



Abigail Alliance for Better Access to Developmental Drugs

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Letter to FDA Docket #: 2003P-0274/CP1

December 15, 2003

To: Dr. Mark McClellan, FDA Commissioner

From: Frank Burroughs, President, Abigail Alliance

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12/15/03

After more than two years of efforts to spur meaningful dialogue and action at the FDA regarding better access to developmental drugs and after presenting the Abigail Alliance initiative, Tier 1 'Initial Approval' to Dr. Mark McClellan, advocacy groups, and the public, on behalf of tens of thousands of cancer patients and others with life threatening illnesses, the Abigail Alliance filed the FDA Citizens Petition in June of this year.

Although there were several meetings with the FDA including at the highest levels on the issue, no action of any sort has been taken to address the vital issue of getting promising new drugs to the many precious people who have run out of options in their battle to live. This is nothing short of a tragedy. We remain puzzled and disappointed at the FDA's continuing lack of interest in addressing this massive problem.

Representative Dan Burton conducted a hearing way back on June 20, 2001 to highlight the plight of patients that cannot get into clinical trials for drugs that show early efficacy and safety, and that offer a significant chance of saving or extending their lives. Two FDA officials and several patient advocates (including me) testified at the hearing. In the two and a half years since, no action has been taken by the FDA.

Although there are some major organizations that have filed letters to the FDA docket opposing 'Tier 1 Initial Approval', there are many organizations and individual patients that support this vital initiative. As pointed out in Abigail Alliance letters in response to the letters opposing 'Tier 1 Initial Approval', there are incorrect statements in those letters and a general lack of understanding of the initiative.

What is most important is that the voice of patients fighting for their lives is finally heard, and that meaningful action is taken. Just a few of these individual stories are clearly brought out in letters sent by patients and family members describing their battles for life and the regulatory hurdles that prevent them from succeeding.

Action to address these problems is long past due. Supporting the status quo does nothing to help these tens of thousands of people. I am old enough to remember the long and difficult struggle of the Civil Rights Movement. For decades across the country, nothing was done to address racial inequities and many worked feverishly to obstruct progress. Some opposed that progress solely because they feared change. It took many decades, but the changes eventually came when enough individuals found the strength to demand them, and heroic elected and appointed leaders supported those demands. We are a much improved society as a result. The issue of people fighting for their lives is also a vital civil rights issue. We are now demanding change and waiting to find out if we have the heroic leaders needed to support it.

You have been presented with an opportunity. We hope you have the courage and vision to act on it.

Frank Burroughs

President, Abigail Alliance for Better Access to Developmental Drugs



Washington Capitals Hockey Team-proud supporter of the Abigail Alliance

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