DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MEMORANDUM

DATE: May 7, 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. /S/
Director, Advisors and Consultants Staff
Center for Drug Evaluation and Research

SUBJECT: Conflict of Interest Waiver for Peter C. Adamson, M.D.

I am writing to request a waiver for Peter C. Adamson, M.D., a temporary voting member of the Pediatric Subcommittee 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. Adamson 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. Adamson 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. Adamson 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 (BPCA). The BPCA establishes a process for studying on-patent and off-patent drugs for use in pediatric populations, and to improve pediatric therapeutics through collaboration on scientific investigation, clinical study design, weight of evidence, and ethical and labeling issues. This matter is coming before the Pediatric Subcommittee of the Oncologic Drugs Advisory Committee and is a particular matter of general applicability. The subcommittee's discussions will not focus on any specific product or company. Rather, the discussions 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. Adamson has advised the Food and Drug Administration that he has a financial interest that could potentially be affected by his participation in the subcommittee's discussions. Dr. Adamson is a consultant for [redacted] concerning the development of [redacted], a biological product not currently approved for use in the United States.

As a temporary voting member participating in the Pediatric Subcommittee of the Oncologic Drugs Advisory Committee, Dr. Adamson 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. Adamson 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. Adamson, which would permit him to participate in the matter previously described.

First, Dr. Adamson's participation in the subcommittee's discussions will not have a special or distinct effect on his financial interest since the topics under discussion will not focus on any specific product or company. The BPCA 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. The meeting will include a review of those drugs that have already been studied for pediatric oncology uses under BPCA and to seek subcommittee 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 is 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.

Second, it unlikely that Dr. Adamson's participation will have a direct and predictable impact on his financial interest. The biological product on which he consults is designed to [redacted] in some patients receiving high dose therapy. [redacted] is not approved for use in the United States and is not currently an active Biologics Licensing Application (BLA). Even if it is submitted as a BLA, it will not have an indication that will distinguish between adults and children (i.e. used for all ages), making this interest truly irrelevant to the discussion of the BPCA.

Third, Dr. Adamson's financial interest is not so substantial as to preclude his participation in this meeting. The compensation he receives is nominal.

In addition, because the topic at issue is a particular matter of general applicability that could affect all pharmaceutical firms, it is extremely difficult to locate a similarly qualified individual without a disqualifying financial interest.

Moreover, Dr. Adamson has extensive insight in and knowledge of the BPCA in general and more specifically how to harness the BPCA to expand the development of drugs for pediatric oncology. His expertise is in pharmacology and experimental therapeutics in Pediatric Oncology. He has been involved in the development of novel anti-cancer drugs for children with refractory cancer, and studied the clinical pharmacology of anti-cancer drugs in children. Dr. Adamson's primary focus has been to determine what happens to the drug in the body after it's been delivered. These aspects of drug development are the core of how and when the BPCA can be implemented and what should be included in a Written Request. Dr. Adamson's expertise and knowledge base are essential to the subcommittee discussion in this regard. The agency feels that his expertise is both critical and unique to this discussion given his years of involvement in drug development for pediatric oncology. Dr. Adamson's background, breadth of knowledge, and experience with the issues associated with pediatric oncology products, makes him uniquely qualified to participate.

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 committee. 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. Peter Adamson is a Professor of Pediatrics and Pharmacology at the University of Pennsylvania School of Medicine, Chief of the Division of Clinical Pharmacology and Therapeutics at The Children's Hospital of Philadelphia (CHOP) and Director of the Office for Clinical and

Translational Research at CHOP's Joseph Stokes, Jr. Research Institute. He is Board Certified in Pediatric Hematology/Oncology and in Clinical Pharmacology. Dr. Adamson is an internationally recognized leader in pediatric cancer drug development. Prior to becoming the Director of the Office for Clinical and Translational Research at CHOP, he was the Program Director of the General Clinical Research Center (GCRC) and Principal Investigator of its NICHD funded Pediatric Pharmacology Research Unit (PPRU). His laboratory focuses on the clinical pharmacology of new drugs for childhood cancer. I believe that Dr. Adamson's participation will help provide a foundation for developing advice and recommendations that are fair and comprehensive.

Accordingly, I recommend that you grant Dr. Peter C. Adamson a waiver that will permit him 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. Adamson 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
Food and Drug Administration

Date