

COPY OF LETTER FOR ADDITON TO:

FDA Docket #: 2003P-0274/CP1

2625 '03 DEC 15 P3:46
Carole E. Steele
3501 Blair Rd.
Falls Church, VA 22041
[Date]

Mark B. McClellan, MD, PhD
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. McClellan:

My husband has Stage IV colon cancer, and I am writing to urge FDA to do everything possible to make Erbitux and Avastin widely available, as soon as possible, to patients like him. Like many others, we are running out of alternatives.

We fully appreciate FDA's caution in approving drugs aimed at non-life-threatening conditions, but it is very frustrating to see the agency's lack of flexibility in addressing our circumstances. Please use your existing authority to implement Tier One Initial Approval as proposed by the Abigail Alliance for Better Access to Developmental Drugs. According to the presentation by the Alliance-FDA Advisor Steve Walker at the March 12 meeting of FDA's Oncologic Drugs Advisory Committee, "If [Erbitux] was available the statistics for colon cancer patients would change."

I believe hundreds of thousands of lives, perhaps including my husband's, could be saved or extended if FDA would adopt a greater sense of urgency about life-threatening conditions when other options have been exhausted.

By copy of this letter, I am urging my representatives in Congress and the Secretary of Health and Human Services to add their voices to the effort to implement Tier One Initial Approval, especially since there is no reason not to do it. It would benefit public officials, drug companies and above all, cancer victims, and would hurt no one.

Thank you.

Sincerely,

Carole E. Steele

cc:
Sen. George Allen
Rep. Thomas M. Davis III
Sen. John W. Warner
Secretary Tommy G. Thompson

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