CANCER LEADERSHIP COUNCIL

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

March 20, 2007

Filed Electronically

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

RE: [Docket No. 2006N-0061] – RIN 0910-AF13
Charging for Investigational Drugs

AND

[Docket No. 2006N-0062] – RIN 0910-AF14
Expanded Access to Investigational Drugs for Treatment Use

To Whom It May Concern:

The undersigned organizations of the Cancer Leadership Council are writing to support the efforts of the Food and Drug Administration (FDA) to clarify the standards for sponsors to establish expanded access programs and the circumstances in which sponsors may charge for investigational drugs.

Cancer patient advocates support access to investigational therapies for those individuals who are not eligible for participation in clinical trials, but we have had reservations about the potential impact of such access on clinical trials participation. We believe the proposed expanded access rule defines standards for expanded access programs that balance the needs of individual patients and the requirement to maintain a strong clinical trials system.

We have heard complaints from some physicians that the process for securing individual patient access is a burdensome one, and we are also aware that patients are sometimes confused about the reasons they are not able to enroll in an expanded access program or obtain individual access. As the agency moves to implement its new rules, we urge that it consider ways to improve the communication to patients regarding the standards for expanded access and individual access and to alleviate the burdens of participation.

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We also support the proposed rule on charging for investigational drugs, which will provide specificity regarding the limits on charges for investigational drugs. This will restrain companies that might seek to commercialize their products prematurely but at the same time facilitate certain investigator-initiated trials exploring new uses of approved drugs. We note that FDA, the Centers for Medicare & Medicaid Services, and the National Cancer Institute collaborate on important matters related to the development of new cancer therapies. It would be useful for this collaborative federal effort to consider the reimbursement implications of this new rule and ensure there are no obstacles to Medicare payment for these investigational drugs.

We commend the agency for taking action on the issue of expanded access and look forward to the implementation of these new rules.

Sincerely,

Cancer Leadership Council

American Cancer Society
American Psychosocial Oncology Society
American Society of Clinical Oncology
Bladder Cancer Advocacy Network
Cancer Care
Cancer Research and Prevention Foundation
Gilda's Club Worldwide
Kidney Cancer Association
Lance Armstrong Foundation
National Coalition for Cancer Survivorship
National Prostate Cancer Coalition
North American Brain Tumor Coalition
Multiple Myeloma Research Foundation
Ovarian Cancer National Alliance
Us TOO International Prostate Cancer Education and Support Network
The Wellness Community
Y-ME National Breast Cancer Organization