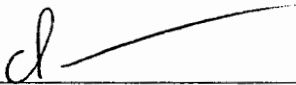


**MEMORANDUM**Food and Drug Administration
Rockville MD 20857

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. 
Director, Advisors and Consultants Staff
Center for Drug Evaluation and Research

SUBJECT: Conflict of Interest Waiver for Maha Hussain, M.D.

I am writing to request a waiver for Maha Hussain, 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. We have determined that you are the appointing official for purposes of section 208. Therefore, you have the authority to grant Dr. Hussain 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. Hussain 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. Hussain 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. Hussain has advised the Food and Drug Administration (FDA) that she has financial interests that could potentially be affected by her participation in this matter. Dr. Hussain and ~~own a modest amount of stock in~~

~~These stocks represent less than of their total net worth.~~

~~makes both are competing products to Gemzar.~~

As a member of the Oncologic Drugs Advisory Committee, Dr. Hussain 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. Maha Hussain 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. Hussain that would allow her to participate fully in the matter described above.

First, Dr. Hussain's stock interests represent a minimal percentage of her total net worth and are not so substantial as to preclude her participation in this matter.

Second, it is important to consider that Dr. Hussain's stock interests are in competing manufacturers, and not in the company whose product is coming before the committee for consideration. It is unlikely that the committee's recommendations regarding another product would have a direct and predictable impact on any of the competing products or companies. ~~are large, diverse pharmaceutical firms that manufacture and distribute a large number of products. They do not depend on one or two~~

products for their economic survival. Given the above considerations, I believe that the potential for a conflict of interest is minimal.

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. Hussain'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. Maha Hussain is Professor of Internal Medicine and Urology at the University of Michigan. She specializes in medical oncology and genitourinary cancer and her main research interest is clinical research to develop new therapies for the treatment of prostate, bladder, and kidney cancer. Prior to joining the University of Michigan, Dr. Hussain served as the genitourinary oncology section chief in the division of hematology/oncology and team leader for the Multidisciplinary Genitourinary Oncology Program at the Barbara Ann Karmanos Cancer Institute. She is a national expert and leader in the management of prostate and bladder cancer and chairs the Advisory Prostate Cancer Subcommittee at the Southwest Oncology Group. Dr. Hussain is the author of more than 60 articles and book chapters. I believe that Dr. Hussain'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 Dr. Hussain 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

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

CONCURRENCE: *Jenny Slaughter for* 2-6-06
Jenny Slaughter Date
Director, Ethics and
Integrity Staff
Office of Management Programs
Office of Management

DECISION:

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