



DEPARTMENT OF HEALTH & HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Rockville MD 20857

DATE: September 15, 2006

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

THROUGH: Jenny Slaughter
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 Douglas Fish, M.D.

I am writing to request a waiver for Douglas Fish, M.D., a 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 18 U.S.C. §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. Douglas Fish a waiver under section 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 has a financial interest. Since Dr. Fish is a special Government employee, he is under a statutory obligation to refrain from participating in any deliberations that involve a 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. Fish has been asked to participate in all official matters concerning clinical trial design issues in the

development of products for the treatment of chronic hepatitis C virus infection, particularly those related to the identification of appropriate control arms, populations for study, endpoints, and long-term follow-up. These matters are coming before the Antiviral Drugs Advisory Committee for consideration and are particular matters of general applicability.

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. Fish has advised the Food and Drug Administration that he and his employer have financial interests that could potentially be affected by his participation in the matter described above. Dr. Fish's employer, the Albany Medical College, was awarded a research contract by _____ to conduct a long-term, follow-up study of _____ versus _____ based therapy in patients with chronic hepatitis C infections. Dr. Fish's only involvement in the study is as the Head of the Division of HIV Medicine at Albany Medical College. He does not receive any personal remuneration or salary support from the contract. _____ and _____ are affected products.

Dr. Fish's Division of HIV Medicine was also awarded several unrestricted educational grants from _____ to support five upcoming Continued Medical Education (CME) programs on hepatitis C and human immunodeficiency virus (HIV) infections and one CME program on an update from the Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC). Dr. Fish reviews the curriculum for the CME programs. However, he does not receive any personal remuneration or salary support from the grants.

Lastly, Dr. Fish is a member of _____ Speaker's Bureau on HIV and antiretroviral therapy. These topics are unrelated to the matter coming before the committee. _____ manufactures several affected products.

As a member of the Antiviral and Renal Drugs Advisory Committee, Dr. Fish could potentially become involved in matters that could affect his or his employer's financial interests. Under section 208, 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. Fish 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. Douglas Fish that would allow him to participate fully in the matter described above.

First, Dr. Fish's personal and imputed financial interests in _____ and _____ are not so substantial as to preclude his participation in this matter. He receives no personal remuneration or salary support for the study sponsored by _____ and minimal compensation for his speaking activities for _____'s Speaker's Bureau. In addition, _____'s funding for the clinical study of _____ is not substantial in relation to the Albany Medical College's total research budget. The study is funded by _____ for _____ per patient enrolled, with one patient currently enrolled in the study.

Second, with respect to the _____-sponsored study of _____, it is important to note that _____ is already approved and marketed as _____ for the treatment of hepatitis C virus infections.

Third, the uniqueness of Dr. Fish's qualification justifies granting this waiver. As head of the Division of HIV Medicine, Dr. Fish oversee the medical care of a prison population with a large number of HCV infected inmates. He is also involved in a senior member of the committee, and has an excellent understanding of regulatory issues related to a variety of antiviral products. Therefore, he will be able to assist the less experienced members of the committee in adhering to the meeting agenda.

Fourth, the difficulty of locating a similarly qualified individual without a disqualifying financial interest to serve on the committee also justifies granting this waiver. Because

the universe of hepatologists is small, and that of those involved in the care and clinical evaluation of therapy for hepatitis C virus infections is even smaller, it has been exceedingly difficult to find consultants and committee members, who are knowledgeable about clinical trial design issues in the development of products for the treatment of the chronic HCV infected population, yet have not had any involvement with sponsors in the development of new treatments for this disease. The division feels that only hepatologists have the requisite expertise to discuss both treatment of HCV infections and clinical trial design. A reduction in the number of hepatologists in the committee, therefore, will render much of the discussion useless, and may call into question the validity of any committee recommendations to the Agency.

Moreover, this waiver is also justified, in part, because of the general nature of particular matters of general applicability. It is well recognized that particular matters of general applicability pose far less risk of a conflict of interest. Particular matters of general applicability include regulations, legislation, guidelines, points-to-consider, and policies governing classes of organizations, individuals, and products. Particular matters of general applicability do not include particular matters involving specific parties, such as specific grants, contracts, recommendations regarding a specific product, or enforcement matters involving known parties. The committee's discussions of clinical trial design issues such as the identification of appropriate control arms, populations for study, endpoints, and long-term follow-up in the development of products for the treatment of chronic hepatitis C infections will not have a unique and distinct impact on Dr. Fish's financial interest, but rather may affect classes of similarly situated products and manufacturers to the same extent. While this participation may be covered by section 208, it poses far less risk of bias than participation in matters that relate specifically to a particular firm or organization in which Dr. Fish has an interest.

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. Douglas G. Fish, M.D., is an HIV specialist at Albany Medical Center who is involved in both HIV patient care and clinical research. He completed his graduate medical education at Ohio State University College of Medicine, his Internal Medicine residency at the University of Tennessee Medical Center, and an Infectious Disease fellowship at the University of Arizona Health Sciences and Tucson Veterans Administration Hospital. Dr. Fish is currently Medical Director of the AIDS Treatment Center and the in-patient HIV Unit at Albany Medical Center and Division Head of the Division of HIV Medicine and an Assistant Professor of Medicine at Albany Medical College. His division is primarily involved in HIV and Hepatitis clinical trials. He is a member of the State AIDS Services Delivery Consortium Advisory Council, the New York State AIDS Drug Assistance Program Advisory Panel, and the Infectious Disease Society of America. His clinical expertise is also invaluable since he oversees the medical care of a prison population with a large number of HCV infected inmates. I believe that Dr. Fish's participation will contribute to the diversity of opinions and expertise represented on the committee and will provide a foundation for developing advice and recommendations that are fair and comprehensive.

**APPEARS THIS WAY
ON ORIGINAL**

Accordingly, I recommend that you grant Dr. Fish a waiver that would allow him to participate in all official matters concerning the discussion of the clinical trial design issues such as the identification of appropriate control arms, populations for study, endpoints, and long-term follow-up in the development of products for the treatment of chronic hepatitis C infections. I believe that such a waiver is appropriate because in this case, the need for the services of Dr. Douglas Fish outweighs the potential for a conflict of interest created by the financial interest attributable to him.

CONCURRENCE: 15/ 9/26/06
Jenny Slaughter 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 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.

15/ 9/28/06
Randall Lutter, Ph.D. Date
Associate Commissioner for
Policy and Planning
Food and Drug Administration