DEPARTMENT OF HEALTH & HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Rockville MD 20857

DATE: October 30, 2003

TO: Peter J. Pitts
Associate Commissioner
for External Relations
Food and Drug Administration

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

FROM: for Igor Cerny, Pharm.D. Susan Peters
Acting Director, Advisors and Consultants Staff
Center for Drug Evaluation and Research

SUBJECT: General Matters Waiver Under 18 U.S.C. §208(b)(3) for Marie Davidian, Ph.D.

Marie Davidian, Ph.D., has been appointed as a special Government employee. This memorandum constitutes a determination, in accordance with 18 U.S.C. §208(b)(3), that the need for the individual's services on the Committee, with respect to matters of general applicability, 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.

Dr. Davidian's participation in matters of general applicability may affect certain financial interests of her or of persons and organizations whose financial interests are imputed to her under 18 U.S.C. §208.

This would include the following:

1. Financial investments in pharmaceutical companies, health care industries, and any other industries that might be affected by the recommendations, for example, funds received from interest in [redacted] mutual funds;

2. Employment with research institutions, state and local governments, pharmaceutical companies, health care industries, or other organizations that may be affected by the Committee's recommendations (no interests currently reported);

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

4. Grants, contracts, or other funding for research or other services received from non-federal entities, including industries and foundations, that might be affected by the Committee's recommendations, for example, consultant fees received from [redacted]

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

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

As a special Government employee, Dr. Davidian potentially could become involved in matters that could affect her financial interests. Under 18 U.S.C. §208, Dr. Davidian is prohibited from participating personally and substantially in a particular matter affecting these interests. However, you have the authority under 18 U.S.C. §208(b)(3) to grant a waiver permitting Dr. Davidian to participate in matters of general applicability.

For the following reasons, I believe that it would be appropriate for you to grant a waiver to Dr. Davidian that would allow her to participate in matters of general applicability.

First and foremost, this waiver is justified, in part because of the general nature of the matters to be considered by the Committee. It is well recognized that matters of general applicability pose far less risk of a conflict of interest. Matters of general applicability include regulations, legislation, guidelines, points-to-consider, and policies governing classes of organizations, individuals, and products. Matters of general applicability do not include particular matters involving specific parties, such as specific grants, contracts, recommendations regarding a specific product, or enforcement matters involving known parties. Matters of general applicability will not have a unique and distinct impact on any of Dr. Davidian's personal or imputed financial interests, but rather may affect classes of similarly situated products and manufacturers to the same extent.

This waiver is also justified because the Committee has a need for Dr. Davidian's services, in light of her expertise in the fields of statistics, applied mathematics and computer science. Her participation will contribute to the diversity of views and expertise represented.

Further, 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 a Committee will have interests, financial and otherwise, related to the work of the Committee. This includes not only employment interests, but also investments and pension interests, as experience has demonstrated that persons employed in medical professions frequently acquire investments and pension interests in organizations related to their expertise. Financial interests simply are unavoidable in view of the work and membership requirements of advisory committees.

Moreover, the diversity of expertise required by the Charter ensures that no one participant is in a position to determine policy in favor of any one affected interest. Advisory committees are used to conduct public hearings on matters of importance that come before the Food and Drug Administration, to review the issues involved, and to provide

advice and recommendations to the Commissioner. The Commissioner has sole discretion concerning action to be taken and policy to be expressed on any matter considered by an advisory committee. In addition, the Federal Advisory Committee Act requires fair balance and openness, which serve as important checks against real or apparent threats to the objectivity of Committee action.

Please note that this waiver only allows participation in particular matters of general applicability. It will not permit Dr. Davidian to participate in any matters involving specific parties that may affect her financial interests, or the interests of any person or organization described above. When the work advising the Center for Drug Evaluation and Research or when advising the Committee moves from matters of general applicability to more specific matters (e.g., recommendations specific to an identified product), which could specifically affect Dr. Davidian's personal and imputed financial interests, the Food and Drug Administration will examine Dr. Davidian's interests in relation to the particular matter, and either obtain a specific waiver allowing her to participate, or exclude her from participating in the particular matter.

CONCURRENCE: Mary Ann Kilkar for DATE: 11-4-03
Jenny Slaughter
Director, Ethics and Integrity Staff
Office of Management Programs

DECISION:

X General matters waiver granted based on my determination, made in accordance with 18 U.S.C. §208(b)(3) that the need for the individual's services outweighs the potential for a conflict of interest created by the financial interests attributable to the individual.

_____ Waiver denied.

Peter J. Pitts DATE: 11/13/03
Peter J Pitts
Associate Commissioner
for External Relations
Food and Drug Administration