



A PATIENT-CENTERED FORUM OF NATIONAL ADVOCACY ORGANIZATIONS ADDRESSING PUBLIC POLICY ISSUES IN CANCER

May 29, 2007

Filed Electronically

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane – Room 1061
Rockville, Maryland 20852

RE: Draft Guidance for the Public, FDA Advisory Committee Members,
and FDA Staff on Procedures for Determining Conflict of Interest
and Eligibility for Participation in FDA Advisory Committees;
Availability – Docket No. 2007D-0101

To Whom It May Concern:

Members of the Cancer Leadership Council (CLC)—cancer patients, providers and researchers—write to express support for the efforts of the Food and Drug Administration (FDA) to safeguard the integrity of the agency’s advisory committee deliberations and thus enhance public confidence in FDA drug review processes. However, we are concerned that, in several respects, the Draft Guidance goes too far by defining problematic financial interests on the part of prospective advisory committee members in a manner that may deprive the agency of vital scientific and medical expertise.

First, we question the propriety of equating the financial interests of large non-profit entities like academic medical centers or voluntary health organizations with those of individuals who are employees or board members or otherwise affiliated with such entities and who might be prospective advisory committee members. Limits on participation should be based on the financial interests of the individual, not on the quantum of funding to a non-profit institution with which the individual is affiliated. Given the financial realities of funding for clinical research, it is doubtful that many major academic institutions would not be affected by the \$50,000 limit, thus potentially disqualifying all their physician researchers from participation as advisory committee members. If this limit is not amended, there is a real risk that the pool of qualified experts appropriate for advisory committee service will be severely depleted.

Second, there is concern that the Draft Guidance might be read to impute industry funds provided to non-profit advocacy or educational organizations to individuals serving as officers or board members of such organizations. For medical societies, such an interpretation might mean

that none of its leadership could serve on advisory committees, which would unquestionably undermine the quality of advisory committee review. For smaller non-profit patient advocate organizations, it might deter engagement of highly qualified physician researchers from involvement with our organizations, which would be a crippling blow to efforts to attract top-quality leadership.

Neither of these problems is insoluble. The focus simply needs to be shifted from the institution to the individual. The quantum of funding to a large institution should have no bearing on the qualification of individual employees or board members unless a direct and personal impact on the individual can be identified.

We encourage FDA to revise its Draft Guidance to address these concerns, alleviating burdens on advisory committee participation by qualified individuals that lack direct and substantial personal financial interest in the matters before FDA advisory committees. It is important that the advisory committee process be free of inappropriate financial influence, but perhaps equally important that advisory committees have the benefit of guidance from highly qualified physician researchers who can lead FDA to the best results for patients dependent on the integrity of the agency's review processes.

Sincerely,

Cancer Leadership Council

American Psychosocial Oncology Society
American Society of Clinical Oncology
C3: Colorectal Cancer Coalition
Cancer Care
Cancer Research and Prevention Foundation
International Myeloma Foundation
Kidney Cancer Association
Lance Armstrong Foundation
The Leukemia & Lymphoma Society
Lymphoma Research Foundation

Multiple Myeloma Research Foundation
National Coalition for Cancer Survivorship
National Lung Cancer Partnership
North American Brain Tumor Coalition
Ovarian Cancer National Alliance
Sarcoma Foundation of America
Us TOO International Prostate Cancer
Education and Support Network
Y-ME National Breast Cancer Organization