



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

**MEMORANDUM**

**DATE:** March 7, 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 Barbara Alexander, M.D.

I am writing to request a waiver for Barbara Alexander, M.D., a temporary voting member of the Antiviral 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. Alexander, 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. Alexander is a special Government employee, she 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 her, her spouse, minor child, or general partner; an organization or entity for which she serves as an officer, director, trustee, general partner, or employee; and,

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a person with whom she is negotiating for, or has an arrangement concerning, prospective employment.

Dr. Alexander has been asked to participate in all official matters concerning New Drug Application (NDA) 022-128, maraviroc 300 milligram tablets, sponsored by Pfizer, proposed for the treatment of antiretroviral-experienced patients with chemokine (c-c motif) receptor 5 (CCR5) - tropic human immunodeficiency virus (HIV). This issue is coming before the Antiviral Drugs Advisory Committee and is a particular matter involving specific parties.

The function of the Antiviral Drugs Advisory Committee, as stated in its Charter, 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 acquired immune deficiency syndrome, human immunodeficiency virus related illnesses, and other viral, fungal and mycobacterial infections, and to make appropriate recommendations to the Commissioner of Food and Drugs.

Dr. Alexander has advised the Food and Drug Administration that she has a financial interest that could potentially be affected by her participation in the matter coming before the committee. Dr. Alexander is a **member of \_\_\_\_\_'s speaker's program. She lectures on fungal infections,** a topic unrelated to Pfizer's maraviroc.

As a temporary voting member participating in the Antiviral Drugs Advisory Committee meeting, Dr. Alexander potentially could become involved in matters that could affect her financial interest. Under 18 U.S.C. §208(a), she 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. Alexander 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. Alexander, which would permit her to participate in the matter previously described.

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First, this waiver is justified because Dr. Alexander's interest in \_\_\_\_\_ is unrelated to maraviroc.

Second, Dr. Alexander's financial interest is not so substantial as to preclude her participation in this matter. She receives minimal compensation for her speaking.

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. Alexander's participation will contribute to the balance of views and the diversity of expertise represented. 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. Alexander is Director, Transplant Infectious Diseases Services and Head, Mycology Section, Clinical Microbiology Laboratory, Duke University Medical Center. Her clinical interests and skills are related to infectious complications occurring in immunocompromised hosts. Dr. Alexander's participation is essential to the evaluation of maraviroc, a new class of HIV drugs. Maraviroc, a CCR-5-receptor antagonist, is the first in a class of HIV drugs that works by targeting a host receptor of a T-lymphocyte (a cell that coordinates the immune response to many infections). No other HIV drugs interact with this or any other human immune cell receptor. In addition to blocking HIV entry at this host receptor site, there are potential side effects of maraviroc's CCR5-receptor blockade including predisposition to other kinds of infections and complications of infections. A crucial part of the advisory committee's risk-benefit discussion of maraviroc will involve the potential for maraviroc to cause or contribute to infectious adverse events. Dr. Alexander is the only clinician on the committee, or among committee nominees, with expertise in opportunistic infections, such as fungi and cytomegalovirus (CMV), in severely immunocompromised hosts. Her training in infectious diseases and organ transplantation goes beyond the expertise of most of the members of the committee, who mostly focus on strictly HIV issues. Given the special issues of this novel HIV drug, the Center considers Dr. Alexander a pivotal discussant for this meeting. In the

