DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MEMORANDUM

DATE: May 11, 2007

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

THROUGH: Vince Tolino
Director, Ethics and Integrity Staff
Office of Management Programs
Office of Management

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

SUBJECT: 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 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 Dr. Mortimer 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. Mortimer is a special Government employee, she 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 her, her spouse, minor child, or general partner; an organization or entity for which she serves as an officer, director, trustee, general partner, or employee; and, a

person with whom she is negotiating for, or has an arrangement concerning, prospective employment.

Dr. Mortimer has been asked to participate in all official matters concerning the review of oncology products granted pediatric exclusivity under the Best Pharmaceuticals for Children Act. This matter is coming before the Pediatric Subcommittee of the Oncologic Drugs Advisory Committee and is a particular matter of general applicability. The general discussions will not focus on any specific product or company. Rather, these issues could have an effect on all pharmaceutical firms.

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. Temporary subcommittees consisting of two or more committee members may be established as needed to address specific issues within their respective areas of expertise. Subcommittees make preliminary recommendations regarding specific issues for subsequent action by the full Committee.

Dr. Mortimer has advised the Food and Drug Administration that she has a financial interest that could potentially be affected by her participation in the deliberations concerning the review of oncology products granted pediatric exclusivity under the Best Pharmaceuticals for Children Act. Dr. Mortimer is a member of ———'s Speaker's Bureau regarding ———.

As a member of the Oncologic Drugs Advisory Committee participating in the Pediatric Subcommittee of the Oncologic Drugs Advisory Committee, Dr. Mortimer potentially could become involved in matters that could affect her financial interest. Under 18 U.S.C. §208(a), 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. Mortimer 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. Mortimer, which would permit her to participate in the matter previously described.

First, Dr. Mortimer's participation in the Subcommittee's discussions will not have a special or distinct effect on her financial interest since the topics under discussion will not focus on any specific product or company.

Second, Dr. Mortimer's financial interest in [redacted] is not so substantial as to preclude her participation in this meeting.

Third, the compensation she receives from [redacted] is nominal.

Moreover, the Best Pharmaceuticals for Children's Act is legislation that provides a financial incentive to pharmaceutical companies who agree to study their marketed drugs for pediatric uses. To initiate the process, the agency must make a determination that a particular drug could have health benefits in children and then issue the drug manufacturer a formal written request which specifies how to study the drug in children. This legislation is particularly important for pediatric oncology as it provides the financial incentive to develop drugs for uses that are not otherwise financially lucrative. This meeting will include a review of those drugs already studied for pediatric oncology uses under the BPCA and seek input on ways to improve the process to allow for more efficient and timely evaluation of therapies that could offer benefit for pediatric oncology patients.

It's critical to note that the discussion will be of past experience with the BPCA, so the drugs that will be discussed will not be the ones that could be directly and predictably affected by the outcome of the meeting.

Under the BPCA, the agency must determine which of the thousands of drugs marketed for adult uses have the potential for health benefits in children. Thus, the perspective of an adult oncologist on the subcommittee is essential in order for a balanced discussion. Dr. Mortimer will be the only adult oncologist at this meeting, which gives her the

opportunity for a unique contribution to this meeting. The agency feels that her expertise in oncology treatments that apply to all ages, supportive care, and drug development are both critical and unique to this discussion. Experts in adult oncology can help bridge the gaps in knowledge as the agency determines which drugs should be further studied in pediatric patients with cancer. Dr. Mortimer is board certified in internal medicine and medical oncology. Her training was at a variety of prominent medical institutions, including Washington University and the Fred Hutchison Cancer Center, where she developed an understanding of the issues involved in treating pediatric oncology patients. Her extensive publications indicate knowledge of an array of issues in oncology that do not have age restrictions, such as supportive care. Dr. Mortimer has been a member of the Oncologic Drugs Advisory Committee for three years, during which time she has provided the agency with expert advice on drug development. Dr. Mortimer's background, breadth of knowledge, and experience with the issues associated with oncology drug development also contribute to making her uniquely qualified to participate on this advisory committee meeting.

The Federal Advisory Committee Act (FACA) requires that committee membership be fairly balanced in terms of points of view represented and the functions to be performed by the various committee members. 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. Joanne Mortimer is Professor of Clinical Medicine, Medicine Translational Oncology Program at the University of California San Diego Cancer Center. Her expertise is in the improvement of the quality of life for women undergoing treatment for breast cancer. As an expert on the detection and treatment of women with advanced cancers, Dr. Mortimer is instrumental in identifying which women will benefit from hormonal therapies. In addition, she also serially assesses the impact of adjuvant therapy on the quality of life for women with early stages of breast cancer. Dr. Mortimer's clinical and research experience in cancer will contribute to the diversity of opinions and expertise represented on the subcommittee and will provide foundation

for developing advice and recommendations that are fair and comprehensive.

Accordingly, I recommend that you grant Joanne Mortimer, M.D., a waiver that will permit her to participate fully in all official matters concerning the review of oncology products granted pediatric exclusivity under the Best Pharmaceuticals for Children Act. I believe that such a waiver is appropriate because in this case, the need for the services of Dr. Mortimer outweighs the potential for a conflict of interest created by the financial interest involved.

CONCURRENCE: /S/ 5/21/07

Vince Tolino
Director, Ethics and Integrity Staff
Office of Management Programs
Office of Management

Date

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/ 6/1/07

Randall W. Lutter, Ph.D.
Associate Commissioner for
Policy and Planning
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Date