

**MEMORANDUM**

DATE: April 5 2005

TO: Sheila Dearybury Walcoff Esq.  
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 Kenneth I. Shine M.D.

Kenneth I. Shine 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 Kenneth I. Shine'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 Kenneth Shine 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 Kenneth Shine's participation in particular matters of general applicability. No such interest 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 committees recommendation such as ( \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_ ).
3. Grants, contracts, or other funding for research or other services received from the federal government that might be affected by Kenneth Shine's participation in particular matters of general applicability, No such interest currently report.
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 Kenneth Shine's 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 Kenneth Shine's participation in particular matters of general applicability. No such interest currently reported.
6. Any interest of a group or organization in which Kenneth Shine appointed as an officer, director, trustee, employee, or general partner that might be affected by Kenneth Shine's participation in particular matters of general applicability. No such interest currently reported.

As a special Government employee, Kenneth Shine 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, Kenneth Shine 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 Kenneth Shine 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 any of Kenneth Shine'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 Kenneth Shine's services, in light of his expertise in internal medicine, cardiology, and science administration. His participation will contribute to the diversity of views and expertise represented with respect to particular matters of general applicability.

Moreover, Kenneth Shine will be participating in an advisory capacity only. The Food and Drug Administration has sole

