DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

DATE: August 6, 2007

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

I am writing to request a waiver for James Neaton, Ph.D., a temporary voting member of the Cardiovascular and Renal 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. Neaton 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. Neaton 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. Neaton has been asked to participate in all official matters concerning discussions of the updated information on the risks and benefits of erythropoiesis-stimulating agents, when used in the treatment of anemia due to chronic renal failure. This discussion follows a March 9, 2007, FDA Public Health Advisory regarding the use of these agents.

This matter is coming before a joint meeting of the Cardiovascular and Renal Drugs and the Drug Safety and Risk Management Advisory Committees. This issue is a particular matter involving specific parties.

The function of the Cardiovascular and Renal Drugs Advisory Committee, as stated in its Charter, 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 cardiovascular and renal disorders and to make appropriate recommendations to the Commissioner of Food and Drugs.

Dr. Neaton has advised the Food and Drug Administration that he has a financial interest that could potentially be affected by his participation in the matter at issue. Dr. Neaton is a member of ———— Data Safety Monitoring Board overseeing a clinical trial unrelated to erythropoiesis-stimulating agents. He receives minimal compensation for his role. ———————————————————————————————————————.

As a temporary voting member of the Cardiovascular and Renal Drugs Advisory Committee, Dr. Neaton 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. Neaton 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. Neaton that would permit him to participate in the matter previously described.

First, it is important to consider that Dr. Neaton's interest in ——— is unrelated to erythropoiesis-stimulating agents.

Second, Dr. Neaton's financial interest in ——— is not so substantial as to preclude his participation in this meeting. He receives minimal compensation for serving on the Data Safety Monitoring Board.

Third, the uniqueness of Dr. Neaton's qualification justifies granting this waiver. According to the Review Division, Dr. Neaton has vast experience in the use of statistical models for analysis of outcomes from clinical studies. This analytical experience is unique among the committees members for its depth of expertise and Dr. Neaton's insights would importantly inform assessments of the strengths and limitations of the clinical data relating to the use of erythropoiesis-stimulating agents. His participation in the meeting would help ensure a thorough and balanced discussion. Such a discussion is imperative because of the potential significant public health impact of the committees' recommendations.

Additionally, the Agency was unable to find a similarly qualified individual without disqualifying financial interests to serve at the meeting. Of the three [3] statisticians and epidemiologists invited, Dr. Neaton possesses the strongest background in the use of statistical models, and can best express the limitations of the statistical models presented. Although Drs. ——— and ———— have secondary expertise in biostatistics and biometrics, Dr. Neaton's skills in the analysis of outcome data from clinical studies are unique to this meeting.

Finally, 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 committees' 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. James Neaton is a Professor of biostatistics at the University of Minnesota's School of Public Health. Dr. Neaton has received many academic awards and honors for teaching and is a Fellow of the American Statistical Association. He is also principal investigator for clinical research programs on AIDS and other clinical programs and studies with National Institutes of Health and

the National Cancer Institute. Dr. Neaton has been involved in numerous clinical studies and programs in various roles as investigator, consultant, data analyst and member of data safety monitoring committees. Dr. Neaton has an extensive publication record in major statistical and clinical journals that has emphasized drug safety, including cardiovascular risk and mortality assessment. I believe his participation will contribute to the diversity of opinions and expertise represented on the committees' and will provide a foundation for developing advice and recommendations that are fair and comprehensive.

Accordingly, I recommend that you grant James Neaton, Ph.D., a waiver that will permit him to participate in all official matters concerning the discussions of updated information on the risks and benefits of erythropoiesis-stimulating agents, when used in the treatment of anemia due to chronic renal failure. This discussion follows a March 9, 2007, FDA Public Health Advisory regarding the use of these agents. I believe that such a waiver is appropriate because in this case, the need for the services of Dr. Neaton outweighs the potential for a conflict of interest created by the financial interest attributable to him.

CONCURRENCE: /S/ 8/08/07

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/ 8/20/07

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

Date