C L C CANCER LEADERSHIP COUNCIL

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

May 27, 2005

Lester M. Crawford, D.V.M., Ph.D.
Acting Commissioner
Food and Drug Administration
5600 Fishers Lane – Room 1471
Parklawn Bldg. – Mail Stop – HF-1
Rockville, Maryland 20857

Dear Dr. Crawford:

The undersigned patient advocate, professional and research organizations support measures to make clinical research more efficient in service to people with cancer. We thus support the suggestions of the Food and Drug Administration (FDA) to facilitate the appropriate use of a central institutional review board (IRB) that might, whenever possible, replace the multiple, duplicative reviews conducted by local IRBs.

Research resources are limited, and needless duplication of effort has no place in a resource-constrained research system. Aside from cost concerns associated with duplicative local IRB review, such duplication can also interfere with accrual to trials and eventually lead to delays in access to potentially life-extending interventions.

In light of these considerations, FDA is appropriately seeking ways in which to streamline the research process through reduction of duplicative reviews. FDA has listed various reasonable means by which "local" issues can be taken into account in a centralized review. Though FDA's intention is clearly to assist the process of centralized review, IRBs need clear guidance concerning how to satisfy the perceived requirement of "local" review. For this purpose, a number of options is not as helpful as the delineation of one clear means of meeting the "local" review requirement.

Instead, we suggest that FDA provide a simple, clear and straightforward protocol for addressing local issues. Thus, if an institution decides that it wishes to utilize central review to the greatest extent possible, it could be allowed to complete a brief questionnaire indicating whether or not there are any issues peculiar to the local interests that require specific local attention. If the response indicates that there are no such local interests or issues, then the local IRB should be regarded as having discharged its obligations under the human subjects regulations.

We believe this relatively modest change in the Guidance could provide a stimulus to local IRBs to more frequently accept the appropriateness of centralized review. In addition, it would encourage more discussion about the continuing utility of requiring human subjects reviews to

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take into account local considerations in every clinical trial. In the age of the internet and other modes of rapid communication, it is worth questioning the usefulness of giving priority to local issues when most scientific and ethical issues cut across geographical boundaries.

Thank you for promoting consideration of these important issues by publication of the Draft Guidance, and we look forward to future Guidances that we hope will further the discussion of the cost-effectiveness and utility of centralized human subjects reviews.

Sincerely,

Cancer Leadership Council

Alliance for Lung Cancer
American Society of Clinical Oncology
American Society for Therapeutic Radiology & Oncology
Cancer Care, Inc.
Cancer Research and Prevention Foundation
International Myeloma Foundation
Kidney Cancer Association
The Leukemia & Lymphoma Society
Lymphoma Research Foundation
Multiple Myeloma Research Foundation
National Coalition for Cancer Survivorship
Ovarian Cancer National Alliance
Pancreatic Cancer Action Network
Sarcoma Foundation of America
Us TOO International Prostate Cancer Education and Support Network
The Wellness Community
Y-ME National Breast Cancer Organization