



AMERICAN SOCIETY OF CLINICAL ONCOLOGY



NATIONAL COALITION  
FOR CANCER SURVIVORSHIP

*The power of survivorship. The promise of quality care.*

October 5, 2007

Andrew C. von Eschenbach  
Commissioner  
Parklawn Building  
5600 Fishers Lane  
Rockville, MD 20857

Dear Dr. von Eschenbach:

As you know, there has been considerable media attention recently to the question of patient access to unapproved cancer drugs, including your own description of Food and Drug Administration (FDA) policy in that regard (*USA Today*, August 21, 2007). Cancer patients are understandably eager to have access to new treatment options, and their physicians support that desire so long as it does not jeopardize the effort to demonstrate the safety and efficacy through clinical trials.

The American Society of Clinical Oncology (ASCO) and the National Coalition for Cancer Survivorship (NCCS) jointly submitted a citizen petition in early 2006 to encourage FDA to clarify and consolidate existing authorities for expanded access to make the opportunities more comprehensible for patients, providers and pharmaceutical sponsors. We sought from FDA a more detailed and straightforward description of the standards and processes that might apply to potential expanded access programs.

We were pleased when FDA issued a proposed regulation in December 2006 that, if adopted, would make significant progress toward that end without posing substantial challenges to clinical trial accrual (Docket No. 2006N-0062). The proposal was published December 14, 2006, and comments were required to be submitted by March 14, 2007. The comments were generally supportive, despite concerns expressed by some that the proposed regulation did not go far enough in enhancing access.

At this time, we are writing to direct your attention once again to the urgency of this need. We encourage you and your colleagues at FDA to move expeditiously to finalize and publish the regulation governing expanded access so that patients, providers and sponsors may enjoy greater clarity regarding opportunities and obligations in this program.

Thank you for your immediate attention to this important matter.

Sincerely,

A handwritten signature in black ink that reads "Joseph S. Bailes".

Joseph S. Bailes, MD  
Chair, ASCO Government Relations Council

A handwritten signature in black ink that reads "Ellen L. Stovall".

Ellen L. Stovall  
NCCS President and CEO