MEMORANDUM

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Biologics Evaluation and Research

DATE : October 21, 2005

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

SUBJECT: Conflict of Interest Waiver for
Steven Piantadosi, M.D., Ph.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 Steven Piantadosi, M.D, Ph.D., a Center for Biologics Evaluation and Research (CBER) consultant from the conflict of interest prohibitions of 18 U.S.C. 208(a). Dr. Piantadosi has been asked to participate in the November 17, 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. Piantadosi 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. Piantadosi 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 November 17, 2005. The Committee will discuss developing new Pneumococcal Vaccines for adults.

Dr. Piantadosi reported he consults with Wyeth and German Merck, affected firms for this meeting. He is on two Data Safety Monitoring Boards for clinical trials with Wyeth. He also consults with German Merck on a protocol for a phase III randomized open label study of [redacted] and [redacted] The consulting is unrelated to the topic.

Under section 208, Dr. Piantadosi 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. Piantadosi that would allow him to participate in the discussions before the Committee. The discussions will affect all pneumococcal vaccines for adults and all firms involved in their manufacturer. The discussions of the Committee do not involve any product approvals.

The waiver is justified because the Committee has a special need for Dr. Piantadosi's services because of his unique expertise, experience, and viewpoints with respect to the issue before the Committee.

Dr. Piantadoi is employed with the Johns Hopkins University School of Medicine. He has extensive experience applying a broad array of biostatistical and mathematical techniques to the analysis of both clinical and laboratory data in cancer studies. He has served on numerous committees and published well over a hundred articles in refereed journals and textbooks.

For these reasons, I believe Dr. Piantadosi'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 Steven Piantadosi, M.D., Ph.D., a waiver that would allow him to participate in the discussions before the November 17, 2005 meeting and any similar meeting where these interests are waivable. I believe that such a waiver is appropriate because, in this case, the need for Dr. Piantadosi's services outweighs the potential for a conflict of interest created by the financial interest attributable to him.

CONCURRENCE:

Jenny Slaughter — 10/27/05
Jenny Slaughter
Director, Ethics and Integrity Staff
Division of Management Programs, OM
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.

10/31/05
Sheila Dearybury Walcoff, Esq.
Associate Commissioner for
External Relations FDA
Date