

MEMORANDUMFood and Drug Administration
Rockville MD 20857

DATE: February 2, 2006

TO: Jason D. Brodsky
Acting Associate Commissioner
Office for External Relations
Food and Drug Administration

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

FROM: Igor Cerny, Pharm.D. *IIC*
Director, Advisors and Consultants Staff
Center for Drug Evaluation and Research

SUBJECT: Conflict of Interest Waiver for Silvana Martino, D.O.

I am writing to request a waiver for Silvana Martino, D.O., 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. We have determined that you are the appointing official for purposes of section 208. Therefore, you have the authority to grant Dr. Martino 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 her employer has a financial interest. Since Dr. Martino 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 her employer.

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. Martino has been asked to participate in all official matters concerning New Drug Application (NDA) 20-509, S-039 Gemzar (Gemcitabine HCl), sponsored by Eli Lilly & Company, proposed indication: for use in combination with Carboplatin for the treatment of patients with advanced ovarian cancer that has relapsed at least 6 months after completion of platinum-based therapy.

Dr. Martino has advised the Food and Drug Administration (FDA) that she and _____ have a financial interest that could potentially be affected by her participation in this matter. Dr. Martino serves as a consultant _____ concerning breast cancer. _____ reimburses Dr. Martino's employer, the Cancer Institute Medical Group (CIMG), for the time she spends consulting. In the last 12 months the CIMG as received moderate compensation from _____

As a member of the Oncologic Drugs Advisory Committee, Dr. Martino could potentially become involved in matters that could affect her and her employer's financial interest. 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. Silvana Martino 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. Martino that would allow her to participate fully in the matter described above.

First, arguably Dr. Martino's reported interest in _____ does not constitute a financial interest in the particular matter within the meaning of 18 U.S.C. §208(b)(3), since her consulting is unrelated to Gemzar or its competing products. Nevertheless, we recommend that this waiver be granted.

Second, it is unlikely that Dr. Martino's and her employer's interest will affect her impartiality. Even if _____ would be more or less likely, in the future, to continue its consulting relationship with Dr. Martino, the financial impact on her employer would probably be minimal since this is not a substantial financial interest.

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. Martino's participation in 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. Silvana Martino is an oncologist with the John Wayne Cancer Institute and the Cancer Institute Medical Group in Santa Monica, California. She specializes in carcinoma of the breast, is Chair of the Breast Cancer Committee of the Southwest Oncology Group (SWOG) and a member of SWOG's Advisory Board for the Committee on Women's Health and Special Populations. Dr. Martino is particularly dedicated to educating the public about early breast cancer detection and about treatment options. She has co-authored over 100 scientific publications on breast cancer and has lectured throughout the nation on breast cancer-related topics. I believe that Dr. Martino's participation will contribute to the diversity of expertise and viewpoints represented on the committee.

Accordingly, I recommend that you grant Dr. Martino a waiver that would allow her to participate in all official matters concerning New Drug Application (NDA) 20-509, S-039 Gemzar (Gemcitabine HCl), sponsored by Eli Lilly & Company, proposed indication: for use in combination with Carboplatin for the treatment of patients with advanced ovarian cancer that has relapsed at least 6 months after completion of platinum-based therapy. I believe that such a waiver is appropriate because in

**APPEARS THIS WAY
ON ORIGINAL**

this case, the need for the services of Dr. Martino outweighs the potential for a conflict of interest created by the financial interest attributable to her.

CONCURRENCE: Maureen Killian for 2/6/06
Jenny Slaughter Date
Director, Ethics and
Integrity Staff
Office of Management Programs
Office of Management

DECISION:

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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.
J. D. Brodsky 2.9.06
Jason D. Brodsky Date
Acting Associate Commissioner
Office for External Relations
Food and Drug Administration