moderate compensation from ~~_____~~ for his services.

Finally, 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. Patterson is Professor of Medicine and Pathology, Division of Infectious Diseases at the University of Texas Health Sciences Center at San Antonio, Director, Epidemiology Laboratory, and Chief Medical Services, the South Texas Veterans Health Care System. She is board certified in Internal Medicine with a subspecialty in Infectious Diseases. She has published extensively, demonstrating her vast clinical and research expertise in microbiology, streptococcus pneumonia, antimicrobial resistance and respiratory disease. Her expertise in these areas is demonstrated by her numerous publications and membership in various professional societies, such as the American College of Physicians, Infectious Disease Society of America, and the American Society for Microbiology. I believe her participation will contribute to the diversity of opinions and expertise represented on the committees and will provide a foundation for developing advice and recommendations that are fair and comprehensive.

Accordingly, I recommend that you grant Jan Patterson, M.D., a waiver that will permit her 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 this waiver is appropriate

because in this case, the interests are not so substantial as be deemed likely to affect the integrity of the services which the Government may expect from Jan Patterson, M.D.

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 208(b)(1), that the "interest is not so substantial" as to be deemed likely to affect the integrity of the services which the Government may expect from such employee.

Waiver denied.
Jason D. Brodsky 2/6/06
Date
Jason D. Brodsky
Acting Associate Commissioner
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