DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MEMORANDUM

DATE: March 13, 2007

TO: Randall W. Lutter, Ph.D.
Associate Commissioner for Policy and Planning
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 Polly Parsons, M.D.

I am writing to request a waiver for Polly Parsons, M.D., a temporary voting member of the Pulmonary and 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. Therefore, you have the authority to grant Dr. Parsons, 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. Parsons is a special Government employee, she 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 her, her spouse, minor child, or general

partner; an organization or entity for which she serves as an officer, director, trustee, general partner, or employee; and, a person with whom she is negotiating for, or has an arrangement concerning, prospective employment.

Dr. Parsons has been asked to participate in all official matters concerning the efficacy supplement to New Drug Application (NDA) 21-077 for the approved product Advair Diskus 500/50 (fluticasone propionate/ salmeterol inhalation powder) for the proposed indication of increased survival and reduced exacerbations in patients with chronic obstructive pulmonary disease (COPD). Advair Diskus 500/50 is sponsored by GlaxoSmithKline. This matter is coming before the Pulmonary and Allergy Drugs Advisory Committee and is a particular matter involving specific parties.

The function of 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 make appropriate recommendations to the Commissioner of Food and Drugs.

Dr. Parsons has advised the Food and Drug Administration that she has a financial interest that could potentially be affected by her participation in the matter at issue. Dr. Parsons is a member of ———'s Scientific Advisory Board for acute lung injury. The compensation she expects to receive is nominal. ——— manufactures ———————————————————, a competing product to Advair Diskus.

As a temporary voting member participating in the Pulmonary and Allergy Drugs Advisory Committee meeting, Dr. Parsons potentially could become involved in matters that could affect her financial interest. Under 18 U.S.C. §208(a), she 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. Parsons 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. Parsons, which

would permit her to participate in the matter previously described.

First, Dr. Parsons' interest is not so substantial as to preclude her participation in this matter. She expects to receive minimal compensation for her service.

Second, Dr. Parsons' interest is unrelated to the product at issue, the competing products, and the issues coming before the committees. ———'s scientific advisory board discusses matters related to acute lung injury.

Third, the uniqueness of Dr. Parsons' qualifications justifies granting this waiver. Dr. Polly Parsons is a pulmonologist who has extensive experience in clinical trials and previous committee experience, all of which will make her participation in the meeting invaluable. For this particular meeting, it is crucial to have participants that have experience in pulmonary medicine (pulmonologists) and clinical trials. She has participated in the design and conduct of large, multicenter, trials and has received numerous grants to conduct trials. Her experience with the design, conduct, and analysis of such trials gives her insight that will enrich the discussion because the focus of this meeting will be mostly regarding the conduct and analysis of a large clinical trial. The combination of her pulmonary medicine expertise and her clinical trial experience will be extremely valuable for the deliberations.

Lastly, the Division of Pulmonary and Allergy Products feels that because of the nature of the issues to be discussed it is essential to have a number of experts in pulmonary medicine and clinical trial design participate in the advisory committee meeting. In an attempt to gain this necessary expertise, the Division along with the Advisors and Consultants Staff contacted ten pulmonologists, two Special Government Employee consultants in addition to eight current committee members. Of these 10, nine accepted indicating that they were interested and available to attend the AC meeting. The one who declined, did so as a result of a scheduling conflict. An additional three were recused outright based on their responses to conflict of interest screening. Following completion of the conflict of interest screening process, it was determined that each of the six remaining pulmonologists

would require a waiver to participate in the meeting. After consultation with the Division, it was determined that they would seek waivers for only 1 of the standing members and 1 of the consultants, based on the critical need for expertise in the aforementioned areas. The Division is seeking broad and diverse perspectives on the issues at hand in an effort to approach the topic in an objective and scientific manner. If any of the pulmonologists are recused, it will leave insufficient pulmonology expertise on the panel for this meeting. To that end, we are requesting that the waiver be granted for Dr. Parsons to participate as there has been a genuine effort to secure individual participation and representation with minimal conflict of interest.

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 committee. The Committee's 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. Parsons is the Director of Pulmonary and Critical Care Medicine at the University of Vermont. She completed a fellowship in pulmonary medicine at the University of Colorado Health Sciences Center. These qualifications ensure that Dr. Parsons will bring a broad knowledge of pulmonary medicine that is necessary for the discussion.

I believe that Dr. Parsons' participation will help provide a foundation for developing advice and recommendations that are fair and comprehensive.

Accordingly, I recommend that you grant Polly Parsons, M.D., a waiver that will permit her to participate fully in all official matters concerning the efficacy supplement to New Drug Application (NDA) 21-077 for the approved product Advair Diskus 500/50 (fluticasone propionate/ salmeterol inhalation powder) for the proposed indication of increased survival and reduced exacerbations in patients with chronic obstructive pulmonary disease (COPD). I believe that such a waiver is

appropriate because in this case, the need for the services of Dr. Parsons outweighs the potential for a conflict of interest created by the financial interest involved.

CONCURRENCE: _____/s/_____ 3/30/07
Vince Tolino — Date
Director, Ethics and Integrity Staff
Office of Management Programs
Office of Management

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/_____ 4/4/07
Randall W. Lutter, Ph.D. — Date
Associate Commissioner for
Policy and Planning
Food and Drug Administration