



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: 712(c)(2)(B) 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 section 712(c)(2)(A) of the Federal Food, Drug, and Cosmetic Act. Waivers under section 712(c)(2)(B) may be granted by the appointing official where "necessary to afford the advisory committee essential expertise" and where the individual has made a disclosure to FDA of the financial interests at issue. We have determined that you are the appointing official for purposes of section 712(c)(2)(B). Therefore, you have the authority to grant Dr. Sanchez a waiver under section 712(c)(2)(B).

Section 712(c)(2)(A) prohibits Federal executive branch employees, including special Government employees, from participating in any particular matter in which the employee or an immediate family member has a financial interest that could be affected by the advice given to the FDA with respect to the matter. 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.

The function of the Vaccines and Related Biological Products Advisory Committee is, as stated in its Charter, 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 meeting of the 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 an advisory committee 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 a financial interest 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 meeting, Dr. Sanchez could become involved in matters that could affect his financial interests. Under section 712(c)(2)(A), he is prohibited from participating in such matters. However, as noted above, you have the authority under section 712(c)(2)(B) to grant a waiver permitting Dr. Sanchez to participate in such matters if necessary to afford this committee essential expertise.

For the following reasons, I believe that it would be appropriate for you to grant a waiver to Dr. Pablo Sanchez that would allow him to participate fully in the matter described because his voting participation is necessary to afford the committee essential expertise.

First, the waiver is 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 issue 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. 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 comprehensive.

Second, Dr. Sanchez is a standing member of the Vaccines and Related Biological Products Advisory Committee (VRBPAC), whose membership began in October 2007. His presence at this meeting will provide continuity and will add historical relevance for future VRBPAC meetings on similar topics. Because Dr. Sanchez is an appointed standing member of the Committee providing 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.

