



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration

Center for Biologics Evaluation and Research

MEMORANDUM

DATE : November 21, 2005

FROM : William Freas, Ph.D. Willie Freas
Director, Division of Scientific Advisors and Consultants

SUBJECT: Conflict of Interest Waiver for
Daniel Scharfstein, Sc.D.

TO : Sheila Dearybury Walcoff, Esq.
Associate Commissioner for
External Relations, FDA

Through: Jenny Slaughter
Director, Ethics and Integrity Staff
Division of Management Programs, OM

I am writing to request a waiver for Daniel Scharfstein, Sc.D, a Center for Drug Evaluation and Research (CDER) consultant from the conflict of interest prohibitions of 18 U.S.C. 208(a). Dr. Scharfstein has been asked to participate in the December 15, 2005 meeting of the Vaccines and Related Biological Products Advisory Committee. 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 interests involved" and where the individual has made a disclosure of the financial interests at issue. Because you are the appointing official, you have the authority to grant Dr. Scharfstein 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, to his knowledge, the employee, his spouse, minor children, or general partner; an organization in which he is serving as officer, director, trustee, general partner, or employer, or a person or organization with which he is negotiating for or has arrangement concerning prospective employment has a financial interest. Because Dr. Scharfstein 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 or to his employer.

The function of the Committee, as stated in its Charter, is to advise the Commissioner of the Food and Drug Administration in discharging responsibilities as they relate to assuring safe and effective biological products for human use and, as required, any other product for which the Food and Drug Administration has regulatory responsibility.

The Committee is scheduled to meet on December 15, 2005. The Committee will hear presentations and make recommendations on the safety and efficacy of a Zoster vaccine manufactured by Merck.

Dr. Scharfstein reported he is on the Data Safety Monitoring Board for NIAID to advise on AIDS vaccines clinical trials. NIAID is a competing firm for this meeting. He receives a fee for his services. He has been on the DSMB since November 2004.

Under section 208, Dr. Scharfstein is prohibited from participating in any matter affecting these interests, unless he receives a waiver. However, as noted above, you have the authority under 18 U.S.C. 208(b) (3) to grant a waiver.

For the following reasons, I believe that it would be appropriate for you to grant a waiver to Dr. Scharfstein that would allow him to participate in the discussions before the Committee. The discussions will affect the safety and efficacy of a Zoster vaccine manufactured by Merck.

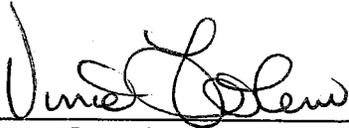
The waiver is justified because the Committee has a special need for Dr. Scharfstein's services because of his unique expertise, experience, and viewpoints with respect to the issue before the Committee. Dr. Scharfstein is employed with Johns Hopkins University School of Public Health. He is a renowned expert in biostatistics. Dr. Scharfstein focuses on the development of statistical methods for analyzing studies with informative missing or censored data. He is also an expert in the areas of causal inference, longitudinal data analysis, survival analysis, group sequential clinical trials, and semiparametric models.

For these reasons, I believe Dr. Scharfstein's participation in the deliberations of the Committee will help provide a foundation for developing advice and recommendations that are fair and comprehensive.

Accordingly, I recommend that you grant Daniel Scharfstein, Sc.D., a waiver that would allow him to participate in the discussions before the December 15, 2005 meeting and any similar meeting where his DSMB membership is unrelated. I believe that such a waiver is

appropriate because, in this case, the need for Dr. Scharfstein's services outweighs the potential for a conflict of interest created by the financial interest attributable to him.

CONCURRENCE:



for Jenny Slaughter
Director, Ethics and Integrity Staff
Division of Management Programs, OM

11-23-05
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.
Associate Commissioner for
External Relations FDA

11-30-05
Date