



**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 John Carpenter, M.D.

I am writing to request a waiver for John Carpenter, 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 John Carpenter, 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. Carpenter is a special Government employee, he 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 him, his spouse, minor child, or general partner; an organization or entity for which he serves as an officer, director, trustee,

general partner, or employee; and, a person with whom he is negotiating for, or has an arrangement concerning, prospective employment.

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. Carpenter has been asked to participate in all official matters concerning New Drug Application (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.

Dr. Carpenter has advised the Food and Drug Administration that he has a financial interest that could potentially be affected by his participation in the matter described above. Dr. Carpenter serves on \_\_\_\_\_'s Speaker's Bureau. He gives general topic lectures on the treatment of breast cancer.

\_\_\_\_\_ make \_\_\_\_\_, a competing product to Abraxane.

As a member of the Oncologic Drugs Advisory Committee, Dr. Carpenter potentially could become involved in matters that could affect his financial interest. Under 18 U.S.C. §208(a), 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. Carpenter 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. John Carpenter that would permit him to participate in the matter described previously.

First, Dr. Carpenter's interest in \_\_\_\_\_ is unrelated to the particular matter in which he is being asked to

participate. Arguably, his interest does not constitute financial interest in the particular matter within the meaning of 18 USC §208(a). Nevertheless, I recommend that this waiver be granted.

Second, Dr. Carpenter's interest in \_\_\_\_\_ is not so substantial as to preclude his participation in the matter described previously. He receives minimal compensation for his Speaker's Bureau activities.

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. Carpenter is Professor of Medicine and Clinical Pathology at the University of Alabama at Birmingham. He is also the Director of Cancer Education at the Comprehensive Cancer Center, and Director for Bone Marrow Laboratories at the University. Dr. Carpenter is a member of several local, state, and national committees, including the American Cancer Society. His research focuses on breast cancer management and prevention, testicular tumors, and bone marrow interpretation, and he has written extensively on these topics. I believe Dr. Carpenter's participation will contribute to the diversity of opinions and expertise represented on the committee and will provide a foundation for developing advice and recommendations that are fair and comprehensive.

APPEARS THIS WAY  
ON ORIGINAL

Accordingly, I recommend that you grant John Carpenter, M.D., a waiver that would allow him to participate in all official matters concerning New Drug Application (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 John Carpenter, M.D., outweighs the potential for a conflict of interest created by the financial interest attributable to him.

CONCURRENCE: \_\_\_\_\_ /s/ \_\_\_\_\_ 8/4/06  
Jenny Slaughter Date  
Director, Ethics and Integrity Staff  
Office of Management Programs  
Office of Management

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/ \_\_\_\_\_ 8/11/06  
Randall Lutter, Ph.D. Date  
Associate Commissioner for  
Policy and Planning  
Food and Drug Administration