



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DATE: August 11, 2008

TO: Randall W. Lutter, Ph.D.
Deputy Commissioner for Policy
Food and Drug Administration

THROUGH: Vince Tolino /S/
Director, Ethics and Integrity Staff
Office of Management Programs
Office of Management

Michael F. Ortwerth, Ph.D. /S/
Director, Advisory Committee Oversight and Management Staff
Office of Policy, Planning, and Preparedness

FROM: William Freas, Ph.D. /S/
Director, Division of Scientific Advisors and Consultants
Center for Biologics Evaluation and Research

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

I am writing to request a waiver for Dr. Pablo Sanchez, a member of the Vaccines and Related Biological Products Advisory Committee, from the conflict of interest prohibitions of 18 U.S.C. §208(a). 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. We have determined that you are the appointing official for purposes of section 208. Therefore, you have the authority to grant Dr. Pablo Sanchez, 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 the employee or his employer has a financial interest. Because Dr. Sanchez is a special Government employee, he 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 his employer.

The function of the Vaccines and Related Biological Products Advisory 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.

Dr. Sanchez has been asked to participate in the September 25, 2008 Vaccines and Related Biological Products Advisory Committee meeting. The Committee will discuss the use of MDCK Cells for manufacture of Live Influenza Vaccines.

This matter is coming before a meeting of the Vaccines and Related Biological Products Advisory Committee. This is a particular matter involving specific parties.

Dr. Sanchez has advised the Food and Drug Administration (FDA) that he has financial interests that could potentially be affected by his participation in the matters described above. Dr. Sanchez consults with [REDACTED]. He is a member of the [REDACTED]. He has received no remuneration since 2005. Consulting is ongoing.

As a member of the Vaccines and Related Biological Products Advisory Committee, Dr. Sanchez potentially could become involved in matters that could affect his financial interests. Under section 208, he is prohibited from participating in such matters. However, as noted above, you have the authority under 18 U.S.C. §208(b)(3) to grant a waiver permitting Dr. Sanchez to participate in such matters as you deem appropriate.

For the following reasons, I believe that it would be appropriate for you to grant a waiver to Dr. Sanchez that would allow him to participate in the matter described because the need for his services greatly outweighs the conflict of interest created by this financial interest.

First, Dr. Sanchez is a standing member of the Vaccines and Related Biological Products Advisory Committee (VRBPAC), whose membership began in October 2007. He is a committed VRBPAC committee member. 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. Sanchez's service because of his unique expertise, experience, and viewpoints with respect to the issues before the Committee. Dr. Sanchez is Professor of Pediatrics, Department of Pediatrics, Division of Neonatal-Perinatal Medicine. He is a pediatrician, and the only member with a combined expertise in pediatrics and neonatology. The Manufacture of MDCK cells in Live Influenza Vaccines would have a significant impact on the pediatric population. Dr. Sanchez's expertise in pediatrics and neonatology will add relevant discussion to the topics.

Moreover, 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 advisory committee. Also, 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. Sanchez is a pediatrician with expertise focusing on neonatology. Since the topic before the Committee includes the possibility of MDCK cells for use in live influenza vaccines that would affect the pediatric population, I believe Dr. Sanchez'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. Dr. Sanchez is a new member appointed to VRBPAC in October 2007. Because Dr. Sanchez is an appointed standing member of this Committee in providing required expertise and contributing to the balance of points of view, equitable geographic distribution and diversity of the Committee in accordance with FACA, a replacement for Dr. Sanchez was not sought. For these reasons, I believe that participation by Dr. Sanchez in the committee's deliberations will contribute to the diversity of opinions and expertise represented on the committee.

Accordingly, I recommend that you grant Dr. Pablo Sanchez, a waiver that would allow him to participate in all official matters concerning the discussion of the use of MDCK Cells for manufacture of Live Influenza Vaccines. I believe that such a waiver is appropriate because in this case, the need for the services of Dr. Sanchez outweighs the potential for a conflict of interest created by the financial interest attributed to him.

DECISION:

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.

/s/
Randall W. Lutter, Ph.D.
Deputy Commissioner for Policy

8/29/08
Date