DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

DATE: November 1, 2007

TO: Randall W. Lutter, Ph.D.
Deputy Commissioner for Policy
Food and Drug Administration

THROUGH: Vince Tolino /S/ 10-31-07
Director, Ethics and Integrity Staff
Office of Management Programs
Office of Management

Michael F. Ortwerth, Ph.D. /S/ 11-8-07
Deputy Director, Advisory Committee Oversight and Management Staff
Office of Policy, Planning, and Preparedness

FROM: Igor Cerny, Pharm.D. /S/
Director, Advisors and Consultants Staff
Center for Drug Evaluation and Research

SUBJECT: 712(c)(2)(B) Conflict of Interest Waiver for Joanne Mortimer, M.D.

I am writing to request a waiver for Joanne Mortimer, M.D., a member of the Oncologic Drugs Advisory Committee, from the conflict of interest prohibitions of section 712(c)(2)(A) of the Federal Food, Drug, and Cosmetic Act. Waivers under section 712(c)(2)(B) may be granted by the appointing official where it is "necessary to afford the advisory committee essential expertise" and where the individual has made a disclosure to FDA of the financial interests at issue. We have determined that you are the appointing official for purposes of section712(c)(2)(B). Therefore, you have the authority to grant Joanne Mortimer, M.D. a waiver under section 712(c)(2)(B).

Section 712(c)(2)(A) prohibits Federal executive branch employees, including special Government employees, from participating in any particular matter in which the employee or an immediate family member has a financial interest that could be affected by the advice given to the FDA with respect to the matter. Because Joanne Mortimer, M.D. 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.

The function of the Oncologic Drugs Advisory Committee is 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. Mortimer has been asked to participate in all official matters concerning supplemental BLA 125085/91, Avastin (bevacizumab), sponsored by Genentech, Inc., proposed indication, in combination with paclitaxel, for the treatment of patients who have not received chemotherapy for their locally recurrent or metastatic, HER2 negative breast cancer.

This matter is coming before the Oncologic Drugs Advisory Committee. This issue is a particular matter involving specific parties.

Dr. Mortimer has advised the Food and Drug Administration (FDA) that she has a financial interest that could potentially be affected by her participation in the matter described above. Dr. Mortimer is a consultant to ——— on an unrelated issue. ———

As a member of the Oncologic Drugs Advisory Committee, Dr. Mortimer could become involved in matters that could affect her financial interest. Under section 712(c)(2)(B), she is prohibited from participating in such matters. However, as noted above, you have the authority under section 712(c)(2)(B) to grant a waiver permitting Dr. Mortimer to participate in such matters if necessary to afford these committees essential expertise.

For the following reasons, I believe that it would be appropriate for you to grant a waiver to Dr. Joanne Mortimer that would allow her to participate fully in the matter described because her voting participation is necessary to afford the committee essential expertise.

According to the Review Division, the uniqueness of Dr. Mortimer's qualification justifies granting this waiver. Dr. Mortimer is the only committee member who is a breast cancer specialist which gives her the opportunity for a unique contribution to this meeting. Her extensive publications indicate knowledge of an array of issues in oncology including but not limited to, pain management, breast cancer and imaging techniques. Dr. Mortimer has been a member of the Oncologic Drugs Advisory Committee for almost four years, during which time she has provided the agency with expert advice on specific topic issues and broader issues of drug development and clinical trial design.

Locating qualified individuals without disqualifying financial interest to serve on this advisory committee has been very difficult, even after screening all committee members and numerous Special Government Employees (SGEs). A total of 7 members and SGEs with expertise in breast cancer were invited, of which Dr. Mortimer is one of two able to attend and the only member with breast cancer expertise. Of the 7 other breast cancer specialists invited, one was unable to attend, one was recused through conflict of interest screening and three were unable to complete appointment paperwork in time for Conflict of Interest screening. Any other breast cancer experts that were identified were employed by the National Cancer Institute bringing about numerous conflicts of interest since the National Cancer Institute conducted the trial being reviewed at the meeting. In order to have a thorough discussion and review of the resubmitted supplemental BLA, it is imperative that the committee is represented by more than one breast cancer expert who can bring this expertise to an application with a breast cancer indication.

Moreover, 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.

Accordingly, I recommend that you grant Joanne Mortimer, M.D., a waiver that would allow her to participate in all official matters concerning supplemental BLA 125085/91, Avastin (bevacizumab), sponsored by Genentech, Inc., proposed indication, in combination with paclitaxel, for the treatment of patients who have not received chemotherapy for their locally recurrent or metastatic, HER2 negative breast cancer. I believe that such a waiver is appropriate because in this case, Dr. Mortimer's voting participation is necessary to afford the committee essential expertise.

DECISION:

X Waiver granted based on my determination, made in accordance with section 712(c)(2)(B) of the Federal Food, Drug, and Cosmetic Act, that voting participation is necessary to afford the committee essential expertise.

___ Waiver granted based on my determination, made in accordance with section 712(c)(2)(B) of the Federal Food, Drug, and Cosmetic Act, that nonvoting participation is necessary to afford the committee essential expertise.

___ Waiver denied.

/S/ 11-15-07

Randall W. Lutter, Ph.D. Date
Deputy Commissioner for Policy
Food and Drug Administration