DEPARTMENT OF HEALTH & HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Rockville MD 20857

DATE: October 30, 2003

TO: Peter J. Pitts
Associate Commissioner
for External Relations
Food and Drug Administration

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

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

SUBJECT: General Matters Waiver Under 18 U.S.C. §208(b)(3) for Edmund V. Capparelli, Pharm.D.

Edmund V. Capparelli, Pharm.D., has been appointed as a special Government employee. This memorandum constitutes a determination, in accordance with 18 U.S.C. §208(b)(3), that the need for the individual's services on the Committee, with respect to matters of general applicability, 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.

Dr. Capparelli's participation in matters of general applicability may affect certain financial interests of his or of persons and organizations whose financial interests are imputed to him under 18 U.S.C. §208.

This would include the following:

1. Financial investments in pharmaceutical companies, health care industries, and any other industries that might be affected by the Committee's recommendations (no interests currently reported);

2. Employment with research institutions, state and local governments, pharmaceutical companies, health care industries, or other organizations that may be affected by the Committee's recommendations (no interests currently reported);

3. 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);

4. Grants, contracts, or other funding for research or other services received from non-federal entities, including industries and foundations, that might be affected by the Committee's recommendations, for example, consultant fees received from [redacted]

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

6. Any interest of a group or organization in which Dr. Capparelli is appointed as an officer, director, trustee, employee or general partner that might be affected by the Committee's recommendations (no interests currently reported);

As a special Government employee, Dr. Capparelli potentially could become involved in matters that could affect his financial interests. Under 18 U.S.C. §208, Dr. Capparelli is prohibited from participating personally and substantially in a particular matter affecting these interests. However, you have the authority under 18 U.S.C. §208(b)(3) to grant a waiver permitting Dr. Capparelli to participate in matters of general applicability.

For the following reasons, I believe that it would be appropriate for you to grant a waiver to Dr. Capparelli that would allow him to participate in matters of general applicability.

advice and recommendations to the Commissioner. The Commissioner has sole discretion concerning action to be taken and policy to be expressed on any matter considered by an advisory committee. In addition, the Federal Advisory Committee Act requires fair balance and openness, which serve as important checks against real or apparent threats to the objectivity of Committee action.

Please note that this waiver only allows participation in particular matters of general applicability. It will not permit Dr. Capparelli to participate in any matters involving specific parties that may affect his financial interests, or the interests of any person or organization described above. When the work advising the Center for Drug Evaluation and Research or when advising the Committee moves from matters of general applicability to more specific matters (e.g., recommendations specific to an identified product), which could specifically affect Dr. Capparelli's personal and imputed financial interests, the Food and Drug Administration will examine Dr. Capparelli's interests in relation to the particular matter, and either obtain a specific waiver allowing him to participate, or exclude him from participating in the particular matter.

Mary Ann Gillman for DATE: 11-4-03
Jenny Slaughter
Director, Ethics and Integrity Staff
Office of Management Programs

DECISION:

X General matters waiver granted based on my determination, made in accordance with 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 interests attributable to the individual.

_____ Waiver denied.

DATE: 11/13/03
Peter J Pitts
Associate Commissioner
for External Relations
Food and Drug Administration