



FOOD AND DRUG ADMINISTRATION
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

MEMORANDUM

DATE: January 23, 2007

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

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

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

Through: Vince Tolino
Director, Ethics and Integrity Staff
Division of Management Programs, OM

I am writing to request a waiver for Robert Couch, M.D., a consultant of the Vaccines and Related Biological Products Advisory Committee at the February 27-28, 2007 meeting, from conflict of interest prohibitions of 18 U.S.C. 208(a). For Topic 1, the Committee will hear and make recommendations on the safety and immunogenicity of an H5N1 inactivated influenza vaccine, manufactured by Sanofi Pasteur. This is a particular matter involving specific parties. For Topic 2, the Committee will discuss pandemic influenza vaccine strategies/clinical development of pandemic influenza vaccines. This is a particular matter of general applicability. For Topic 3, the Committee will discuss and make recommendations on the selection of strains to be included in the influenza virus vaccine for the 2007-2008 season. This is a particular matter of general applicability. Topic 4, the Committee will discuss influenza B strain- discussion on circulating lineages. This is a particular matter of general applicability. 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. Because you are the appointing official, you have the authority to grant Dr. 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, 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 employee, or a person or

organization with which he is negotiating for or has arrangement concerning prospective employment has a financial interest. Dr. Couch is a special Government employee and 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 February 27-28, 2007. For Topic 1, the Committee will hear and make recommendations on the safety and immunogenicity of an H5N1 inactivated influenza vaccine, manufactured by Sanofi Pasteur. For Topic 2, the Committee will discuss pandemic influenza vaccine strategies/clinical development of pandemic influenza vaccines. For Topic 3, the Committee will discuss and make recommendations on the selection of strains to be included in the influenza virus vaccine for the 2007-2008 season. Topic 4, the Committee will discuss influenza B strain- discussion on circulating lineages.

Dr. Couch has advised the FDA that he has a financial interest related to the above topics that could potentially be affected by his participation in the matter at issue. Dr. Couch has reported that he has 2 related contracts with NIAID. He is also a subcontractor on an unrelated NIAID contract. According to Dr. Couch, these contracts involve general studies on live inactivated influenza vaccine. None of Dr. Couch's contracts are directly on H5N1. One of his NIAID contracts is on live and inactivated influenza vaccine trials. Dr. Couch serves as the PI on this contract which was awarded to his employer, Baylor University. In 2006, Baylor received approximately \$2M. Dr. Couch does not receive any personal remuneration. Dr. Couch is also a co-PI on a vaccine trial that is part of NIAID's Vaccine and Treatment Evaluation Units. There are seven current VTEU contracts awarded of which one is Baylor College of Medicine. The Units evaluate new and improved vaccine and therapeutic candidates in clinical trials/studies. Part of the VTEU includes H5 vaccines trials. Dr. Keitel is the PI on these studies. To date, Dr. Couch has not been involved in any H5 studies. In 2006, Baylor received approximately \$4M. Dr. Couch does not receive any personal remuneration. Dr. Couch is also involved with an unrelated study with the [REDACTED] contact. He serves as a co-PI on a subcontractor for this study. His institution received [REDACTED] per year from 7/2006-6/30/2007. Dr. Couch provides [REDACTED]

Under Section 208, Dr. Couch 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. Couch that would allow him to participate in the discussions before the Committee.

First, Dr. Couch is a consultant of the Vaccines and Related Biological Products Advisory Committee (VRBPAC). He has attended previous VRBPAC meetings on influenza, providing new and up-to-date information regarding the topic. His presence at this meeting will provide continuity and will add historical relevance for future VRBPAC meetings on similar topics.

Second, the waiver is also justified because the Committee has a special need for Dr. Couch's services because of his unique expertise, experience, and viewpoints with respect to the issue before the Committee. Dr. Couch is Professor of Medicine, Department of Microbiology, 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.

Further, the Federal Advisory Committee Act requires that committee membership be fairly balanced in terms of the points of view represented and the functions to be performed by the various advisory committee members and Dr. Couch's participation will contribute to the balance of views represented and the diversity of opinions and expertise. 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. Dr. Couch is a recognized international leader in research with respiratory infectious diseases, with special expertise in influenza. Dr. Couch has consulted for the Committee on the topic of influenza in the past, contributing invaluable expertise and view points. His presence at this meeting will provide continuity and will add historical relevance for future VRBPAC meetings on similar topics. In addition, Dr. Couch will be providing background and possible vaccine options for the discussion on circulating lineages of influenza B strains (Topic 4). 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.

The Division reviewed the CBER pool of current SGEs. There were no SGEs in the CBER pool who had the necessary influenza expertise who were less conflicted. In addition, Dr. Couch possesses the necessary knowledge to brief the Committee on the history of B strain influenza.

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

