

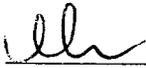


MEMORANDUM

DATE: January 3, 2006

TO: Sheila Dearybury Walcoff, Esq.
Associate Commissioner 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 Peter A. Gross, M.D.

I am writing to request a waiver for Peter A. Gross, M.D., a member of the Drug Safety and Risk Management Advisory Committee, from the conflict of interest prohibitions of 18 U.S.C. §208(a). Waivers under section 208(b)(3) may be granted by the appointing official 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 Peter A. Gross, M.D., 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, a person with whom he is negotiating for, or as an arrangement concerning, prospective employment.

The function of the Drug Safety and Risk Management Advisory Committee, as stated in its Charter, 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 committee also advises the Commissioner of Food and Drugs regarding the scientific and medical evaluation of all information gathered by the Department of Health and Human Services and the Department of Justice with regard to safety, efficacy, and abuse potential of drugs or other substances, and recommends actions to be taken by the Department of Health and Human Services with regard to the marketing, investigation, and control of such drugs or other substances.

Dr. Gross has been asked to participate in all official matters concerning (1) briefing on developments in the Office of Drug Safety; (2) updates on the Drug Safety Oversight Board; (3) the Agency actions for the COX-2 selective Nonsteroidal Anti-inflammatory Drugs (NSAIDs); and, (4) the risk management program for the isotretinoin products.

Dr. Gross has advised the Food and Drug Administration (FDA) that he has financial interests that could potentially be affected by his participation in the matters described above. Dr. Gross serves as a member of _____ Advisory Board. This issue is unrelated to the issues coming before the committee for consideration. Dr. Gross receives minimal fees for his participation with _____. In addition, Dr. Gross and his spouse own a modest amount of stock in _____ makes products that could potentially be affected by the committee's discussions.

As a member of the Drug Safety and Risk Management Advisory Committee, Dr. Gross potentially could become involved in

Page 3 - Sheila Dearybury Walcoff, Esq.

matters that could affect his financial interest. 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. 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 Peter A. Gross, M.D., that would permit him to participate in the matters previously described.

First, and foremost, this waiver is justified because Dr. Gross' involvement as a member of _____ Advisory Board does not constitute a financial interest in the particular matters within the meaning of 18 U.S.C. §208(a) since his this activity is unrelated to the issues coming before the committee for consideration. Nevertheless, I recommend that this waiver be granted.

Second, it is important to consider that Dr. Gross' financial interests in _____ are not so substantial as to preclude his participation in these matters.

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. Peter A. Gross, M.D. 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), 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 help provide a foundation for developing advice and recommendations that are fair and comprehensive.

Accordingly, I recommend that you grant Peter A. Gross, M.D., a waiver that will permit him to participate in all official concerning (1) briefing on developments in the Office of Drug Safety; (2) updates on the Drug Safety Oversight Board; (3) the Agency actions for the COX-2 selective Nonsteroidal Anti-inflammatory Drugs (NSAIDs); and, (4) the risk management program for the isotretinoin products. 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 interest attributable to him.

CONCURRENCE: *Mary Ann Kellan for* *1-6-06*
Jenny Slaughter Date
Director, Ethics and
and Integrity Staff
Office of Management Programs
Office of Management

DECISION:

✓
Waiver granted based on my determination, made in accordance with section 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.
Sheila Dearybury Walcoff *1-9-06*
Sheila Dearybury Walcoff, Esq. Date
Associate Commissioner for
External Relations
Food and Drug Administration