



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

June 25, 2008

Andrew von Eschenbach, MD
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Dr. von Eschenbach:

The undersigned cancer patient advocacy, provider and research organizations are writing to express our concern regarding the delay of the Food and Drug Administration in issuing final rules on expanded access programs and limits on charging for investigational products (Docket Nos. 2006N-0061 and 2006N-0062). The proposed rules were published more than a year ago, on December 14, 2006, and the comment period closed on March 14, 2007. Once again, the Cancer Leadership Council strongly supports and eagerly anticipates the prompt issuance of these rules in final form.

The adoption of the expanded access program outlined in the proposed rule would be responsive to the needs of cancer patients seeking access to investigational treatments. Moreover, the rule on charging for investigational drugs will enhance patient opportunities to access those new products and to participate in clinical trials. We do not understand why the agency does not move expeditiously to finalize these measures.

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We request your personal attention to publication, without further delay, of the final rules regarding these important matters. Thank you in advance for your assistance in this regard.

Sincerely,

Cancer Leadership Council

American Cancer Society Cancer Action
Network
American Psychosocial Oncology Society
American Society of Clinical Oncology
Bladder Cancer Advocacy Network
Breast Cancer Network of Strength
C3: Colorectal Cancer Coalition
Cancer Care
Children's Cause for Cancer Advocacy
Coalition of Cancer Cooperative Groups
Gilda's Club Worldwide
International Myeloma Foundation

Kidney Cancer Association
The Leukemia & Lymphoma Society
Lymphoma Research Foundation
National Coalition for Cancer Survivorship
National Lung Cancer Partnership
North American Brain Tumor Coalition
Ovarian Cancer National Alliance
Prevent Cancer Foundation
Sarcoma Foundation of America
Us TOO International Prostate Cancer
Education and Support Network
Wellness Community

cc: The Honorable Mike Leavitt

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