

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

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**DATE :** January 17, 2005

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

**SUBJECT:** Waiver of General Applicability for  
Robert Couch, M.D.

**TO :** Sheila Dearybury Walcoff, Esq.  
Associate Commissioner for External Relations  
Food and Drug Administration

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

I am writing to request a general matters waiver for Robert Couch, M.D., a consultant of the Vaccines and Related Biological Products Advisory Committee at the February 16, 2005 meeting. This memorandum constitutes a determination that the need for Dr. Couch's services on the Committee outweighs the potential for a conflict of interest created by any personal or imputed financial interest that he may have in matters of general applicability in which he is expected to participate on the Committee. 18 U.S.C. 208(b)(3).

The Committee will review and evaluate available scientific data concerning the strain selection for influenza virus vaccine for the 2005-2006 season. It is expected that the Committee will focus largely, if not exclusively, on matters of general applicability, as opposed to matters involving specific parties or matters that uniquely and distinctly affect any particular person or organization.

These matters may affect certain financial interests of Dr. Couch's or of persons and organizations with which he may have certain relationships. This would include:

Financial investments in medical product companies, food related companies, drug related companies, health care industry, and any other industry that might be affected by the recommendations of the Committee (no interests currently reported);

Employment with research institutions, state and local governments, medical product manufacturers, food related companies, drug related

companies, health care industry or other organizations that may be affected by the Committee's recommendations, for example, the Baylor College of Medicine where he is employed. Also included is his consulting and membership with [REDACTED]

Grants, contracts or other funding for research or other services received from the federal government that might be affected by the Committee's recommendations, for example, his NIAID/NIH contract;

Grants, contracts or other funding for research or other services received from non-federal sources, including industry and foundations, that might be affected by the Committee's recommendations (no interests currently reported);

Expert witness, litigation or advocacy services in matters that might be affected by the recommendations of the Committee (no interests currently reported);

Any interest of a group or other organization in which Dr. Couch is appointed as an officer, director, trustee, employee or general partner that might be affected by the Committee's recommendations (no interests currently reported).

Under 18 U.S.C. 208, Dr. Couch may not participate in any particular matter affecting these interests, unless he receives a waiver. However, pursuant to my authority to grant waivers under 18 U.S.C. 208(b)(3), I have determined that the need for the services of Robert Couch, M.D. on this Committee, with respect to matters of general applicability, outweighs any concern that these types of interests might create a potential for a conflict of interest. Consequently, Dr. Couch may participate in matters of general applicability affecting any current and future financial interests of the types described above. This determination is based on the following considerations:

The Food and Drug Administration has a particularly strong need for Dr. Couch's service. Dr. Couch is Professor of Medicine, Department of Microbiology, Baylor College of Medicine. He is one of the top influenza specialist in the world and directs the Influenza Research Center at Baylor College of Medicine. He has extensive research on other respiratory infectious diseases, and has a strong epidemiological background in respiratory infectious diseases.

Furthermore, the Committee Charter requires the appointment of individuals who are authorities knowledgeable in a variety of scientific and medical professions. Consequently, it is expected that persons qualified to serve on the Committee will have interests, financial and otherwise, in the work of the Committee. This includes not only employment interests, but also investment and pension interests, as experience has shown that persons employed in

the biomedical area frequently acquire investment and pension interests in organizations related to their expertise. In short, financial interests simply are unavoidable in view of the work and membership requirements of the Committee.

Likewise, the very diversity of interests required by the Charter will ensure that no one member is in a position to determine policy in favor of any one affected interest. In addition to the specific requirements of the Charter, the Federal Advisory Committee Act requires fair balance and openness, which serves as important checks against real or apparent threats to the objectivity of Committee action.

Finally, the Committee is expected to focus mainly on matters of general applicability, rather than matters involving specific parties. It is well-recognized that such general matters pose less risk of a conflict of interest. Matters of general applicability include regulations, legislation, and policies governing classes of organizations, individuals, and products.

However, this does not include matters involving specific parties, such as specific grants (as opposed to general recommendations for increased funding in a given area), contracts, product approval applications, or enforcement matters involving known parties.

Please note that this waiver is limited to general matters. It will not allow Dr. Couch to participate in any matters involving specific parties that may affect his financial interests, or any person or organization described above. If the work of the Committee turns from matters of general applicability to more specific matters (e.g., recommendations regarding a specific product), participants will seek additional advice.

CONCURRENCE:

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

1/27/05  
Date

DECISION:

X

General Matters 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 Walcott  
Sheila Dearybury Walcott, Esq.

1-31-05  
Date

Associate Commissioner for External Relations, FDA