

ALLIANCE FOR CHILDHOOD CANCER

06-6657

August 9, 2006

Alliance Members

Co-Chairs

Craig Lustig, MPA
The Children's Cause for
Cancer Advocacy

Mary Jo Kupst, PhD
Society of Pediatric Psychology

American Academy of
Pediatrics

American Cancer Society

American Pediatric
Surgical Association

American Psychological
Association

American Society for
Therapeutic
Radiology/Oncology

American Society of
Clinical Oncology

American Society of Pediatric
Hematology & Oncology

Association of Pediatric
Oncology Nurses

Association of Pediatric
Oncology Social Workers

Cancer Research and
Prevention Foundation/ Hope
Street Kids

Candlelighters Childhood
Cancer Foundation

Craig Lifeline

Children's Brain Tumor
Foundation

Children's Oncology Group

CureSearch National Childhood
Cancer Foundation

Lance Armstrong Foundation

National Children's Cancer
Society

National Coalition for
Cancer Survivorship

Patient Advocate Foundation

Pediatric Brain Tumor
Foundation

Sarcoma Foundation of America

The Children's Cause for
Cancer Advocacy

The Leukemia & Lymphoma
Society

The Wellness Community

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

Dear Dr. von Eschenbach:

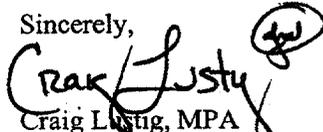
The Alliance for Childhood Cancer is an informal coalition of non-profit organizations that advocates on behalf of children with cancer. As such, the Alliance is intensely interested in federal government policies that affect issues relating to access to new therapies for childhood cancer and the integrity of the clinical trials system that affirms the safety and efficacy of those therapies. We write to bring to your attention a Citizen Petition filed with the Food and Drug Administration (FDA) on March 27 of this year.

The petition was submitted to FDA by the American Society of Clinical Oncology (ASCO) and the National Coalition for Cancer Survivorship (NCCS) to request new guidance from the agency concerning the circumstances in which expanded access programs might be appropriate to provide access to cancer patients and others with life-threatening diseases. We endorse the ASCO/NCCS Citizen Petition and urge your favorable consideration of its recommendations.

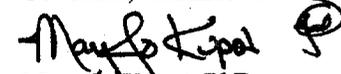
While we appreciate the value of the expanded access programs that will be facilitated through the Citizen Petition, we believe it is also important to recognize that some childhood cancers are so rare that they may never practically be eligible for an organized expanded access protocol. For those who present with highly individualized circumstances, including children with extremely rare cancers, the "compassionate use" option remains important. Therefore, just as FDA should clarify the pathway for expanded access programs, as articulated in the Citizen Petition, the agency should also make a concerted effort to educate patients and providers about compassionate use access and, if consistent with ongoing clinical trials, encourage industry to be responsive to requests for such access.

We look forward to your prompt action to adopt the recommendations included in the March 27 Citizen Petition and in this letter.

Sincerely,



Craig Lustig, MPA
Children's Cause for Cancer Advocacy
Co-Chair, Alliance for Childhood Cancer



Mary Jo Kupst, PhD
Society of Pediatric Psychology
Co-Chair, Alliance for Childhood Cancer