MEMORANDUM

DATE: March 6, 2006

TO: Jason D. Brodsky

Acting Associate Commissioner for External Relations

Food and Drug Administration

THROUGH: Jenny Slaughter

Director, Ethics & Integrity Staff Office of Management Programs, OMS

FROM: Norris Alderson, Ph.D.

Associate Commissioner for Science

SUBJECT: Conflict of Interest Waiver for David R. Parkinson, M.D.

David R. Parkinson is a special Government employee and a member of the Science Board. This memorandum constitutes a determination, in accordance with 18 U.S.C. 208(b)(3), that the need for David Parkinson's participation in particular matters of general applicability, outweighs the potential for a conflict of interest created by any personal or imputed financial interests that he may have in particular matters of general applicability in which he is expected to participated.

Particular matters of general applicability may affect certain personal financial interests or the financial interests of the persons and organizations whose interests impute to David Parkinson under 18 U.S.C. 208. This would include the following:

- 2. Employment with research institutions, state and local governments, pharmaceutical companies, health care industries, or other organizations that may be affected by the committees recommendation such as his position as (______).
- 3. Grants, contracts, or other funding for research or other services received from the federal government that might be affected by participation in particular matters of general applicability. No such interest 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

participation in particular matters of general applicability. No such interest currently reported.

- 5. Expert witness, litigation or advocacy services in matters that might be affected by David Parkinson's participation in particular matters of general applicability. No such interest currently reported.

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

For the following reasons, I believe that it would be appropriate for you to grant a waiver to David Parkinson that would permit him to participate in particular matters of general applicability.

First and foremost, this waiver is justified, in part, because of the general nature of particular matters of general applicability. It is well recognized that particular matters of general applicability pose far less risk of a conflict of interest. Particular matters of general applicability include regulations, legislation, guidelines, points-to-consider, and polices governing classes of organizations, individuals, and products. Particular matters of general applicability do not include particular matters involving specific parties, such as specific grants, contracts, recommendations regarding a specific product, or enforcement matters involving known parties. Particular matters of general applicability will not have a unique and distinct impact on any of David Parkinson's personal or imputed financial interests, but rather may affect classes of similarly situated products and manufacturers to the same extent.

This waiver is also justified because the Agency has a need for David Parkinson's services, in light of his expertise in internal medicine, oncology, and new oncology therapeutics. His participation will contribute to the diversity of views and expertise represented with respect to particular matters of general applicability.

Moreover, David Parkinson will be participating in an

advisory capacity only. The Food and Drug Administration has sole discretion concerning action to be taken and policy to be expressed on particular matters of general applicability.

Please note that this waiver only allows participation in particular matters of general applicability. It will not allow David Parkinson to participate in any matters involving specific parties that may be affected by his financial interests, or the interests of any person or organization described above.

When the matters in which David Parkinson may become involved as a special Government employee move from particular matters of general applicability to more specific matters (e.g., recommendations specific to an identified product), which could specifically affect him personal and imputed financial interests, the Food and Drug Administration will examine his 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.

CONCURRENCE:	/S/	March 7, 2006
Jenny	Slaughter Dat	te
	Director, Ethics & Integrity St	taff
	Office of Management Programs,	OMS
DECISION:		
	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 interest attributable to the individual.	
	Waiver denied.	
	/S/ Jason D. Brodsky Acting Associate Commissioner for External Relations Food and Drug Administration	<u>March 8, 2006</u> Date