



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

MEMORANDUM

DATE : January 11, 2006

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

SUBJECT: Conflict of Interest Waiver for
Irma O.V. Szymanski, M.D.

TO : Jason D. Brodsky
Acting Associate Commissioner for
External Relations, FDA

Through: Jenny Slaughter
Director, Ethics and Integrity Staff
Division of Management Programs, OM

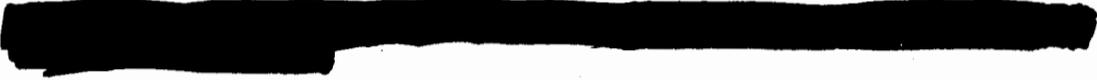
I am writing to request a waiver for Irma O.V. Szymanski, M.D, a consultant to the Center for Biologics Evaluation and Research from the conflict of interest prohibitions of 18 U.S.C. 208(a). Dr. Szymanski has been asked to participate in the meeting of the Blood Products Advisory Committee. Waivers 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 interests 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. Szymanski 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 employer, or a person or organization with which she is negotiating for or has arrangement concerning prospective employment has a financial interest. Because Dr. Szymanski is a special Government employee, she 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.

Dr. Szymanski has been asked to participate in the meeting of the Blood Products Advisory Committee. During the meeting, the Committee will discuss rapid tests for detection of bacterial contamination of platelets, public comments on "Guidance for Industry and FDA Review Staff: collection of platelets by automated methods (DRAFT)", proposed studies to support the approval of Over-the-Counter (OTC) Home-Use HIV Test Kits, and will hear an overview of research conducted in the Office of Blood Research and Review.

Dr. Szymanski reported that she is negotiating employment with the



Under section 208, Dr. Szymanski 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. Szymanski that would allow her to participate in the discussions before the Committee. The discussion does not involve product approval.

The waiver is justified because the Committee has a special need for Dr. Szymanski's services because of her unique expertise, experience, and viewpoints with respect to the issue before the Committee. Dr. Szymanski is Professor of Pathology, Emerita at the University of Massachusetts Medical Center, Worcester, Massachusetts. She was Medical Director of Transfusion Services prior to her retirement. Dr. Szymanski is a Diplomat on the American Board of Pathology. She is considered a world renowned expert in blood banking. Dr. Szymanski's experience in blood banking will be invaluable to the Committee.

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

Accordingly, I recommend that you grant Irma O.V. Szymanski, M.D., a waiver that would allow her to participate in the discussions before the meeting and any similar meeting where these interests are waivable. I believe that such a waiver is

