



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 2085

MEMORANDUM

**DATE:** July 19, 2006

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

**THROUGH:** Jenny Slaughter  
Director, Ethics and Integrity Staff  
Office of Management Programs  
Office of Management

**FROM:** Igor Cerny, Pharm.D. 151  
Director, Advisors and Consultants Staff  
Center for Drug Evaluation and Research

**SUBJECT:** Conflict of Interest Waiver for Peter Gross, M.D.

I am writing to request a waiver for Peter Gross, M.D., a member of the Drug Safety and Risk Management Advisory Committee, who has been invited to attend the Anti-Infective Drugs Advisory Committee meeting, 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. Gross, 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. Gross 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,



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However, as noted above, you have the authority under 18 U.S.C. §208(b)(3) to grant a waiver permitting Dr. Gross 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. Gross, which would permit him to participate in the matters previously described.

First, this waiver is justified because arguably, Dr. Gross' interest does not constitute financial interest in the particular matter within the meaning of 18 U.S.C. §208(a) since these interest is unrelated to the matters at issue; nevertheless, I recommend that this waiver be granted.

**Second, Dr. Gross' financial interest is not so substantial as to preclude his participation in this matter. He receives minimal compensation from \_\_\_\_\_.**

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. Gross' 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. Peter Gross is a Professor of Medicine, Vice Chair and Chief of Medicine at Hackensack University Medical Center. He is board certified in internal medicine and infectious diseases. Dr. Gross leads a panel of nationally recognized experts in the areas of risk perception, risk management, pharmacoepidemiology, clinical pharmacology, clinical research, and medication errors.

His memberships in professional societies include the American Academy of Microbiology, American College of Physicians (Task Force on Adult Immunization), and American Federation for Clinical Research, American Society for Microbiology, and the Infectious Disease Society of America. He has published over 250 original articles and books on influenza vaccine, other immunizations, hospital epidemiology, performance measurement and implementing quality improvement. I believe that Dr. Gross' participation will contribute to the diversity of viewpoints and expertise represented on the committee and will provide a foundation for developing advice and recommendations that are fair and comprehensive.

Accordingly, I recommend that you grant Peter Gross, M.D., a waiver that will permit him to participate in all official matters concerning new drug application (NDA) 21-158/S-006, Factive (gemifloxacin mesylate) tablets, Licensed from LG Life Sciences, Ltd., marketed by Oscient Pharmaceuticals Corporation, for the proposed treatment of acute bacterial sinusitis. I believe that such a waiver is appropriate because in this case, the need for the services of Dr. Gross outweighs the potential for a conflict of interest created by the financial interests attributable to him.

CONCURRENCE:

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Jenny Slaughter  
Director, Ethics and Integrity Staff  
Office of Management Programs  
Office of Management

8/16/06  
Date

DECISION:

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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.

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Waiver denied.

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

8/17/06  
Date