MEMORANDUM

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

DATE : January 17, 2005

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

SUBJECT: Waiver of General Applicability for Ruth Karron, 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 Ruth Karron, M.D., a member 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. Karron'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 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. Karron'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 Johns Hopkins University School of Public Health where she is employed; and her consulting 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, the NIAID 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. Karron 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. Karron 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 Ruth Karron, 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. Karron 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. Karron's service. Dr. Karron is Associate Professor, Department of International Health, Johns Hopkins University School of Public Health. Dr. Karron is specialized in the field of pediatric vaccine research with a particular emphasis on respiratory viral vaccines. She has extensive research on other infectious diseases.

Furthermore, the Committee Charter requires the appointment of individuals who are authorities knowledgable 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. Karron 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: Jenny Slaughter 1/27/05
Jenny Slaughter, Director — Date
Ethics and Integrity Staff
Division of Management Programs, OM

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.

SDWalcoff 1-31-05
Sheila Dearybury Walcoff, Esq. — Date
Associate Commissioner for External Relations, FDA