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 Otis Brawley, M.D.

I am writing to request a waiver for Otis Brawley, 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 Otis Brawley, 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. Brawley 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. Brawley 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 characterized as 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. Brawley 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. Brawley owns stock in [redacted]. [redacted], a subsidiary of [redacted], a subsidiary of [redacted], makes [redacted], a competing product to Orplatna.

As a temporary voting member of the Oncologic Drugs Advisory Committee, Dr. Brawley 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. Brawley 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. Otis Brawley that would permit him to participate in the matter described previously.

First, it is significant to note that Dr. Brawley's financial interest in [redacted] is not so substantial as to preclude his participation in this matter. This stock represents less than [redacted]% of his net worth.

Second, 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. Brawley's financial interest when determining the action to be taken.

Moreover, Dr. Brawley's expertise makes him an invaluable resource to the FDA for this meeting and his expertise will greatly enhance the deliberations of the Committee. Dr. Brawley is one of the nation's foremost leaders in cancer prevention, and a preeminent clinician and scholar in research on health disparities. Dr. Brawley's research interests include the screening, epidemiology, diagnosis, prevention, and treatment of hormonal cancer. He has additional interests in clinical trial design, inclusion of minorities in trials and the availability of state-of-the-art health care to the socioeconomically disadvantaged. His work concerning racial differences in patterns of medical care and similar outcomes among racial and ethnic groups when there is equal treatment is widely cited in medical and lay literature. He is the recipient of numerous awards and was recently named a Georgia Cancer Coalition Eminent Scholar. Dr. Brawley served as a senior member in the Division of Cancer Prevention and Control at the National Cancer Institute where he was part of a group instrumental in the development and launching of the Prostate Cancer Prevention Trial. This 18,000-man trial looked at screening and epidemiologic issues in prostate cancer as well as the potential for prevention of benign prostatic hyperplasia and prostate cancer.

Lastly, the Division of Oncologic Drug Products feels that because of the indication being sought for the product coming before the committee and given the population of individuals under study, Dr. Brawley's expertise and background would not only enhance the discussion, but would provide clarity and perspective on the particular issues involved with the application under consideration. Dr. Brawley is one of only three prostate cancer experts who will be present for this important prostate cancer application. Prostate cancer is one

of the most common cancers and disproportionately occurs in African Americans. It is important to have African American representation for this application. Dr. Brawley is the only African American among the Committee members and consultants for this application.

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. Otis Brawley is Professor of hematology, oncology, and medicine at the Emory University School of Medicine and Professor of Epidemiology at the Emory Rollins School of Public Health. He also serves as Associate Director of the Winship Cancer Institute at Emory University. In addition Dr. Brawley is Chief of Hematology and Oncology Services and the Medical Director of the Georgia Cancer Coalition Center of Excellence at Grady Memorial Hospital. He also served as Chief of the NCI Intramural Prostate Cancer Clinic from 1993-1995. From 1995 to April 2001, he served as Assistant Director of the Office of Special Populations Research at the National Cancer Institute. Because of Dr. Brawley's wide understanding and experience in the study of prostate cancer, I believe that his participation will help provide a foundation for developing advice and recommendations that are fair and comprehensive.

Accordingly, I recommend that you grant Otis Brawley, 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 Otis Brawley, 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