

2. Employment with research institutions, state and local governments, pharmaceutical companies, health care industries, or other organizations that may be affected by Dr. Hussain'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. Hussain'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. Hussain's participation in particular matters of general applicability. (No interests currently reported).
5. Expert witness, litigation or advocacy services in matters that might be affected by Dr. Hussain's participation in particular matters of general applicability. (No interests currently reported).
6. Any interest of a group or organization in which Dr. Hussain is appointed as an officer, director, trustee, employee, or general partner that might be affected by Dr. Hussain's participation in particular matters of general applicability. (No interests currently reported).

As a special Government employee, Dr. Hussain potentially could become involved in matters that could affect her financial interests or the financial interests of persons and organizations whose interests impute to her under 18 U.S.C. §208. Under 18 U.S.C. §208, Dr. Hussain 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 Dr. Hussain 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. Hussain that would permit her 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 poses 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 Dr. Hussain'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 Dr. Hussain's services, in light of her expertise in the field of genitourinary cancer. Her participation will contribute to the diversity of views and expertise represented with respect to particular matters of general applicability.

Moreover, Dr. Hussain 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. Hussain to participate in any matters involving specific parties that may be affected by her financial interests, or the interests of any person or organization described above. When the matters in which Dr. Hussain 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. Hussain's personal and imputed financial

interests, the Food and Drug Administration will examine her interests in relation to the particular matter, and either obtain a specific waiver allowing him to participate, or exclude her from participating in the particular matter.

CONCURRENCE: Jenny Slaughter 11/7/05
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.
Sheila Dearybury Walcoff, Esq. 11-7-05
Sheila Dearybury Walcoff, Esq. Date
Associate Commissioner for
External Relations
Food and Drug Administration