



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

DATE : January 9, 2007

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

SUBJECT: 208(b)(3) Waiver for Ruth Karron, M.D.

TO : Randall Lutter, Ph.D.  
Associate Commissioner for Policy and Planning

Through: Vince Tolino  
Director, Ethics and Integrity Staff  
Office of Management Programs, OM

I am writing to request a waiver for Ruth Karron, M.D., a member of the Vaccines and Related Biological Products Advisory Committee at the February 27-28, 2007 meeting, from conflict of interest prohibitions of 18 U.S.C. 208(a). The Committee will hear and make recommendations on the safety and immunogenicity of an H5N1 Inactivated Influenza Vaccine, manufactured by Sanofi Pasteur. This is a particular matter involving specific parties. Topic 2, the Committee will discuss pandemic influenza vaccine strategies/clinical development of pandemic influenza vaccines. This is a particular matter of general applicability. Topic 3, the Committee will discuss and make recommendations on the selection of strains to be included in the influenza virus vaccine for the 2007 - 2008 season. This is a particular matter of general applicability. Topic 4, the Committee will discuss influenza B Strain - discussion on circulating lineages. This is a particular matter of general applicability. Waivers under Section 208(b)(3) may be granted by the appointing official where "the need for the individual's services outweighs the potential for a conflict of interest created by the financial interest involved" and where the individual has made a disclosure of the financial interests at issue. Because you are the appointing official, you have the authority to grant Dr. Karron a waiver under Section 208(b)(3).

Section 208(a) prohibits Federal executive branch employees, including special Government employees, from participating personally and substantially in matters in which, to her knowledge, the employee, her spouse, minor children, or general partner; an organization in which she is serving as officer, director, trustee, general partner, or employee, or a person or organization with which she is negotiating for or has arrangement concerning prospective employment has a financial interest. Dr. Karron is a

special Government employee and is under a statutory obligation to refrain from participating in any deliberations that involve a particular matter having a direct and predictable effect on a financial interest attributable to her or to her employer.

The function of the Committee, as stated in its Charter, is to advise the Commissioner of the Food and Drug Administration in discharging responsibilities as they relate to assuring safe and effective biological products for human use and, as required, any other product for which the Food and Drug Administration has regulatory responsibility.

The Committee is scheduled to meet on February 27-28, 2007. The Committee will hear and make recommendations on the safety and immunogenicity of an H5N1 Inactivated Influenza Vaccine. The Committee will discuss pandemic influenza vaccine strategies/ clinical development of pandemic influenza vaccines. The Committee will discuss and make recommendations on the selection of strains to be included in the influenza virus vaccine for the 2007 - 2008 season. The Committee will discuss influenza B Strain - discussion on circulating lineages.

Dr. Ruth Karron has advised the FDA that she has a financial interest related to the discussions that could potentially be affected by her participation in the matter at issue. Dr. Karron has reported that she is a member of [REDACTED] Data Safety Monitoring Board for [REDACTED]. According to Dr. Karron, her consulting is unrelated to the matter coming before the Committee. She reported that she received approximately [REDACTED] per year in consulting fees from 2004. Her membership is still ongoing. She also consults with [REDACTED] on [REDACTED]. She receives approximately [REDACTED] per year beginning January 2004 to present. Dr. Karron also reported that her institution receives approximately \$29M from NIAID to support research on numerous live attenuated vaccines including H5N1 and pandemic strains. Data from this research is not being used to support the efficacy of Sanofi Pasteur's vaccine. The topics being discussed at the meeting could possibly equally affect over 20 firms. The research support is from the federal government rather than a regulated entity.

Under 18 U.S.C. 208, Dr. Karron is prohibited from participating in any matter affecting these interests, unless she receives a waiver. However, as noted above, you have the authority under 18 U.S.C. 208(b)(3) to grant a waiver.

For the following reasons, I believe that it would be appropriate for you to grant a waiver to Dr. Karron that would allow her to participate in the discussions before the Committee.

First, Dr. Karron is a standing member and chair of the Vaccines and Related Biological Products Advisory Committee (VRBPAC), whose membership began in February 2003. Dr. Karron is also the current VRBPAC Chair and has been in the role since February 2006. Her presence at this meeting will provide the continuity and structure to the members necessary for maintaining focus and objectivity.

Second, the waiver is also justified because the Committee has a special need for Dr. Karron's service because of her unique expertise, experience, and viewpoints with respect to the issue before the Committee. Dr. Karron is Professor, Department of International Health, The Johns Hopkins University School of Medicine. She is an esteemed pediatrician, with research interests in respiratory viruses and respiratory virus vaccines.

Dr. Karron has participated in several national research committees and policy conferences concerning pediatric infectious diseases. Dr. Karron would bring important perspective to the Committee discussions.

Further, the Federal Advisory Committee Act requires that committee memberships be fairly balanced in terms of the points of view represented and the functions to be performed by the various advisory committee members and Dr. Karron's participation will contribute to the balance of views represented and the diversity of opinions and expertise. The committee's intended purpose would be significantly impaired if the agency could not call upon experts who have become eminent in their fields, notwithstanding the financial interests and affiliations they may have acquired as a result of their demonstrated



Acknowledgment and Consent for Disclosure of Potential Conflict(s) of Interest and Waivers  
under 18 U.S.C. §208(b)(3) and 21 U.S.C. §355(n)(4)

Name of Participant: Ruth Karron, M.D.

Committee: Vaccines and Related Biological Products Advisory Committee

Meeting Date: February 27-28, 2007

I acknowledge that contingent upon public disclosure of the following financial interest listed below related to the review of the safety and immunogenicity of an H5N1 Inactivated Influenza Vaccine, manufactured by Sanofi Pasteur; to discuss pandemic influenza vaccine strategies/clinical development of pandemic influenza vaccines, to discuss and make recommendations on the selection of strains to be included in the influenza virus vaccine for the 2007 – 2008 season; and to discuss the influenza B Strain – discussion on circulating lineages. I am eligible to receive waivers under 18 U.S.C. §208(b)(3) and 21 U.S.C. §355(n)(4).

<u>Type of Interest</u>	<u>Nature</u>	<u>Magnitude</u>
Consulting (unrelated)	Competing Firm	Less than \$10,000
Consulting (unrelated)	Competing Firm	Less than \$10,000
Contract (related)	Competing Firm	More than \$300,000

I hereby request that FDA make this information publicly available on my behalf. I understand that without public disclosure of the interests the waiver is not valid.

RS  
Ruth Karron, M.D.

2/5/07  
Date