



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

DATE : February 27, 2003

FROM : William Freas, Ph.D. William Freas
Chief, Scientific Advisors & Consultants Staff, CBER

SUBJECT: Waiver of General Applicability Under 18 U.S.C.
§208(b)(3) for James R. Allen, M.D., M.P.H.

TO : Linda Arey Skladany, Esq.
Associate Commissioner for External Relations
Food and Drug Administration

THROUGH: Jenny Slaughter
Chief, Ethics and Integrity Branch
Division of Management Programs, OHRMS

James R. Allen, M.D., M.P.H., has been appointed as a special Government employee and a member of the Blood Products Advisory Committee. He has been asked to participate in the March 13-14, 2003, Blood Products Advisory Committee meeting. This memorandum constitutes a determination in accordance with 18 U.S.C. §208(b)(3) that the need for Dr. Allen'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.

The Committee will review and evaluate available scientific data concerning the safety, effectiveness, and appropriate use of blood intended for use in the diagnosis, prevention, or treatment of human diseases having an impact on the public health as determined by the Commissioner of Food and Drugs. The Committee will also make recommendations to the Commissioner regarding the regulation of such products.

The Committee will be discussing 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 interest of Dr. Allen'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 American Social Health Association (ASHA), where he is employed;

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);

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. Allen is appointed as an officer, director, trustee, employee or general partner that might be affected by the Committee's recommendations, for example, his membership on the Board of Trustees for [REDACTED] from 1999 to present; and his membership on the Board of Trustees for the [REDACTED] from 1999 to present.

Under 18 U.S.C. §208, Dr. Allen 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 James R. Allen, M.D., M.P.H., 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. Allen 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. Allen's services. Dr. Allen is the President and Chief Executive Officer, American Social Health Association (ASHA). He served as the Assistant Surgeon General from 1990-1992. He also served as a Commission Corps Officer in the U.S. Public Health Service. In the past, Dr. Allen has held several significant appointments in the Centers for Disease Control and Prevention. During his tenure, as an epidemiologist, he had extensive experience and oversight at the CDC concerning public health initiatives regarding the implementation of the federal AIDS program. Dr. Allen's vast experience in public health related to infectious disease control and environmental controls would greatly enhance the Committee discussions.

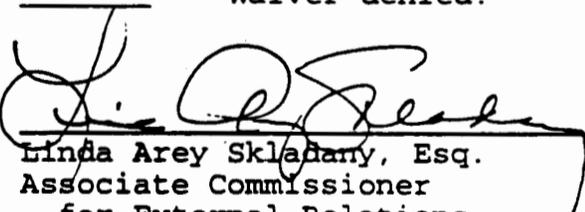
Furthermore, the Committee Charter requires the appointment of individuals who are authorities knowledgeable in a variety of scientific and medical professions. Consequently, it is expected that persons qualified to serve on the Committee will have interests, financial and otherwise, in the work of the 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 this 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 serve as important checks against real or apparent threats to the objectivity of Committee action.

Please note that this is a waiver of general applicability. It will not allow Dr. Allen to participate in any matters involving specific parties that may affect his financial interests, or any person or organization described above. When the work of 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. Allen's personal and imputed financial interests, the Food and Drug Administration will examine Dr. Allen's interests in relation to the particular matter, and either obtain a specific waiver allowing him to participate, or exclude him from participating in the particular matter.

CONCURRENCE:  3/7/03
Date
Jenny Slaughter
Chief, Ethics and Integrity Branch
Division of Management Programs, OHRMS

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 conflict of interest created by the financial interests attributable to the individual.

 Waiver denied.
 3/10/03
Date
Linda Arey Skladany, Esq.
Associate Commissioner
for External Relations
Food and Drug Administration