



DEPARTMENT OF HEALTH & HUMAN SERVICES

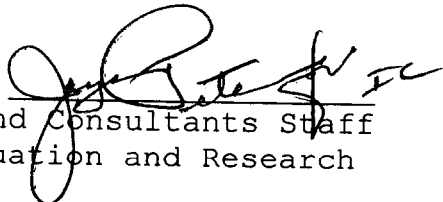
MEMORANDUM

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 Steven E. Gay,
M.D., M.S.

I am writing to request a waiver for Steven E. Gay, M.D., M.S., a member of the Pulmonary Allergy 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(b)(3). Therefore, you have the authority to grant Dr. Gay 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. Gay 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. Gay has been asked to participate in all official matters concerning discussions of the continued need for the designation of over-the-counter (OTC) epinephrine-metered dose inhalers (MDIs) for the treatment of asthma as an essential use of ozone-depleting substances (ODSs) under 21 CFR 2.125. The committees' discussions will not focus on any particular product or sponsor and are a particular matter of general applicability. This matter is coming before a joint meeting of the Nonprescription Drugs Advisory Committee and the Pulmonary Allergy 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 Pulmonary Allergy 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 pulmonary disease and diseases with allergic and/or immunologic mechanisms and to make appropriate recommendations to the Commissioner of Food and Drugs.

Dr. Gay has advised the Food and Drug Administration that he has financial interests that could potentially be affected by his participation in the matters described above. Dr. Gay is a member of Speaker's Bureaus for

[REDACTED], [REDACTED], and [REDACTED]. He lectures on the treatment and evaluation of asthma and Chronic Obstructive Pulmonary Disease (COPD). All of his talks deal with the appropriate approved guidelines for the diagnosis, evaluation, and treatment of COPD. Although he does discuss products in his lectures, he does not limit it to any one company's product. Dr. Gay receives nominal to moderate compensation for his lecturing.

[REDACTED], and [REDACTED], and [REDACTED] are products that could be affected by the committees' discussions. In addition, [REDACTED], a subsidiary of [REDACTED] makes a generic version of [REDACTED].

As a member of the Pulmonary Allergy Drugs Advisory Committee, Dr. Gay potentially could become involved in matters that could affect his financial interests. 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. Gay 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. Gay that would permit him to participate in the matters previously described.

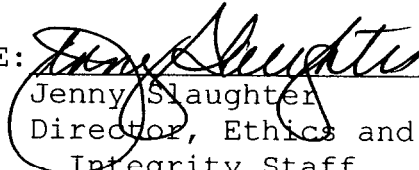
First and foremost, this waiver is justified, in part, because of the general nature of particular matters of general applicability. Dr. Gay's participation in the committees' discussions of the continued need for the designation of OTC epinephrine-MDI's for the treatment of asthma as an essential use of ozone-depleting substances will not have a unique and distinct impact on any of his personal financial interests, but rather may affect classes of similarly situated products and manufacturers to the same extent. It is well recognized that particular matters of general applicability pose far less risk of a conflict of interest because they do not focus on any particular product or sponsor.

Second, this waiver is justified because Dr. Gay's interests are not so substantial as to preclude his participation in this matter.

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. Gay'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. Gay is Clinical Assistant Professor of Internal Medicine, Director, Critical Care Support Services, Director, Bronchoscopy Service, and Associate Director of Lung Transplantation Program, at the University of Michigan Medical Center. He specializes in pulmonary and critical care medicine and his clinical interests are in exercise physiology, interstitial lung disease, Chronic Obstructive Pulmonary Disease (COPD), and lung transplantation. Dr. Gay's research focuses on High Resolution Computed Tomography (HRCT) in the evaluation of lung disease, exercise physiology, pathophysiology, and outcomes research in COPD. He has written and lectured extensively concerning the diagnosis, evaluation and treatment of COPD and asthma. Dr. Gay's participation is essential for an appropriate discussion of the public health benefit derived from the availability of over-the-counter epinephrine-metered dose inhalers for the treatment of asthma products in the OTC setting and the continued need for the designation of these products as an essential use of ozone-depleting substances. I believe that Dr. Gay's participation in the committees' deliberations will help provide a foundation that for developing advice and recommendations that are fair and comprehensive.

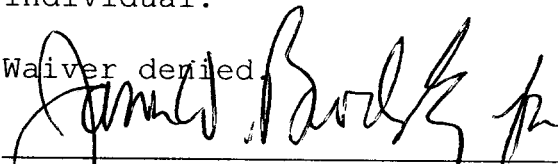
Accordingly, I recommend that you grant Steven E. Gay, M.D., M.S., a waiver that will permit him to participate in all official matters concerning the committees' discussions of the continued need for the designation of over-the-counter epinephrine-metered dose inhalers for the treatment

of asthma as an essential use of ozone-depleting substances under 21 CFR 2.125. I believe that such a waiver is appropriate because in this case, the need for the services of Dr. Gay outweighs the potential for a conflict of interest created by the financial interests 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