DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

MEMORANDUM

DATE: June 25, 2007

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

THROUGH: Vince Tolino
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 Gross, M.D.

I am writing to request a waiver for Peter Gross, M.D., a Temporary Voting Member to the Drug Safety and Risk Management Advisory Committee, 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 Peter 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 has an arrangement concerning, prospective employment.

Dr. Gross, a Temporary Voting Member of the Drug Safety and Risk Management Advisory Committee, has been invited to participate in the August 1, 2007, joint meeting of the Dermatologic and Ophthalmic Drugs and the Drug Safety and Risk Management Advisory Committees. At this meeting, the committees will be briefed on iPLEDGE, the risk management program for isotretinoin products. Presentations will provide updates on risk management activities for isotretinoin since the full implementation of iPLEDGE on March 1, 2006. Isotretinoin is a drug used to treat severe recalcitrant nodular acne that has not responded to other therapies. This issue is a particular matter involving specific parties (e.g., affecting all isotretinoin products and their manufactures).

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 advised the Food and Drug Administration that he has a financial interest that could potentially be affected by his participation in the matter previously described. Dr. Gross is a member of ———————'s Speaker's Bureau. His speaking concerns influenza and its treatment. ——————— makes ———————, an affected product.

As a Temporary Voting Member of the Drug Safety and Risk Management Advisory Committee, Dr. Gross potentially could become involved in 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. Peter 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. Peter Gross that would permit him to participate in the matter described previously.

First, it is important to consider that Dr. Gross' interest in ———————— is unrelated to isotretinoin, used in the treatment of severe recalcitrant nodular acne, and iPLEDGE, the risk management program for isotretinoin.

Second, Dr. Gross' personal financial interest in ———————— ———— is not so substantial as to preclude his participation in this matter. Dr. Gross receives minimal compensation for serving on the Speaker's Bureau.

Third, the uniqueness of Dr. Gross' qualification justifies granting this waiver. The agency is holding this joint meeting because the risk issues have potentially extremely serious consequences for women taking isotretinoin and their unborn fetuses, and public health. Meaningful, scientific discussion and recommendations need the participation of drug risk experts from a wide variety of professions, particularly epidemiology, teratology, pharmacy, and risk management and communication. Dr. Gross is an expert in pharmacy therapeutics and has vast experience in clinical research and epidemiology. This expertise alone makes him a highly desirably participant for this meeting. Additionally, he served as the Chair of the Drug Safety and Risk Management Advisory Committee (DSaRM) and oversaw two isotretinoin meetings that discussed the isotretinoin risk management program. The first meeting he chaired, a joint meeting with the Dermatology and Ophthalmic Drugs Advisory Committee in February 2004, addressed the effectiveness of the isotretinoin risk management program for the prevention of fetal exposure to Accutane and its generic equivalents, and considered whether changes to this isotretinoin risk management program would be appropriate. The second meeting he chaired concerned a safety update on the risk

management program for isotretinoin. According to the Review Division, as the Chair of DSaRM during those meetings, Dr. Gross provided excellent leadership for the committee's deliberations and recommendations to the agency. Dr. Gross' participation in the upcoming August 1, meeting would be especially valuable, because he already has in depth knowledge of and an important historical perspective on isotretinoin safety issues and the risk management program. His participation would ensure valuable continuity of medical and scientific experience and understanding of the particular issues pertaining to iPLEDGE. Dr. Gross' experience in conducting clinical trials, expertise, and understanding of FDA's regulatory framework are critical for the discussion and thus justify granting him a waiver to participate 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 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. 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 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 would allow him to participate fully in the August 1, 2007, joint meeting of the Dermatologic and Ophthalmic Drugs and the Drug Safety and Risk Management Advisory Committees. At this meeting, the committees will be briefed on iPLEDGE, the risk management program for isotretinoin products. Presentations will provide updates on risk management activities for isotretinoin since the full implementation of iPLEDGE on March 1, 2006. I believe that such a waiver is appropriate because in this case, the need for the services of Peter Gross, M.D., outweighs the potential for a conflict of interest created by the financial interest attributable to him.

CONCURRENCE: /S/ 6/28/07

Vince Tolino
Director, Ethics and Integrity Staff
Office of Management Programs
Office of Management

Date

DECISION:

X 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.

/S/ 7/6/07

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

Date