



DEPARTMENT OF HEALTH & HUMAN SERVICES

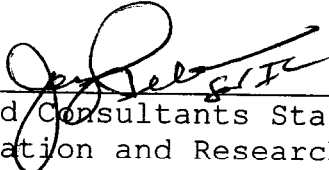
MEMORANDUM

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 Thomas Carpenter,
M.D.

I am writing to request a waiver for Thomas Carpenter, M.D., a member of the Endocrinologic and Metabolic 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. Carpenter 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. Carpenter 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. Carpenter 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. Carpenter has advised the Food and Drug Administration that he has a financial interest that could potentially be affected by his participation in the matter described previously. Dr. Carpenter is a member of the Speaker's Bureau for [REDACTED] that is current studying an investigational product for use in the treatment of obesity. He lectured in March 2005 on hypophosphatemia and received modest compensation. He has no lectures currently scheduled.

As a member of the Endocrinologic and Metabolic Drugs Advisory Committee, Dr. Carpenter 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. Carpenter 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. Thomas Carpenter 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.

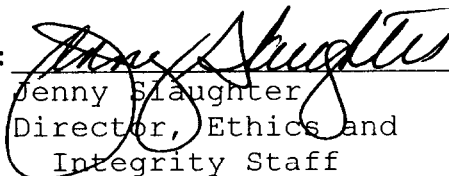
First and foremost, this waiver is justified because arguably, Dr. Carpenter's interest does not constitute a financial interest in the particular matter within the meaning of 18 U.S.C. §208(a), since he lectures on topics unrelated to Orlistat and its competing products. Nevertheless, in the utmost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

Second, Dr. Carpenter's financial interest is not so substantial as to preclude his participation in this matter. He receives minimal compensation for his speaking.

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. Carpenter'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. Carpenter is Professor of Pediatrics, Yale University School of Medicine. He is board certified in pediatrics with a subspecialty in endocrinology. He is a member of numerous professional societies, such as the American Federation for Medical Research, the American Pediatric Society, the Society of Pediatric Research, and the Endocrine Society. He has written extensively on topics concerning rickets, disorders of bone and mineral metabolism, parathyroid disease, and hypercalcemic disorders in children. I believe that Dr. Carpenter's participation in the committees' discussions and deliberations will help provide a foundation for developing advice and recommendations that are fair and comprehensive.

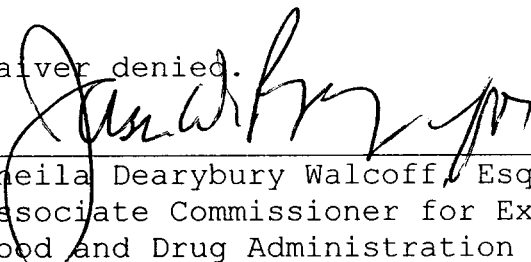
Accordingly, I recommend that you grant Dr. Thomas Carpenter a waiver that will permit him to participate in all official matters concerning consideration of the safety and efficacy of new drug application (NDA) 21-887, proposing over-the-counter (OTC) use of Orlistat (tetrahydrolipstatin) 60 milligram (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. Carpenter's services outweighs the potential for a conflict of interest created by the financial interest attributable to him.

CONCURRENCE:  12/28/05
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.  12/29/05
Date
Sheila Dearybury Walcoff, Esq.
Associate Commissioner for External Relations
Food and Drug Administration