



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

DATE : March 23, 2007

FROM : William Freas, Ph.D. 1/3/
Director, Division of Scientific Advisors and
Consultants

SUBJECT: 208(b)(3) Waiver for Carolyn Kerscmar, 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 Carolyn Kerscmar, M.D., an advisory committee member with the Center for Drugs Evaluation and Research attending the Vaccines and Related Biological Products Advisory Committee meeting on May 16, 2007 meeting, from conflict of interest prohibitions of 18 U.S.C. 208(a). Topic 1, the Committee will discuss and make recommendations on the safety and effectiveness of FluMist in a pediatric population less than 59 months of age, manufactured by MedImmune. This is a particular matter involving specific parties. Topic 2, overview of Laboratory of Bacterial Polysaccharides and Laboratory of Sexually Transmitted Diseases, Division of Bacterial Parasitic and Allergenic Products, Office of Vaccines Research and Review. This discussion does not require conflict of interest screening. 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. Kerscmar 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. Kerscmar 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 May 16, 2007. The Committee will discuss and make recommendations on the safety and effectiveness of FluMist in a pediatric population less than 59 months of age. This is a particular matter involving specific parties.

Dr. Kerksmar has advised the FDA that she has a financial interest related to Topic 1 that could potentially be affected by her participation in the matter at issue. Dr. Kerksmar has reported that she has consulted for [REDACTED]. She is a member of the Asthma Advisory Board. According to Dr. Kerksmar, her consulting is unrelated to the matter coming before the Committee. The consulting began in July 2006 - present. She receives no personal remuneration for this consulting.

In addition, Dr. Kerksmar's institution was awarded an unrelated research contract from NIAID to study asthma from July 1, 2006 to July 31, 2009. Her institution receives \$400,000 per year. Dr. Kerksmar receives [REDACTED] per year salary support from this research contract. Dr. Kerksmar also reported that her institution received an unrelated research contract from [REDACTED] to study asthma from July 1, 2006 to July 31, 2009 for [REDACTED] per year. Dr. Kerksmar receives [REDACTED] salary support from this research contract. Arguably, these interests do not constitute a financial interest in the matter under 18 U.S.C. §208(a). Nevertheless, in the utmost of caution, I recommend that this waiver be granted.

Under 18 U.S.C. 208, Dr. Kerksmar 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. Kerksmar that would allow her to participate in the discussions before the Committee.

First, Dr. Kerscmar is a standing member of the Pulmonary-Allergy Drugs Advisory Committee, Center for Drugs Evaluation and Research. She is familiar with committee procedures and her presence at this meeting will provide expertise, relevant data, and objectivity to the topic discussion.

Second, the waiver is also justified because the Committee has a special need for Dr. Kerscmar's service because of her unique expertise, experience, and viewpoints with respect to the issue before the Committee. Dr. Kerscmar is Director, Department of Pediatrics, Children's Asthma Center, Rainbow Babies and Children's Hospital. Dr. Kerscmar is a pediatrician with expertise in pediatric pulmonology. Another consultant with pediatric expertise was invited and was unable to attend, however he did not have the pulmonary expertise necessary for discussion on this topic.

Dr. Kerscmar has participated in several national research committees and policy conferences concerning pediatric infectious diseases. Dr. Kerscmar 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. Kerscmar'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. Kerscmar's expertise focuses on pediatric pulmonology. Dr. Kerscmar'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. Kerscmar's participation in the deliberations of the advisory committee will help provide a foundation for developing advice and recommendations that are fair and comprehensive.

Accordingly, I recommend that you grant Carolyn Kerscmar, M.D., a waiver that would allow her to participate in the discussions before the May 16, 2007 meeting. I believe that such a waiver is appropriate because, in this case, the need for the individual's

