DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

**MEMORANDUM**

**DATE:** November 16, 2005

**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 Bruce Pollock, M.D., Ph.D.

I am writing to request a waiver for Bruce Pollock, M.D., Ph.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., Ph.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 as an arrangement concerning, prospective employment.

The function of the Psychopharmacologic Drugs Advisory Committee, as stated in its Charter, is 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 new drug application (NDA) 21-514, proposed trade name Methypatch (Methylphenidate Transdermal System, MTS), sponsored by Noven Pharmaceuticals, Inc., and Shire Pharmaceutical Group plc, proposed indication for the treatment of Attention Deficit Hyperactivity Disorder (ADHD). Shire Pharmaceutical Group plc acquired the worldwide sales and marketing rights to MTS from Noven in February 2003.

Dr. Pollock has advised the Food and Drug Administration that he has financial interests that could potentially be affected by his participation in the matter described above.

Dr. Pollock is a member of ——— Advisory Board concerning a ——— product and he is a member of ——— Speaker's Bureau. He receives minimal compensation for these activities. ——— a subsidiary of ——— makes ———, competing products to Methypath, ———, makes ———.

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. Bruce 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 waiver to Dr. Pollock that would permit him to participate all official matters concerning NDA 21-514, proposed trade name Methypatch (Methylphenidate Transdermal System, MTS), sponsored by Noven Pharmaceuticals, Inc., and Shire Pharmaceutical Group plc, proposed indication for the treatment of Attention Deficit Hyperactivity Disorder.

First and foremost, this waiver is justified because arguably, Dr. Pollock's interests in ——— do not constitute financial interests in the particular matter within the meaning of 18 U.S.C. §208(a), since he advises and lectures on a product and issues unrelated to the product at issue, and the competing products. Nevertheless, in the utmost of caution, I recommend that this waiver be granted.

Second, Dr. Pollock's financial interests in ——— are not so substantial as to preclude his participation in the matter described previously. He receives minimal compensation for his advisory board activities and speaking.

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 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 (1) 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; and, (2) examination of age-related changes in drug

metabolism and pharmacodynamics toward optimizing treatment with antidepressants and antipsychotics. Dr. Pollock has authored more than 200 published articles. I believe that his participation in the committee's discussions and deliberations will help provide a foundation for developing advice and recommendations that are fair and comprehensive.

Accordingly, I recommend that you grant Bruce Pollock, M.D., Ph.D., a waiver that will permit him to participate in all official matters concerning new drug application (NDA) 21-514, proposed trade name Methypatch (Methylphenidate Transdermal System, MTS), sponsored by Noven Pharmaceuticals, Inc., and Shire Pharmaceutical Group plc, proposed indication for the treatment of Attention Deficit Hyperactivity Disorder. I believe that such a waiver is appropriate because in this case, the need for the services of Dr. Pollock outweighs the potential for a conflict of interest created by the financial interests attributable to him.

CONCURRENCE: Mary Ann Slaughter for JSS 11/17/05

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

Date

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, Esq. 11-18-05

Sheila Dearybury Walcoff, Esq.
Associate Commissioner for External Relations
Food and Drug Administration

Date