DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MEMORANDUM

DATE: November 3, 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., Ph.D.
Director, Advisors and Consultants Staff
Center for Drug Evaluation and Research

SUBJECT: General Matters Waiver under 18 U.S.C. §208(b)(3) for Michael Caldwell, M.D., Ph.D.

Michael Caldwell, M.D., Ph.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 Dr. Caldwell'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 participate.

Particular matters of general applicability may affect certain personal financial interests or the financial interests of the persons and organizations whose interests impute to Dr. Caldwell 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 Dr. Caldwell's participation in particular matters of general applicability (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 Dr. Caldwell's participation in particular matters of general applicability (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 Dr. Caldwell's participation in particular matters of general applicability (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 Dr. Caldwell's participation in particular matters of general applicability for example, funding for research from the [redacted]

5. Expert witness, litigation or advocacy services in matters that might be affected by Dr. Caldwell's participation in particular matters of general applicability (no interests currently reported);

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

As a special Government employee, Dr. Caldwell 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, Dr. Caldwell 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 Michael Caldwell, M.D., Ph.D., 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 Dr. Caldwell 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 policies 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 Dr. Caldwell's imputed financial interest, 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 Dr. Caldwell's services, in light of his expertise in the field of general and vascular surgery. His participation will contribute to the diversity of views and expertise represented with respect to particular matters of general applicability.

Moreover, Dr. Caldwell 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 Dr. Caldwell to participate in any matters involving specific parties that may be affected by his financial interest, or the interests of any person or organization described above. When the matters in which Dr. Caldwell 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 Dr. Caldwell's imputed financial interest, the Food and Drug Administration will examine his interest

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: Mary Ann Callan 11/08/05

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

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.

11-10-05

Sheila Dearybury Walcoff, Esq. Date
Associate Commissioner for
External Relations
Food and Drug Administration