



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

DATE : January 23, 2007

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

SUBJECT: 208(b)(3) Waiver for Robert Webster, Ph.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 Robert Webster, Ph.D., a consultant of the Vaccines and Related Biological Products Advisory Committee at the February 27, 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. 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. Webster 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 his knowledge, the employee, his spouse, minor children, or general partner; an organization in which he is serving as officer, director, trustee, general partner, or employee, or a person or organization with which he is negotiating for or has arrangement concerning prospective employment has a financial interest. Dr. Webster 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 him or to his 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, 2007. The Committee will hear and make recommendations on the safety and immunogenicity of an H5N1 Inactivated Influenza Vaccine. Topic 2, the Committee will discuss pandemic influenza vaccine strategies/ clinical development of pandemic influenza vaccines.

Dr. Robert Webster has advised the FDA that he has a financial interest related to the above topics that could potentially be affected by his participation in the matter at issue. Dr. Webster has reported that he has 2 contracts with NIAID. According to Dr. Webster, his consulting is related to the matter coming before the Committee. One of his NIAID contracts is on combination chemotherapy for pandemic influenza, the institution receives \$221,713 per year, from 02/01/2005 - 01/21/2007, [REDACTED] related. The other contract with NIAID is on influenza pandemic preparedness in Asia, the institution receives \$30,261,144.00 per year, [REDACTED], related.

Under 18 U.S.C. 208, Dr. Webster is prohibited from participating in any matter affecting this interest, unless he 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. Webster that would allow him to participate in the discussions before the Committee.

First, Dr. Webster is a consultant of the Vaccines and Related Biological Products Advisory Committee (VRBPAC). He has attended previous VRBPAC meetings on influenza, providing new and up to date information regarding the topic. His presence at this meeting will provide continuity and will add historical relevance for future VRBPAC meetings on similar topics.

Second, the waiver is also justified because the Committee has a special need for Dr. Webster's service because of his unique expertise, experience, and viewpoints with respect to the issue before the Committee. Dr. Webster is Chair, Department of Virology and Molecular Biology, St. Jude Children's Research Hospital. He is an esteemed virologist, and has research interests in viral immunology and the emergence and control of influenza viruses. Dr. Webster would bring important perspective to the Committee discussions. Dr. Webster is one of the few researchers in the U.S. who is working on public health and pandemic preparedness. The Division reviewed the CBER pool of current SGEs. There were no SGEs in the CBER pool who had the necessary pandemic preparedness expertise who were less conflicted than Dr. Webster.

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: Robert Webster, Ph.D.

Committee: Vaccines and Related Biological Products Advisory Committee

Meeting Date: February 27, 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, 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>
Contract (related)	Competing Firm	\$100,000 - \$300,000
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
Robert Webster, Ph.D.

2/1/07
Date