DEPARTMENT OF HEALTH & HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Rockville MD 20857

DATE: February 22, 2006

TO: Jason D. Brodsky
Acting Associate Commissioner
Office 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.
Director, Advisors and Consultants Staff
Center for Drug Evaluation and Research

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

Edward Sausville, M.D., Ph.D., is a consultant for the Center for Biologics Evaluation and Research, has been asked to participate in the Oncologic Drugs Advisory Committee meeting to discuss pre-clinical requirements and phase I trial issues for the development of oncologic drug products. The committee's discussions will not focus on any particular product or company and are a particular matter of general applicability. This memorandum constitutes a determination, in accordance with 18 U.S.C. §208(b)(3), that the need for Dr. Sausville's participation in the committee's discussions, without voting, outweighs the potential for a conflict of interest created by any personal or imputed financial interests that he may have in this particular matter of general applicability.

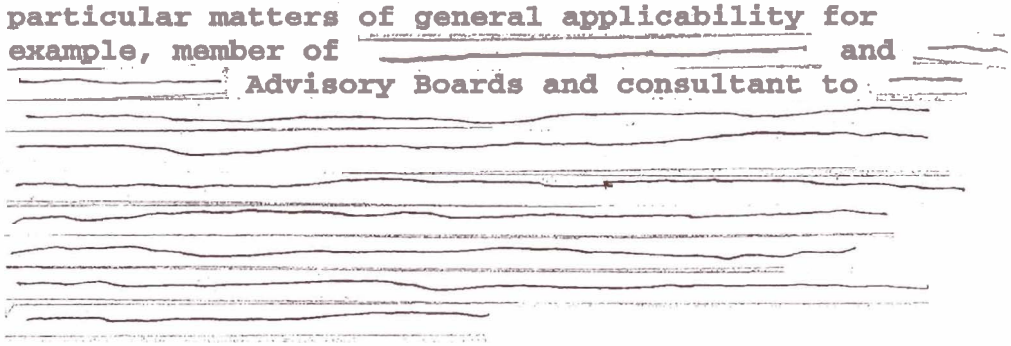
Particular matters of general applicability may affect certain personal financial interests or the financial interests of the persons and organizations whose interests impute to Dr. Sausville under 18 U.S.C. §208. This would include the following:

1 Financial investments in pharmaceutical companies, health care industries, and any other industries that might be affected by Dr. Sausville'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. Sausville'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. Sausville'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. Sausville's participation in particular matters of general applicability for example, member of [redacted] and [redacted] Advisory Boards and consultant to [redacted]**



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

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

As a special Government employee, Dr. Edward Sausville 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. Sausville 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 limited waiver permitting Edward Sausville, M.D., Ph.D., to participate in the committee's discussions, without voting, of pre-clinical requirements and phase I trial issues for the development of oncologic drug products.

For the following reasons, I believe that it would be appropriate for you to grant a limited waiver to Dr. Sausville.

First and foremost, this waiver is justified, in part, because of the general nature of the particular matters of general applicability to be discussed. 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. Sausville's personal financial interests, but rather may affect classes of similarly situated products and manufacturers to the same extent.

Second, this waiver is also justified because the Agency has a need for Dr. Sausville's services, in light of his expertise in biologics, new drug development and bringing new medicines and therapies out of the laboratory to patients. His participation will contribute to the diversity of views and expertise represented with respect to the particular matters of general applicability to be discussed.

Third, Dr. Sausville 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 the particular matters of general applicability under discussion.

Moreover, any conflict or appearance of a conflict will be further mitigated by the fact that FDA has decided to limit Dr. Sausville's participation. Under the terms of this limited waiver, Dr. Sausville will be permitted to participate in the committee's discussions concerning pre-clinical requirements and

phase 1 trial design issues for the development of oncologic products; however, he will be excluded from voting.

Please note that this limited waiver only allows Dr. Sausville's participation in the committee's discussions, without voting, of pre-clinical requirements and phase I trial issues for the development of oncologic drug products. It will not allow Dr. Sausville 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 Dr. Sausville from particular matters of general applicability to more specific matters (e.g., recommendations specific to an identified product), which could specifically affect Dr. Sausville's personal 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: _____ 2/24/06
Jenny Slaughter Date
Director, Ethics and Integrity Staff
Office of Management Programs,
Office of Management

DECISION:

✓ Limited 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.

_____ 2.27.06
Jason D. Brodsky Date
Acting Associate Commissioner
Office for External Relations
Food and Drug Administration