

## MEMORANDUM

DATE: April 19, 2006

TO: Jason D. Brodsky Acting Associate Commissioner Office of 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. /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 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. 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.

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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 regarding New Drug Application (NDA) 21-986, proposed trade name Sprycel (dasatinib) tablets (BMS-354825), sponsored by Bristol Myers Squibb, with the proposed indications for (1) treatment of adults with chronic, accelerated, or blast phase chronic myeloid leukemia with resistance to prior therapy including imatinib, and (2) the treatment of adults with Philadelphia chromosome-positive acute lymphoblastic leukemia and lymphoid blast chronic myeloid leukemia with resistance or intolerance to prior therapy.

As a member of the Oncologic Drugs Advisory Committee, Dr. Hussain 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. 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 Maha Hussain, M.D., that would permit her to participate in the matter previously described. Page 3 - Jason D. Brodsky

Dr. Hussain stock interests are not so substantial as to preclude her participation in this meeting. These interests represent less than 5% of their total net worth.

It is also important to consider that Dr. Hussain's stock interests are in competing firms and not in the company whose product is coming before the committee for consideration. Even if it is likely that the committee's recommendations could have an affect on these companies it would likely be minimal at best. These firms 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 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

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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 will permit her to participate in all official matters concerning New Drug Application (NDA) 21-986, proposed trade name Sprvcel (dasatinib) tablets (BMS-354825), sponsored by Bristol Myers Squibb, with the proposed indications for (1) treatment of adults with chronic, accelerated, or blast phase chronic myeloid leukemia with resistance to prior therapy including imatinib, and (2) the treatment of adults with Philadelphia chromosome-positive acute lymphoblastic leukemia and lymphoid blast chronic myeloid leukemia with resistance or intolerance to prior 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 interests attributable to her.

CONCURRENCE:	/S/				4/20/06
	Jenny Slaughter				Date
	Director,	Ethics and	Integrity	Staff	
	Office of	Management	Programs		
	Office of	Management			
DECISION:					

DECISION:

✓ \_\_\_\_ 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/ Jason D. Brodsky Acting Associate Commissioner Office for External Relations Food and Drug Administration

\_4/25/06\_ Date