



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

June 12, 2006

Via Telecopy

Andrew von Eschenbach, M.D.
Acting Commissioner
Food and Drug Administration
5600 Fishers Lane – Room 14-71
Rockville, Maryland 20857

Dear Dr. von Eschenbach:

On March 27, 2006, a Citizen Petition (attached) was filed with the Food and Drug Administration (FDA) to urge that the agency issue new guidance regarding the availability and contours of expanded access programs to allow access to unapproved drugs for patients not participating in clinical trials. The undersigned organizations write to express their support for the recommendations contained in the Citizen Petition and to encourage FDA to act promptly to issue the recommended guidance.

We believe that the Citizen Petition, submitted by the National Coalition for Cancer Survivorship (NCCS) and American Society of Clinical Oncology (ASCO), strikes the appropriate balance between expanding access to unapproved therapies and preserving the important role of clinical trials in determining the safety and efficacy of new drugs. The proposed guidance emphasizes the sufficiency of current legal and regulatory authorities to support meaningful expanded access programs while pointing out ways in which patients, providers and sponsors can be better educated about the opportunities and responsibilities associated with those programs. Responsible and responsive expanded access programs give hope to patients without undermining the central role of clinical trials in the drug development process.

Andrew von Eschenbach, M.D.

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For the benefit of patients with cancer and other life-threatening diseases, please move expeditiously to implement the recommendations contained in the March 27 Citizen Petition. Thank you for your personal attention to this important initiative.

Sincerely,

Cancer Leadership Council

American Psychosocial Oncology Society
American Society of Clinical Oncology
Bladder Cancer Advocacy Network
Cancer Care
Cancer Research and Prevention Foundation
The Children's Cause for Cancer Advocacy
Coalition of Cancer Cooperative Groups
Fertile Hope
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 Prostate Cancer Coalition
North American Brain Tumor Coalition
Ovarian Cancer National Alliance
Pancreatic Cancer Action Network
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

Enclosure