



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MEMORANDUM

DATE: March 13, 2007

TO: Randall W. Lutter, Ph.D.
Associate 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. /s/
Director, Advisors and Consultants Staff
Center for Drug Evaluation and Research

SUBJECT: Conflict of Interest Waiver for William Vollmer,
Ph.D.

I am writing to request a waiver for William Vollmer, Ph.D., a temporary voting member of the Pulmonary and Allergy Drugs 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 Dr. Vollmer, 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. Vollmer 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. Vollmer has been asked to participate in all official matters concerning the efficacy supplement to New Drug Application (NDA) 21-077 for the approved product Advair Diskus 500/50 (fluticasone propionate/ salmeterol inhalation powder) for the proposed indication of increased survival and reduced exacerbations in patients with chronic obstructive pulmonary disease (COPD). Advair Diskus 500/50 is sponsored by GlaxoSmithKline. This matter is coming before the Pulmonary and Allergy Drugs Advisory Committee and is a particular matter involving specific parties.

The function of Pulmonary-Allergy 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 pulmonary disease and diseases with allergic and/or immunologic mechanisms and make appropriate recommendations to the Commissioner of Food and Drugs.

Dr. Vollmer has advised the Food and Drug Administration that he has a financial interest that could potentially be affected by his participation in the matters at issue. Dr. Vollmer is the Director of the _____
_____. The purpose of the _____
project is to measure the worldwide prevalence of _____
_____ and its risk factors. Funding is provided to his employer, Kaiser Permanente Center for Health Research, by a consortium of pharmaceutical companies which include _____,
_____, _____, and several other pharmaceutical companies not affected by the product and matter coming before the committee. He receives minimal compensation for his work. _____,
_____, and _____ manufacture competing products to Advair Diskus (fluticasone propionate/salmeterol inhalation powder). _____ manufactures _____.

As a temporary voting member participating in the Pulmonary and Allergy Drugs Advisory Committee meeting, Dr. Vollmer 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. Vollmer 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. Vollmer, which would permit him to participate in the matter previously described.

First, the compensation Dr. Vollmer will receive for his role as director of the project is not so substantial as to preclude his participation in this meeting.

Second, the uniqueness of Dr. Vollmer's qualification justifies granting this waiver. Dr. Vollmer is the only biostatistician participating in this advisory committee meeting as a member with the expertise required for the analysis of epidemiologic data. Dr. Vollmer has vast experience coordinating large multi-national epidemiologic studies. Because the focus of the discussion will center upon a large, multi-national, long-term clinical trial in patients with COPD, his experience will provide valuable insight regarding issues in conducting and analyzing the results unique to such studies.

Third, the Division of Pulmonary and Allergy Products feel that because of the nature of the issues to be discussed it is essential to have a number of experts in clinical trials and epidemiology participate in the advisory committee meeting. Further, the Division feels that biostatistics will be a key component of the discussions. In an attempt to gain the necessary expertise, the Division along with the Advisors and Consultants Staff contacted two Special Government Employee consultants in addition to the one standing biostatistician member. Of the three biostatisticians contacted, two accepted indicating that they were interested and available to attend the committee meeting. The one who declined, did so as a result of scheduling conflicts. The two who accepted will both require a waiver to participate in the

meeting due to their current financial interests. After consultation with the Division, it was determined that they would seek waivers for both statisticians because the expertise required for the analysis of controlled clinical trials is different from that used in the analysis of epidemiologic data. Therefore, both biostatisticians are needed for an adequate evaluation of the issues that will be discussed. The Division is seeking broad and diverse perspectives on the issues at hand in an effort to approach the topic in an objective and scientific manner. If any of the biostatisticians are recused, it will leave insufficient biostatistical expertise on the panel to adequately address the meeting issues. To that end, we are requesting that the waiver be granted for Dr. Vollmer to participate as there has been a genuine effort to secure individual participation and representation with minimal conflict of interest.

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 committee. 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. Vollmer received his Ph.D. in biostatistics from the University of Washington in Seattle. He is an adjunct associate professor at the Oregon Health Sciences University in the Department of Pulmonary and Critical Care Medicine and has co-authored articles regarding COPD. These qualifications and his extensive experience with epidemiologic studies in COPD is what make him invaluable to the discussion. I believe that Dr. Vollmer's participation will help provide a foundation for developing advice and recommendations that are fair and comprehensive.

Accordingly, I recommend that you grant William M. Vollmer, Ph.D., a waiver that will permit him to participate in all official matters concerning the efficacy supplement to New Drug Application (NDA) 21-077 for the approved product Advair Diskus 500/50 (fluticasone propionate/ salmeterol inhalation powder) for the proposed indication of increased survival and reduced exacerbations in patients with chronic obstructive pulmonary disease (COPD). I believe that such a

waiver is appropriate because in this case, the need for the services of Dr. Vollmer outweighs the potential for a conflict of interest created by the financial interest involved.

CONCURRENCE: _____/s/_____ 3/30/07
Vince Tolino Date
Director, Ethics and Integrity Staff
Office of Management Programs
Office of Management

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.

_____ 4/2/07
Randall W. Lutter, Ph.D. Date
Associate Commissioner for
Policy and Planning
Food and Drug Administration