



DATE: January 2, 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: 712(c)(2)(B) 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 section 712(c)(2)(A) of the Federal Food, Drug, and Cosmetic Act. Waivers under section 712(c)(2)(B) may be granted by the appointing official where "necessary to afford the advisory committee essential expertise" and where the individual has made a disclosure to FDA of the financial interests at issue. We have determined that you are the appointing official for purposes of section 712(c)(2)(B). Therefore, you have the authority to grant Dr. Couch a waiver under section 712(c)(2)(B).

Section 712(c)(2)(A) prohibits Federal executive branch employees, including special Government employees, from participating in any particular matter in which the employee or an immediate family member has a financial interest that could be affected by the advice given to the FDA with respect to the matter. 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.

The function of the Vaccines and Related Biological Products Advisory Committee is, as stated in its Charter, 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 meeting of the 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 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 a financial interest that could potentially be affected by his participation in the matters described above. Dr. Couch is the Principal Investigator on a contract awarded by NIAID for general studies on 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 could become involved in matters that could affect his financial interests. Under section 712(c)(2)(A), he is prohibited from participating in such matters. However, as noted above, you have the authority under section 712(c)(2)(B) to grant a waiver permitting Dr. Couch to participate in such matters if necessary to afford this committee essential expertise.

For the following reasons, I believe that it would be appropriate for you to grant a waiver to Dr. Robert Couch that would allow him to participate fully in the matter described because his voting participation is necessary to afford the committee essential expertise.

First, the waiver is 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 is a recognized international leader in research with respiratory infectious diseases, with special expertise in influenza. Since the topics before the Committee include an influenza vaccine that will be administered to the general population, I believe Dr. Couch's participation will contribute to the diversity of expertise and viewpoints represented and will help provide a foundation for developing advice and recommendations that are fair and comprehensive. In addition, Dr. Couch will be providing background and possible vaccine options for the discussion on influenza vaccine. Dr. Couch has consulted for the Committee on the topic of influenza in the past, contributing invaluable expertise and view points. He will be providing required expertise and contributing to the balance of points of view, equitable geographic distribution and diversity of the Committee in accordance with FACA.

