



DATE: January 9, 2008

TO: Randall W. Lutter, Ph.D.
Deputy Commissioner for Policy
Food and Drug Administration

THROUGH: Vince Tolino /s/
Director, Ethics and Integrity Staff
Office of Management Programs
Office of Management

Michael F. Ortwerth, Ph.D. /s/
Deputy Director, Advisory Committee Oversight and Management Staff
Office of Policy, Planning, and Preparedness

FROM: William Freas, Ph.D. /s/
Director, Division of Scientific Advisors and Consultants
Center for Biologics Evaluation and Research

SUBJECT: 208(b)(3) Conflict of Interest Waiver for Robert Couch, M.D.

I am writing to request a waiver for Dr. Robert Couch, a consultant of the Vaccines and Related Biological Products 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 Dr. Robert Couch, 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 or his employer has a financial interest. Because Dr. Couch 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 his employer.

The function of the Vaccines and Related Biological Products Advisory 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.

Dr. Couch has been asked to participate in the February 21, 2008 Vaccines and Related Biological Products Advisory Committee meeting. Topic 2, the Committee will discuss strain selection for influenza virus vaccine for the 2008 – 2009 season. Topic 3, the Committee will discuss clinical development of influenza vaccines for pre-pandemic uses.

These matters are coming before an advisory committee meeting of the Vaccines and Related Biological Products Advisory Committee. Topic 2 and Topic 3 are particular matters of general applicability.

Dr. Couch has advised the Food and Drug Administration (FDA) that he has financial interests that could potentially be affected by his participation in the matters described above. Dr. Couch is involved with one contract supported by NIAID. Dr. Couch serves as the PI on a contract awarded to Baylor College of Medicine for the general study of live and inactivated influenza vaccine. In 2007, Dr. Couch received [REDACTED] salary support from this contract.

As a consultant of the Vaccines and Related Biological Products Advisory Committee, Dr. Couch potentially could become involved in matters that could affect his 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. Couch 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. Couch that would allow him to participate in the matter described because the need for his services greatly outweighs the conflict of interest created by this financial interest.

First, Dr. Couch is a consultant of the Vaccines and Related Biological Products Advisory Committee (VRBPAC). He is a committed VRBPAC committee consultant. His presence at this meeting will provide continuity as Dr. Couch has attended previous VRBPAC meetings on these topics and provided expert advice.

Second, the waiver is also justified because the Committee has a special need for Dr. Couch's service because of his unique expertise, experience, and viewpoints with respect to the issue before the Committee. Dr. Couch is Distinguished Service Professor, Department of Molecular Virology and Microbiology, and Professor of Medicine, and Director of the Center for Infection and Immunity Research, Baylor College of Medicine. He is an esteemed leader in research in respiratory infectious diseases. His research focuses on influenza. Dr. Couch would bring important perspective to the Committee discussions. I believe that participation by Dr. Couch in the committee's deliberations will contribute to the diversity of opinions and expertise represented on the committee.

