DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

MEMORANDUM

DATE: November 3, 2006

TO: Randall 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 Limited Waiver for Bruce Pollock, M.D.

I am writing to request a limited waiver for Bruce Pollock, M.D., a member of the Psychopharmacologic Drugs 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 Bruce Pollock, 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. Pollock 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.

The functions of the Psychopharmacologic Drugs Advisory Committee, as stated in its Charter, are to review and evaluate data concerning the safety and effectiveness of marketed and investigational human drug products for use in the practice of psychiatry and related fields and make appropriate recommendations to the Commissioner of Food and Drugs.

Dr. Pollock has been asked to participate in all official matters concerning the discussions of the results of the FDA ongoing meta-analysis of suicidality data from adult antidepressant trials. This matter is coming before the Psychopharmacologic Drugs Advisory Committee and is a particular matter involving specific parties.

Dr. Pollock has advised the Food and Drug Administration (FDA) that he has financial interests that could potentially be affected by his participation in this matter. Dr. Pollock is a member of [redacted] Psychiatric Advisory Board. The board has discussed [redacted], an antidepressant that could be affected by the committee's discussions. Further, on [redacted], Dr. Pollock attended a [redacted] Speaker's Bureau update and gave a lecture on data in geriatrics and severe depression. Dr. Pollock believes he may still be listed on [redacted] Speaker's Bureau although he has given no other lectures in the past 12 months, nor does he have any currently scheduled. Dr. Pollock receives minimal compensation for these activities.

In addition, Dr. Pollock is a faculty member of the [redacted], which provides education to international psychiatrists. He receives minimal compensation for his service. [redacted] established the [redacted] in [redacted] to help fight the global burden of Central Nervous System diseases. The activities of the [redacted] are fully dedicated to non-product related activities of any kinds. All activities build upon objective and evidence-based knowledge.

[redacted] and [redacted] **licensed from** [redacted], are products that could be affected by the committee's discussion.

As a member of the Psychopharmacologic Drugs Advisory Committee, Dr. Pollock potentially could become involved in matters that could affect his financial interests. 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. Pollock 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 limited waiver to Bruce Pollock, M.D., which would permit him to participate in the matters previously described. Under the terms of this limited waiver, Dr. Pollock will be excluded from voting.

First, Dr. Pollock's personal financial interests are not so substantial as to preclude his participation in the matter described previously. Dr. Pollock receives minimal compensation for his services.

Second, it is important to consider that although Dr. Pollock has interests which involve products that could be affected by the committee's discussions, the division is presenting a meta-analysis, grouping data for over 400 studies. They grouped all the efficacy study data in order to pick up any adverse events. Therefore, the committee will not be looking at individual study or product data but rather, they will be looking at all the product data in this class.

In addition, Dr. Pollock's expertise makes him an invaluable resource to FDA for this upcoming meeting and his unique expertise will greatly enhance the deliberations of the committee as it seeks advice on this issue for the following reasons. Dr. Pollock is the only geriatric psychiatrist invited to the meeting and therefore is the only person in attendance with the specific expertise to discuss the suicidality data for elderly adults that will be presented to the committee. There is interest from the public regarding the geriatric population in light of the high

suicide rate among this population and the problems that older adults encounter with respect to access to needed medications. In addition to Dr. Pollock's expertise in geriatric psychiatry, he has unique and extensive experience in the areas of pharmacodynamics and clinical trials. Given that the pharmacodynamics of the geriatric population is vastly different from that of the non-geriatric population, specific knowledge in this area is greatly warranted. Dr. Pollock's unique combination of knowledge of pharmacodynamics in the geriatric population is essential in addressing the issues of suicidality in this population. In summary, Dr. Pollock's expertise will lend to well rounded deliberations in providing advice to the Agency on the FDA ongoing meta-analysis of suicidality data from adult antidepressant trials.

Further, to diminish the appearance of a conflict of interest, the Agency has decided to limit Dr. Pollock's participation. Under the terms of this limited waiver, Dr. Pollock will be permitted to participate in the committees' discussions; however, he will be excluded from any vote related to the matter at issue.

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 various advisory committee members and Dr. Pollock's participation in 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. Pollock is Professor of Psychiatry, Pharmacology, and Pharmaceutical Sciences, as well as Chief of the Academic Division of Geriatrics and Neuropsychiatry at the University of Pittsburgh. He is also Director of the Department of Psychiatry's Geriatric Psychopharmacology and Clinical Therapeutics Research Programs. His research includes clinical studies examining neurochemical selectivity, pharmacokinetics, and the effects of conventional or newly derived agents for the treatment of depression and the behavioral disturbances of dementia. He has authored more than 200 published articles.

Accordingly, I recommend that you grant Bruce Pollock, M.D., a limited waiver that will permit him to participate in all matters concerning the discussions of the results of the FDA ongoing meta-analysis of suicidality data from adult antidepressant trials. I believe that such a waiver is appropriate because in this case, the need for the services of Bruce Pollock, M.D., outweighs the potential for a conflict of interest created by the financial interests attributable to him.

CONCURRENCE: /s/ 11/22/06

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

DECISION:

X Limited 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.

_____ Limited waiver denied.

/s/ 11/22/06

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