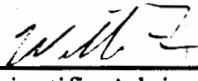




DEPARTMENT OF HEALTH & HUMAN SERVICES  
Public Health Service  
Food and Drug Administration  
Center for Biologics Evaluation and Research

MEMORANDUM

DATE : January 6, 2006

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

SUBJECT: Waiver of General Applicability under 18 U.S.C. 208(b)(3) for John Modlin, M.D.

TO : Jason D. Brodsky  
Acting Associate Commissioner for  
External Relations, Food and Drug Administration

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

I am writing to request a general matters waiver for Dr. John Modlin, a member of the Vaccines and Related Biological Products Advisory Committee. This memorandum constitutes a determination that the need for Dr. Modlin'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 the influenza virus vaccine for the 2006-2007 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. Modlin'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 Dartmouth-Hitchcock Medical Center where he is employed. Also included in his membership on the Data Safety Monitoring Board for , his membership on two Data Safety Monitoring Boards for , and his speaking on behalf of ;

Grants, contracts or other funding for research or other service received from the federal government that might be affected by the Committee's recommendations (no interests currently reported);

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 (no interests currently reported);

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

Under 18 U.S.C. 208, Dr. Modlin 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 John Modlin, 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. Modlin 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. Modlin's service. Dr. Modlin is Professor of Pediatrics and Medicine at the Dartmouth-Hitchcock Medical Center. He is an esteemed pediatric virologist, and a member of numerous professional societies such as the American Society of Microbiology, the Infectious Disease Society for Microbiology, and the Infectious Disease Society of America. Dr. Modlin has participated in several national research committees and policy conferences concerning pediatric infectious diseases. Dr. Modlin would bring important perspective to the Committee discussions.

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 conflict of interest. Matters of general applicability include regulations, legislations, 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. Modlin 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: JS  
Jenny Slaughter, Director  
Ethics and Integrity Staff, Office of  
Management Programs, OM

1/11/06  
Date

General Matters 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.

JS 1-17-06  
Jason D. Brodsky Date  
Acting Associate Commissioner for  
External Relations, Food and Drug Administration