

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. I 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

