

3907 Bentwood Ct.  
Fairfax, VA 22031

Dockets Management Branch  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061, HFA-305  
Rockville, MD 20852  
Attn: Dr. Mark McClellan

8812 '03 DEC -4 A9:58

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

Dear Dr. McClellan:

I am writing to you to express my 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.

My friend, Mike Steele, died of colon cancer in August. Who knows how differently things might have turned out for him -- and all of us who knew him -- if he had had access to Erbitux or Avastin?

The Citizen's Petition provides the FDA with an opportunity to fix its well-intentioned but clearly inadequate policies and regulations that have fallen far short of filling the legitimate need of Americans suffering from life-threatening diseases. It is unacceptable to deny many thousands of Americans each year access to new treatments that offer the most promise for improving, extending and even saving their lives. We must stop abandoning the people that need our help the most.

I support the efforts of the Abigail Alliance for Better Access to Developmental Drugs and the Washington Legal Foundation. Please act now to address this health care emergency. Approve Citizens Petition 2003P-0274/CP1.

Sincerely,

  
Carla Brown

2003P-0274

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