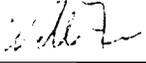




Food and Drug Administration
1401 Rockville Pike
Rockville MD 20852-1448

MEMORANDUM

DATE: July 10, 2006

FROM: William Freas, Ph.D. 
Director, Division of Scientific Advisors and Consultants

TO: Randall Lutter, Ph.D.
Associate Commissioner for Policy and Planning

SUBJECT: General Matters Waiver Under 18 U.S.C. 208(b) (3)
For Jay M. Portnoy, M.D.

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

I am writing to request a general matters waiver for Jay Portnoy, M.D., a member of the Allergenic Products Advisory Committee at the September 13, 2006 meeting. This memorandum constitutes a determination in accordance with 18 U.S.C: 208(b)(3) that the need for Dr. Portnoy's services on the Committee outweighs the potential for a conflict of interest created by any personal or imputed financial interest that he may have in matters of general applicability in which he is expected to participate on the Committee 18 U.S.C. 208(b)(3).

The Committee will discuss a proposed strategy for the reclassification of Class IIIA allergenic products. It is expected that the Committee will focus largely, if not exclusively, on matters of general applicability, as opposed to matters involving specific parties or matters that uniquely and distinctly affect any particular person or organization.

These matters may affect certain financial interest of Dr. Portnoy's or of persons and organizations with which he may have certain relationships. This would include:

Associate Commissioner for Policy and Planning

Financial investments in medical product companies, food related companies, drug related companies, health care industry, and any other industry that might be affected by the recommendations of the Committee (no interests currently reported);

Employment with research institutions, state and local government, medical product manufacturers, food related companies, drug related companies, health care industry or other organizations that may be affected by the Committee's recommendations, for example, the Children's Mercy Hospital where he is employed. Also included is his consulting with [REDACTED]

Grants, contracts or other funding for research or other services received from the federal government that might be affected by the Committee's recommendations (no interests currently reported);

Grants, contracts or other funding for research or other services received from non-federal sources, including industry and foundations that might be affected by the Committee's recommendations (no interests currently reported);

Expert witness, litigation or advocacy services in matters that might be affected by the recommendations of the Committee (no interests currently reported);

Any interest of a group or other organization in which Dr. Portnoy is appointed as an officer, director, trustee, employee or general partner that might be affected by the Committee's recommendations, for example, his membership with the American College of Allergy, Asthma and Immunology, and his membership with the American Academy of Allergy, Asthma and Immunology.

Under 18 U.S.C. 208, Dr. Portnoy may not participate in any particular matter affecting these interests, unless he receives a waiver. However, pursuant to my authority to grant waivers under 18 U.S.C. 208(b)(3), I have determined that the need for the services of Jay M. Portnoy, M.D. on this Committee with respect to matters of general applicability, outweighs any concern that these types of interests might create a potential for a conflict of interest. Consequently, Dr. Portnoy may participate in matters of general applicability affecting any current and future financial interest of the types described above. This determination is based on the following considerations:

The Food and Drug Administration has a particularly strong need for Dr. Portnoy's services. Dr. Portnoy is Chief, Section of Allergy, Asthma and Immunology at the Children's Mercy Hospital. He is board certified in allergy, immunology, and pediatrics. He has a very broad spectrum of knowledge regarding allergenic products. In addition, he has expertise in the diagnosis and management of immunodeficiency, the treatment of exacerbations of asthma in children, and the treatment of allergic disorders. Dr. Portnoy is well published in his areas of expertise, serves on numerous committees, and has received many awards.

Furthermore, the Committee charter requires the appointment of individuals who are authorities knowledgeable in a variety of scientific and medical professions. Consequently, it is expected that persons qualified to serve on the Committee will have interests, financial and otherwise, in the work of the Committee.

