C L C CANCER LEADERSHIP COUNCIL

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

June 3, 2005

Filed Electronically and Via Telecopy

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

RE: Draft Guidance for Industry on Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics; Availability
[Docket No. 2005D-0112]

The undersigned members of the Cancer Leadership Council (CLC) advocate on behalf of cancer patients, providers and research organizations. We understand the importance of clear direction to sponsors of new drugs and biologics with respect to appropriate endpoints that will support approval of potentially life-extending therapies, and we believe that the draft Guidance is a major enhancement of the information available to sponsors, as well as to patients and health care providers. Despite the general usefulness of the draft Guidance, there are two areas in which the Guidance could be improved.

First, we believe that the discussion of "Endpoints Involving Symptom Assessment" is deficient in its failure to recognize the validity of certain patient-reported outcomes. Specifically, we are aware of patient-reported measures that have been validated and widely used to assess quality of life of cancer patients both during and after treatment. Even if these commonly accepted measures were not considered adequate for initial marketing approval of a new drug, certainly it would seem that they could be the basis for supplemental approvals or other means of communicating this important information in the product labeling. As we have said to FDA in many other contexts, more rather than less information is better for cancer patients and those who care for them.

Second, while we grasp the articulated rationale for placebo controls in some circumstances, and we even agree in the abstract with that reasoning, we are also aware that cancer patients desperately wish to avoid being randomized to "no-treatment," even if they are participating in a clinical trial. Given patient and provider preferences against placebo controls and their questionable ethical status, we contend that placebos for cancer patients should be avoided except in the most limited of circumstances. We agree, as the draft Guidance articulates, that in a relatively small number of cancers where there is no standard therapy for either early stage or refractory disease, a "best supportive care," or placebo, arm might be utilized in trials designed

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to demonstrate clinical benefit, specifically survival. But such trials should be commenced only after considering clinical trial design options that would not utilize a placebo control, and those trials that do include a placebo control should be carefully monitored for signs of meaningful activity in the investigational agent with rapid cross-over to treatment for those in the no-treatment group when warranted.

We very much appreciate the new openness reflected in this and other Guidances issued by the new Office of Oncology Drug Products, and we look forward to working with the agency to refine the draft endpoints Guidance to address our concerns.

Sincerely,

Cancer Leadership Council

American Cancer Society
American Psychosocial Oncology Society
American Society of Clinical Oncology
American Society for Therapeutic Radiology & Oncology
Cancer Care, Inc.
Cancer Research and Prevention Foundation
The Children's Cause for Cancer Advocacy
Fertile Hope
International Myeloma Foundation
The Leukemia & Lymphoma Society
Lung Cancer Alliance
Lymphoma Research Foundation
Multiple Myeloma Research Foundation
National Coalition for Cancer Survivorship
National Patient Advocate Foundation
National Prostate Cancer Coalition
North American Brain Tumor Coalition
Ovarian Cancer National Alliance
Pancreatic Cancer Action Network
Sarcoma Foundation of America
The Susan G. Komen Breast Cancer Foundation
Us TOO International Prostate Cancer Education and Support Network
The Wellness Community
Y-ME National Breast Cancer Organization

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