

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration Rockville MD 20857

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 Ronald Bukowski,

M.D.

I am writing to request a waiver for Ronald Bukowski, 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. Bukowski 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 his employer has a financial interest. Since Dr. Bukowski is a special Government employee, he 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 him or his 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. Bukowski 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.

Dr. Bukowski has advised the Food and Drug
Administration (FDA) that he has a financial interest that
could potentially be affected by his participation in the
matter described above. Dr. Bukowski is a consultant to
______ on an unrelated issue. _____ is
the sponsor of ______, a competing product to
Sprycel (dasatinib).

As a member of the Oncologic Drugs Advisory Committee, Dr. Bukowski could potentially become involved in matters that could affect his financial interest. Under section 208, he 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. Ronald Bukowski 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 Ronald Bukowski, M.D., that would permit him to participate in the matter previously described.

First, arguably, Dr. Bukowski's interest in does not constitute a financial interest in the particular matter within the meaning of 18 U.S.C. \$208(b)(3), since his consulting is unrelated to the issue before the committee. Dr. Bukowski consults on renal cancer.

Second, this financial interest is not so substantial as to preclude Dr. Bukowski's participation in the meeting. Dr. Bukowski receives a nominal fee for his consulting services to ______.

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. Bukowski'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. Ronald M. Bukowski, M.D., is the Director, Experimental Therapeutics Program, at the Cleveland Clinic Foundation Taussig Cancer Center. In addition to serving in the Departments of Hematology and Medical Oncology and Immunology at the Cleveland Clinic, he is a board member and medical director of the Kidney Cancer Association. Dr. Bukowski is a member of several professional societies, including the American Association of Cancer Research, the American Society of Clinical Oncology, the American Society of Hematology, and the International Society of Interferon Research. He is also a Fellow of the American College of Physicians. Dr. Bukowski has authored or co-authored over 240 publications since 1976. His special interests include medical oncology, drug development, biologic response modifiers, and genitourinary cancer, and cytogenetics. believe that Dr. Bukowski's participation will help provide a foundation for developing advice and recommendations that are fair and comprehensive.

Accordingly, I recommend that you grant Ronald Bukowski, M.D., a waiver that will permit him to

participate in all official matters concerning 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. I believe that such a waiver is appropriate because in this case, the need for the services of Dr. Bukowski outweighs the potential for a conflict of interest created by the financial interest attributable to him.

CONCURREN	CE:/S/	4/20/06
	Jenny Slaughter	Date
	Director, Ethics and Integrit	cy Staff
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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/	_4/25/06_
	Jason D. Brodsky	Date

Acting Associate Commissioner Office for External Relations Food and Drug Administration