DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

DATE: June 21, 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 Curt Furberg, M.D.

I am writing to request a waiver for Curt Furberg, M.D., a temporary non-voting member of the Endocrinologic and Metabolic 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. Furberg 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. Furberg 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. Furberg has been asked to participate in the committees' discussions and deliberations, without voting, concerning the cardiovascular ischemic/thrombotic risks of the thiazolidinediones, with focus on rosiglitazone, as presented by the FDA and GlaxoSmithKline. This matter is coming before a joint meeting of the Endocrinologic and Metabolic Drugs and the Drug Safety and Risk Management Advisory Committees. This meeting is a particular matter involving specific parties.

The function of the Endocrinologic and Metabolic Drugs Advisory Committee 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 endocrine and metabolic disorders and to make appropriate recommendations to the Commissioner of Food and Drugs.

Dr. Furberg 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. Furberg serves as a member of a Data Safety Monitoring Board (DSMB) for a National Institutes of Health (NIH)-sponsored study of rosiglitazone, the focus of the meeting, and several of its competing products and their effect on mortality and cardiovascular events (e.g., myocardial infarction, stroke). The study is being funded by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and pharmaceutical firms such as GlaxoSmithKline, Novartis Pharmaceuticals, and Pfizer, Inc. Dr. Furberg receives a nominal fee for his DSMB activities.**

As a temporary non-voting member of the Endocrinologic and Metabolic Drugs Advisory Committee, Dr. Furberg 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. Furberg 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. Furberg that would permit him to participate in the matter previously described.

First, this interest is not so substantial as to preclude his participation in this matter. He receives nominal compensation for his DSMB activities.

Second, the uniqueness of Dr. Furberg's qualification justifies granting this waiver. According to the review Division, Dr. Curt Furberg is renown in the field of epidemiology of drug safety and he would bring a broad safety perspective to the joint committee based on his extensive experience and leadership in drug safety. It is critical for FDA to hear many perspectives and draw on a wide range of experts and thought leaders in order to ensure that the agency is as well-informed as possible, particularly when the issue to be addressed by the committees will potentially affect the health and welfare of millions of lives. Due to the significant public health impact of the recommendations of this committee, we strongly believe that Dr. Furberg's expertise in epidemiology and his broad perspective will help ensure adequate and varied scientific analysis and discourse.

In addition, 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. Curt Furberg, M.D., is the Director of Academic Program Development at the Wake Forest University Baptist Medical Center, and an internationally recognized expert in the fields of epidemiology and biostatistics. Dr. Furberg has three decades of experience as a principal investigator, or scientific project officer at the National Heart, Lung, and Blood Institute, for numerous clinical trials. He has also been a member of numerous data and safety monitoring committees. Dr. Furberg is a leading researcher and educator as demonstrated by the 350 books, chapters, and articles that he has authored, and the numerous committees that he has chaired, such as the Steering Committee for the Cardiovascular Health Study, for the National Institutes of Health and other organizations. 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 Curt Furberg, M.D., a limited waiver that will permit him to participate in the committees' discussions and deliberations, without voting,

concerning the cardiovascular ischemic/thrombotic risks of the thiazolidinediones, with focus on rosiglitazone, as presented by the FDA and GlaxoSmithKline. I believe that such a waiver is appropriate because in this case, the need for the services of Dr. Curt Furberg outweighs the potential for a conflict of interest created by the financial interest attributable to him.

CONCURRENCE: /s/ 6/22/07

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

Date

DECISION:

__X__ Limited 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.

_____ Limited Waiver denied.

/s/ 6/29/07

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

Date