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 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 section 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 Maha Hussain, M.D., a waiver under 18 U.S.C. §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. Hussain 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.

Dr. Hussain has been asked to participate in all official matters concerning (1) New Drug Application (NDA) 21-874, proposed trade name Genasense (oblimersen sodium) Injection, sponsored by Genta Incorporation, proposed indication for the treatment of patients with chronic lymphocytic leukemia in combination with fludarabine and cyclophosphamide; (2) NDA 020-287, Fragmin (dalteparin sodium), sponsored by Pfizer, Inc. for the proposed indication of extended treatment of symptomatic venous thromboembolism (VTE), such as proximal deep venous thromboses (DVT) and/or pulmonary embolism (PE), to reduce the occurrence of VTE in patients with cancer; and (3) 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. These matters are coming before the Oncologic Drugs Advisory Committee.

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 advised the Food and Drug Administration that she has financial interests that could potentially be affected by her participation in the matters described previously. Dr. Hussain ________ own stock in ________, ________, ________, ________, and ________. These firms make products that could be affected by the committee's discussions. ________ manufactures ________ and competing products to Fragmin and Abraxane. ________ manufactures a competing product to Genasense. ________ manufactures competing products to Genasense and Fragmin. ________ manufactures competing products to Fragmin and Abraxane. ________ manufactures competing products to Genasense and Abraxane.

As a member of the Oncologic Drugs Advisory Committee, Dr. Hussain potentially could become involved in matters that could affect her financial interests. Under 18 U.S.C. §208(a), 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. Maha Hussain that would permit her to participate in the matters described previously.

First, Dr. Hussain ——————— stock interests are not so substantial as to be deemed likely to affect her impartiality in these matters. The stocks represent less than —% of Dr. Hussain ——————— total net worth.

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 advisory committee. Also, 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 Maha Hussain, M.D., a waiver that would allow her to participate in all official matters concerning (1) New Drug Application (NDA) 21-874, proposed trade name Genasense (oblimersen sodium) Injection, sponsored by Genta Inc., proposed indication for the treatment of patients with chronic lymphocytic leukemia in combination with fludarabine and cyclophosphamide; (2) NDA 020-287, Fragmin (dalteparin sodium), sponsored by Pfizer, Inc., for the proposed indication of extended treatment of symptomatic venous thromboembolism (VTE), such as proximal deep venous thromboses (DVT) and/or pulmonary embolism (PE), to reduce the occurrence of VTE in patients with cancer; and (3) 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. I believe that such a waiver is appropriate because in this case, the need for the services of Maha Hussain, M.D., outweighs the potential for a conflict of interest created by the financial interests attributable to her.

CONCURRENCE: /s/ 8/4/06

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

Date

DECISION:

X Waiver granted based on my determination, made in accordance with section 18 U.S.C. §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.

/s/ 8/4/06

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

Date