



DEPARTMENT OF HEALTH & HUMAN SERVICES

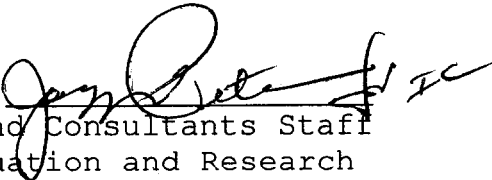
MEMORANDUM

Food and Drug Administration
Rockville MD 20857

DATE: December 20, 2005

TO: Sheila Dearybury Walcoff, Esq.
Associate Commissioner for External Relations
Food and Drug Administration

THROUGH: Jenny Slaughter
Director, Ethics and Integrity Staff
Office of Management Programs
Office of Management

FROM: Igor Cerny, Pharm.D. 
Director, Advisors and Consultants Staff
Center for Drug Evaluation and Research

SUBJECT: Conflict of Interest Waiver for Alastair J.J.
Wood, M.D.

I am writing to request a waiver for Alastair J.J. Wood, M.D., a member of the Nonprescription Drugs Advisory Committee, from the conflict of interest prohibitions of 18 U.S.C. §208(a). Waivers under section 208(b)(3) may be granted by the appointing official when it is determined that "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. Wood 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. Wood 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 as an arrangement concerning, prospective employment.

Dr. Wood has been asked to participate in all official matters concerning consideration of the safety and efficacy of new drug application (NDA) 21-887, proposing over-the-counter (OTC) use of Orlistat (tetrahydrolipstatin) 60 milligram (mg) capsules, sponsored by GlaxoSmithKline Consumer Healthcare, L.P., an associate of GlaxoSmithKline PLC, to promote weight loss in overweight adults when used along with a reduced calorie and low fat diet. This matter is coming before the Nonprescription Drugs Advisory Committee and the Endocrinologic and Metabolic Drugs Advisory Committee for consideration.

The function of the Nonprescription Drugs Advisory Committee is to review and evaluate available data concerning the safety and effectiveness of over-the-counter (nonprescription) human drug products, or any other FDA-regulated product, for use in the treatment of a broad spectrum of human symptoms and diseases and advise the Commissioner either on the promulgation of monographs establishing conditions under which these drugs are generally recognized as safe and effective and not misbranded or on the approval of new drug applications for such drugs. The Committee also serves as a forum for the exchange of views regarding the prescription and nonprescription status, including switches from one status to another, of these various drug products and combinations thereof.

The function of the Endocrinologic and Metabolic Drugs Advisory Committee is to review and evaluate 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. Wood has advised the Food and Drug Administration (FDA) that he has a financial interest that could potentially be affected by his participation in the matter described previously. Dr. Wood is scheduled to consult with [REDACTED] on a product unrelated to Orlistat, its competing products, and obesity. He will receive nominal compensation for this one-time event. [REDACTED] a [REDACTED] makes [REDACTED] and [REDACTED] [REDACTED] competing products to Orlistat.

As a member of the Nonprescription Drugs Advisory Committee, Dr. Wood 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. Wood 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. Alastair J.J. Wood that would permit him to participate all official matters concerning consideration of the safety and efficacy of new drug application (NDA) 21-887, proposing over-the-counter (OTC) use of Orlistat (tetrahydrolipstatin) 60 milligram (mg) capsules, sponsored by GlaxoSmithKline Consumer Healthcare, L.P., an associate of GlaxoSmithKline PLC, to promote weight loss in overweight adults when used along with a reduced calorie and low fat diet.

First and foremost, this waiver is justified because arguably, Dr. Wood's interest does not constitute a financial interest in the particular matter within the meaning of 18 U.S.C. §208(a), since he will consult on a product unrelated to Orlistat and its competing products. Nevertheless, in the utmost of caution, I recommend that this waiver be granted.

Second, Dr. Wood's financial interest is not so substantial as to preclude his participation in this matter. He expects to receive minimal compensation for his consulting.

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 various advisory committee members and Dr. Wood's participation will contribute to the balance of views represented and the diversity of opinions and expertise. 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. Wood is Associate Dean for External Affairs at Vanderbilt University School of Medicine, Assistant Vice Chancellor for Research, Professor of Medicine, Professor of Pharmacology, and an attending physician at the Vanderbilt University Hospital. His research interests are in Molecular Genetics of Adrenergic Receptors, Ethnic Differences in Drug Response, Vascular Response, Drug Metabolism and Disposition. Dr. Wood is a member of numerous professional societies, such as the American Society for Clinical Investigation, American Society for Clinical Pharmacology and Therapeutics, New York Academy of Sciences and The American Heart Association Council on the Circulation. He has written over 100 journal publications and many textbooks and chapters. I believe that Dr. Wood's participation in the committees' discussions and deliberations will help provide a foundation for developing advice and recommendations that are fair and comprehensive.

Accordingly, I recommend that you grant Dr. Alastair J. J. Wood a waiver that will permit him to participate in all official matters concerning consideration of the safety and efficacy of new drug application (NDA) 21-887, proposing over-the-counter (OTC) use of Orlistat (tetrahydrolipstatin) 60 milligram (mg) capsules, sponsored by GlaxoSmithKline Consumer Healthcare, L.P., an associate of GlaxoSmithKline PLC, to promote weight loss in

overweight adults when used along with a reduced calorie and low fat diet. I believe that such a waiver is appropriate because in this case, the need for Dr. Wood's services outweighs the potential for a conflict of interest created by the financial interest attributable to him.

CONCURRENCE: Jenny Slaughter 12/27/05
Date
Jenny Slaughter
Director, Ethics and
Integrity Staff
Office of Management Programs
Office of Management

DECISION:

Waiver granted based on my determination, made in accordance with section 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
Sheila Dearybury Walcoff, Esq. 12/29/05
Date
Associate Commissioner for External Relations
Food and Drug Administration