DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MEMORANDUM

DATE: June 5, 2007

TO: Randall W. Lutter, Ph.D.
Deputy Commissioner for Policy

THROUGH: Vince Tolino
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 T. Farrar, M.D

I am writing to request a waiver for John T. Farrar M.D., a Temporary Voting 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 T. Farrar 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. Farrar 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.

Dr. Farrar has been asked to participate in all official matters concerning New Drug Application (NDA) 021,801, proposed trade name Orplatna (satraplatin capsules), originally developed by Johnson Matthey Pharmaceuticals, a subsidiary of Johnson Matthey PLC, with licensing rights to Spectrum Pharmaceuticals. Spectrum Pharmaceuticals licensed the global rights to GPC Biotech AG, proposed indication for the treatment of patients with androgen independent (hormone refractory) prostate cancer (HRPC) that has failed prior chemotherapy. This matter is coming before the Oncologic Drugs Advisory Committee for consideration and is a particular matter involving specific parties.

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. Farrar has advised the Food and Drug Administration that he has a financial interest that could potentially be affected by his participation in the matter previously described. Dr. Farrar currently serves on ——————————— Pain Advisory Board regarding ———————— related issues and studies. ———— is the sponsor of ——————————— , a competing product to Orplatna.

As a Temporary Voting Member of the Oncologic Drugs Advisory Committee, Dr. Farrar 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. Farrar 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 Farrar that would permit him to participate in the matter described previously.

First, it is significant to note that Dr. Farrar's consulting is unrelated to the issue coming before the committee.

Second, Dr. Farrar's interest is not so substantial as to preclude his participation in this meeting. He receives minimal compensation for his services to ———.

Third, the Committee's role is advisory in nature and the Agency officials making the decisions are not bound by the recommendations of the Committee. Therefore, the Agency will take into consideration Dr. Farrar's involvement when determining the action to be taken.

Moreover, Dr. Farrar's expertise makes him an invaluable resource to FDA for this important meeting. The advisory committee will be considering the safety and efficacy of orplatna (satraplatin) indicated as a second line treatment of patients with hormone refractory androgen independent prostate cancer after failure of prior chemotherapy. A meaningful discussion of the efficacy and safety data will require contributions from oncology and pain related experts based on the data submitted for pain relief and delayed pain progression in the studied population. The overall risk assessment discussion will be informed by contributions from the members of a fully rounded committee. Due to the multivariant complications and issues associated with the endpoints in the pivotal study for the application and given the impact of approval, the need for a specialist familiar and knowledgeable in the area of pain control in this vulnerable population is essential.

Lastly, the difficulty in locating a similarly qualified individual without a disqualifying financial interest to serve on the committee also justifies this waiver. Dr. Farrar is the only special Government employee that we were able to identify and was available to discuss the particular issues involved with pain outcomes in cancer research. Furthermore, he has consulted with the FDA on numerous occasions on applications where assessing outcomes associated with pain has been problematic. Therefore, we request to use the services of Dr. Farrar to assess the product under review; he will serve as the only pain management specialist on the panel. The division has identified Dr. Farrar to be an expert in his field and believes that his participation in the meeting will ensure the level of

expertise and objectivity required to provide recommendations and to discuss the significance of several endpoints related to hormone refractory prostate cancer.

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. Farrar is an experienced professor in Epidemiology at the University of Pennsylvania, School of Medicine. His primary interests and current clinical research is in pharmacoepidemiology and the management of pain, especially in cancer patients. Dr. Farrar's background has been devoted to treatment effectiveness in cancer patients and improving the methodology for pain outcomes measurement and analysis having conducted literature syntheses, research, demonstration and evaluation projects with state of the art scientific methods applied to cancer patients with pain. At the same time he has maintained a clinical practice that focuses on all aspects of pain management.

Accordingly, I recommend that you grant John T. Farrar, M.D., a waiver that would allow him to participate in all official matters concerning New Drug Application (NDA) 021,801, proposed trade name Orplatna (satraplatin capsules), originally developed by Johnson Matthey Pharmaceuticals, a subsidiary of Johnson Matthey PLC, with licensing rights to Spectrum Pharmaceuticals. Spectrum Pharmaceuticals licensed the global rights to GPC Biotech AG, proposed indication for the treatment of patients with androgen independent (hormone refractory) prostate cancer (HRPC) that has failed prior chemotherapy. I believe that such a waiver is appropriate because in this case,

the need for the services of John T. Farrar, M.D., outweighs the potential for a conflict of interest created by the financial interest attributable to him.

CONCURRENCE: /S/ 6/8/07

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/ 6/21/07

Randall W. Lutter, Ph.D.
Deputy Commissioner for Policy

Date