



FOOD AND DRUG ADMINISTRATION
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

MEMORANDUM

DATE : March 24, 2006

FROM : William Freas, Ph.D. W.F.
Director, Division of Scientific Advisors & Consultants,
CBER

SUBJECT: Waiver of General Applicability under 18 U.S.C.
208 (b) (3) for Carol Tacket, 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 Carol Tacket, M.D., a consultant of the Vaccines and Related Biological Products Advisory Committee at the May 19, 2006 Office Site Visit Subcommittee meeting. This memorandum constitutes a determination that the need for Dr. Tacket's services on the Committee outweighs the potential for a conflict of interest created by any personal or imputed financial interest that she may have in matters of general applicability in which she is expected to participate on the Committee. 18 U.S.C. 208(b) (3).

The Subcommittee will review the intramural research programs in the Office of Vaccines Research and Review (OVRR). The purpose of the Subcommittee review is to make recommendations to further the management of dynamic, responsive, and cutting edge research programs in OVRR that facilitates more efficient development of safe and effective biological products. It is expected that the Subcommittee 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. Tacket's or of persons and organizations with which she 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 University of Maryland School of Medicine where she is employed. Also, included is her consulting with [REDACTED], and her membership on the DSMB for Intramural Programs, NIAID, membership on the Clinical Research and Field Studies Study Section, CSR/NIH, membership on the Scientific Advisory Board for [REDACTED], membership on the Scientific Advisory Board for [REDACTED], and membership on two Safety Monitoring Committees for NIAID.

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, her contract and grant with NIAID.

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. Tacket 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. Tacket may not participate in any particular matter affecting these interests, unless she 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 Carol Tacket, 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. Tacket 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. Tacket's service. Dr. Tacket is employed at the University of Maryland School of Medicine as Professor of Medicine, Center for Vaccine Development. She is an expert in epidemiology, pathogenesis, and immune responses to enteric infections vaccine development. She has published over 100 medical research articles.

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. Tacket to participate in any matters involving specific parties that may affect her 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: _____ /s/ _____ 4/5/06
Date
Jenny Slaughter
Director, Ethics and Integrity Staff
Office of Management Programs, OM

DECISION:

✓
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.

_____ /s/ _____ 4/10/06
Date
Jason D. Brodsky
Acting Associate Commissioner
for External Relations, FDA