



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MEMORANDUM

DATE: July 31, 2006

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

THROUGH: Jenny Slaughter
Director, Ethics and Integrity Staff
Office of Management Programs
Office of Management

FROM: Igor Cerny, Pharm.D. _____/s/_____
Director, Advisors and Consultants Staff
Center for Drug Evaluation and Research

SUBJECT: Conflict of Interest Waiver for Alexandra Levine,
M.D.

I am writing to request a waiver for Alexandra Levine, M.D., a member of the Oncologic Drugs Advisory Committee, from the conflict of interest prohibitions of 18 U.S.C. §208(a). The appointing official may grant waivers under 18 U.S.C. §208(b)(3) 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. You are the appointing official for purposes of section 208; therefore, you have the authority to grant Dr. Levine 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 any other person whose interests are imputed to the employee under 18 U.S.C. §208, has a financial interest. Since Dr. Levine is a special Government employee, she is under a statutory obligation to refrain from participating in an official capacity in any particular matter having a direct and predictable effect on a financial interest attributable to her, her spouse, minor child, or general partner; an organization or entity for

which she serves as an officer, director, trustee, general partner, or employee; and, a person with whom she is negotiating for, or has an arrangement concerning, prospective employment.

The functions of the Oncologic Drugs Advisory Committee, as stated in its Charter, are to review and evaluate available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cancer, and to make appropriate recommendations to the Commissioner of Food and Drugs.

Dr. Levine has been asked to participate in all official matters regarding New Drug Application (NDA) 21-660, Abraxane (paclitaxel protein-bound particles for injectable suspension) (albumin-bound), sponsored by Abraxis BioScience, Inc., including trial design issues for adjuvant treatment of node-positive breast cancer. This matter is coming before the Oncologic Drugs Advisory Committee.

Dr. Levine has advised the Food and Drug Administration (FDA) that she has a financial interest that could potentially be affected by her participation in the matter described above. **Dr. Levine is a member of _____'s Speaker's Bureau. She gives general topics lectures on indolent lymphomas and AIDS related malignancies. These topics are unrelated to the issues coming before the committee. _____ manufactures _____, a competing product to Abraxane.**

As a member of the Oncologic Drugs Advisory Committee, Dr. Levine could potentially become involved in matters that could affect her financial interests. Under section 208, she 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. Alexandra Levine 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 Alexandra Levine, M.D., that would permit her to participate in the matter previously described.

First, Dr. Levine's interest in _____ is unrelated to the particular matter in which she is being asked to participate. Arguably, her interest does not constitute financial interest in the particular matter within the meaning of 18 USC §208(a). Nevertheless, I recommend that this waiver be granted.

Second, Dr. Levine's interest in _____ is not so substantial as to preclude her participation in this meeting. She receives minimal compensation for her speaking activities.

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. Levine'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. Levine is a distinguished Professor of Medicine, Chief of Hematology, Medical Director of the University of Southern California/Norris Cancer Hospital, and Bloom Family Chair in Lymphoma Research. Her research interests include lymphoma and Hodgkin's disease, as well as AIDS related malignancies. Dr. Levine worked on the development and testing of an AIDS vaccine with Dr. Jonas Salk from 1997 until 1995, and has also been on the forefront of the study of HIV disease in women. She is a member of numerous professional societies, such as the American Society of Hematology, the American Society of Clinical Oncology, and the International AIDS Society. Dr. Levine has written extensively on such topics as "Treatment of Adult T cell leukemia-lymphoma with a combination of interferon alpha and zidovudine," "Initial studies on active immunization of HIV infected subjects using a gp-120 depleted HIV-1 immunogen, and "AIDS related lymphoma." I believe that Dr. Levine'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.

Accordingly, I recommend that you grant Alexandra Levine, M.D., a waiver that will permit her to participate

