



FOOD AND DRUG ADMINISTRATION
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

MEMORANDUM

DATE: January 9, 2007

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

SUBJECT: 208(b)(3) Conflict of Interest Waiver for John Treanor,
M.D.

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

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

I am writing to request a waiver for John Treanor, M.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). 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. Treanor 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. Treanor 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. Topic II, the Committee will discuss pandemic influenza vaccine strategies/clinical development of pandemic influenza vaccines. This is a particular matter of general applicability.

Dr. John Treanor has advised the FDA that he has a financial interest related to the above topic that could potentially be affected by his participation in the matter at issue. Dr. Treanor has reported that he has a research contract with [REDACTED]. He reported his Institution received [REDACTED] from August 2006-June 2007, on [REDACTED]. He has a research contract with [REDACTED] which the Institution receives [REDACTED] from July 1, 2006-July 1, 2007 on [REDACTED]. He has a research contract with [REDACTED] from September 1, 2005-September 1, 2008 on [REDACTED]. His Institution receives [REDACTED]. He also has a research contract with [REDACTED] from 2005-2007 on [REDACTED]. Dr. Treanor does not receive any personal remuneration from these contracts. He is a member of [REDACTED] Data Safety Monitoring Board from September 2006-present. He has not received any compensation. Dr. Treanor has a research grant with NIAID from 2002-2007 on pandemic vaccine, DNA vaccine, and trivalent influenza vaccine. His Institution received \$1.8 million. Dr. Treanor also has a research SBIR grant with NIAID on peptide vaccine from March 1, 2007-February 28, 2008. His Institution receives \$150,000. Dr. Treanor does not receive any personal remuneration from these grants.

Under Section 208, Dr. Treanor is prohibited from participating in any matter affecting these interests, 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. Dr. Treanor will not be participating as a member for the discussions of Topic I. He will only be making a presentation on Topic I.

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

First, Dr. Treanor is a new consultant of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) whose consultantship began in January 2007. He has not attended any previous VRBPAC meetings as a consultant. There were at least three other consultants considered; one was not available and two were more conflicted than Dr. Treanor. His presence at this meeting will provide continuity for future VRBPAC meetings on similar topics by provide expert background information to the current Committee members.

Second, the waiver is also justified because the Committee has a special need for Dr. Treanor's services because of his unique expertise, experience, and viewpoints with respect to the issue before the Committee. Dr. Treanor is Professor of Medicine, Infectious Disease Unit at the University of Rochester. He is an esteemed infectious disease specialist with research interests in influenza viruses. Dr. Treanor is also a world recognized expert in novel viral vaccines and antivirals. His current research focuses on influenza virus neuroaminidase inhibitors. Further, his research focuses on clinical studies to evaluate experimental measures to control viral diseases, with a particular focus on influenza. Dr. Treanor is an expert in antibody response to influenza vaccination, dose-dependent neutralizing-antibody responses to vaccine, and the effects of yearly vaccination on antibody responses.

The Committee has a special need for Dr. Treanor's services because of his unique expertise, experience, and viewpoints with respect to pandemic influenza vaccine development. Dr. Treanor's knowledge, based on his professional experience, gained by performing clinical trials with H5N1 influenza vaccines, makes his participation essential in Committee discussions regarding the development of future pandemic influenza vaccines. Dr. Treanor has completed the only human clinical study examining immune cross protection between potential pandemic H5N1 influenza strains. These data will be useful in developing pandemic influenza vaccines that may provide protection against multiple strains of potential pandemic influenza viruses. His expertise will greatly benefit the Committee's discussions on the topic of pandemic influenza vaccines.

Further, the Federal Advisory Committee Act requires that committee membership 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. Treanor'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 abilities. Dr. Treanor's research focuses on vaccines, influenza viruses and vaccines. Since the topic before the Committee will focus on influenza vaccines and influenza strains, I believe Dr. Treanor's participation will contribute to the diversity of expertise and viewpoints represented and will help provide a foundation for developing advice and recommendations that are fair and comprehensive.

For these reasons, I believe that Dr. Treanor's participation in the discussions and deliberations of the advisory committee will help provide a foundation for developing advice and recommendations that are fair and comprehensive.

