



**SARCOMA FOUNDATION OF AMERICA**

**P.O. Box 458**

**Damascus, Maryland 20872**

**301-520-7648**

[www.curesarcoma.org](http://www.curesarcoma.org)

November 12, 2003

Dr. Mark McClellan  
FDA Commissioner  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

**RE: Citizen's Petition - Docket No. 2003P-0274/CP1**

Dear Dr. McClellan:

I am writing to you to express our organization's support for the petition asking you to implement the Tier 1 Initial Approval concept. We need immediate, effective action from the Food and Drug Administration to improve access to "investigational" drugs for terminally-ill patients. The Tier 1 Initial Approval concept and the other proposed regulatory changes proposed in the petition represent a reasonable and workable approach for addressing this critical issue.

As patients with a rare cancer, we sympathize with the thousands of Americans who cannot gain access to promising cancer drugs under development because they do not meet the clinical trial criteria for a promising therapy under development. For example, since sarcoma is not a profitable cancer for drug companies, it is rarely the cancer population chosen in a drug company's clinical development plan for intended licensure of a new therapy.

So essentially all rare cancer patients are shown the back of the bus when a new drug comes along. Only when the product is marketed can we gain access to the new agent. Iressa is a good example. Several sarcoma subtypes have EGFR on their cell surface, and thus might be a target for an EGF based therapy. Instead of gaining access to this agent when it began to show promise in clinical trials, sarcoma patients with EGF positive tumors had to wait critical months for access.

Having a tightly regulated program that would allow both clinical trials to occur in large patient groups, and allow other patients to exercise their constitutional rights to privately weigh benefits

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and risks, and to choose the health care for their own situation (the Abigail Alliance Tier 1 proposal), seems like a win-win proposition.

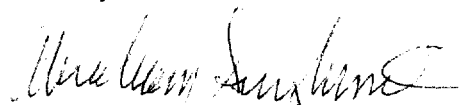
We appreciate how provocative the proposal is, but feel with thousands of Americans dying each day (a World Trade Center loss to the country every other day), and with targeted therapies becoming the norm in cancer drug development, and with future trends towards individualized cancer therapy, important historical trends have merged that demand serious thought be given to proposals such as those ventured by the Abigail Alliance.

Certainly if Tier 1 is not the solution, the FDA must come up with a better mechanism than currently exists to allow a cancer patient to have a chance for life. The image of an overwhelmed cancer patient and his/her family having to embark on coordinating negotiations and communications between a drug company and the government, and finding an oncologist willing to expend enormous time to attempt gaining this access, is the reason patients give up on trying to gain access after a promising Phase I study.

In the absence of internal FDA initiatives, the Citizen's Petition provides the FDA with an opportunity to fix its well-intentioned but unfortunately inadequate policies and regulations that have fallen far short of filling the legitimate need of Americans suffering from life-threatening diseases. A system that denies many thousands of Americans each year access to new treatments that offer the most promise for improving, extending and even saving their lives must be changed. We must stop abandoning the people that need our help the most.

The Sarcoma Foundation of America supports the efforts of the Abigail Alliance for Better Access to Developmental Drugs on behalf of underserved cancer patients. Please act now to address this health care emergency - approve Citizens Petition 2003P-0274/CP1.

Sincerely,

A handwritten signature in black ink, appearing to read "Abraham Sunshine". The signature is fluid and cursive, written over a white background.

Abraham Sunshine, M.D.  
Vice-President