



Myth Buster



Abigail Alliance's Efforts to Save and Extend Lives - Countering the (few) Powerful Opposition's Misinformation

A **few** politically and financially powerful Abigail Alliance opponents, such as ASCO (American Society of Clinical Oncology) and the NCCS (National Coalition for Cancer Survivorship), are using incorrect information to oppose the lifesaving and life-extending efforts of the Abigail Alliance. The record needs to be set straight about the efforts of the Abigail Alliance and our many patient advocate allies.

- **A few power organizations are blocking** the efforts on behalf of patients fighting for their lives. Thousands of lives are being lost. Our opponents sadly ignore this fact. **Every drug for cancer and other serious life-threatening illnesses that the Abigail Alliance has pushed for earlier access to in our six-year history is now approved by the FDA!** Not one drug that the Abigail Alliance pushed for earlier access to was rejected by the FDA.
- **Opponents for some time have been using one (only one) bogus example** regarding safety concerns with earlier access to cancer drugs and other drugs for serious life-threatening illnesses. Particularly the NCCS and the NBCC (National Breast Cancer Coalition) keep using an example **that has nothing to do with earlier access to promising developmental drugs.** The example they use has to do with an **accepted** medical procedure and three **FDA approved** cancer drugs that was practiced a few years ago and found to have serious problems for some patients. **This complex treatment was not initially closely scrutinized as are developmental drugs in the clinical trial process.** There have been no serious problems with the drugs the Abigail Alliance has pushed for earlier access to in our six-year history. Also, there have been no serious problems with investigational drugs that the alliance is currently pushing for earlier access.
- **Many breast cancer patients fighting for the lives** have been denied access to cancer drugs that showed early safety and efficacy. The most recent breast cancer drug the Abigail Alliance pushed for earlier access to is Tykerb, which is now, sadly later rather than sooner, now approved by the FDA.
- **Some in the pharmaceutical industry harbor the myth** that early access to lifesaving and life-extending drugs could hurt the chances of their drugs being approved by the FDA.

But former FDA Commissioner Dr. Lester Crawford reported:

“The FDA, categorically, does not attach special significance to adverse events reported from such expanded access programs as [one critic] has tried to join. We recognize that these programs involve less-controlled use of new drugs, and we assess the reported data accordingly. The development of a new medication is not slowed by side effects occurring outside clinical trials.”

At the first Abigail Alliance meeting with the FDA in August 2001 the Abigail Alliance asked a dozen knowledgeable FDA staffers, “Has a drug for cancer that was successfully going through the clinical trial process ever been rejected by the FDA, because of data outside the clinical trials (e.g. an expanded access program)? The answer was, “We are not aware of this ever happening.”

• **Another myth that is propagated** by a few factions is that the changes being moved forward by the Abigail Alliance would hurt clinical trial enrollment. **This is incorrect.** Clinical trial enrollment would be enhanced. Removing unnecessary and unethical placebos from clinical trials for cancer and other serious life-threatening illnesses would remove the roulette wheel factor that keeps many patients from enrolling in clinical trials. Removing this enrollment barrier would speedup clinical trial enrollment, save developmental costs, and speedup approval.

For six years the Abigail Alliance has clearly put forth that patients would first have to try and enroll in a clinical trial before being eligible for early access.

With many patients not knowing where to find clinical trials, the Abigail Alliance has successfully moved the NIH to add the website information www.clinicaltrials.gov to their plethora of print media advertisements for specific clinical trials, and we are working to get pharmaceutical companies to do the same in their advertising.



• **A few opponents say** that only the rich would have earlier access to new promising investigational drugs. There are very good answers to this. The first is, **if we only have enough life boats to save the women and the children, should everyone go down with the ship?** Another important point is that the pharmaceutical industry provides some help to people who cannot afford approved drugs, and we are certain this would continue if there was earlier access.

One example of the efforts of the Abigail Alliance helping the poor and elderly can be seen in the efforts put forth at the CMS (Center for Medicare and Medicaid):

<http://www.abigail-alliance.org/CMS%20coverage%20analysis%20comments.pdf>

• **It is often said by some that the FDA is the gold standard**, but many are calling for lifesaving and life-extending changes at the FDA. The Abigail Alliance and many others have been saying for quite a few years now that the FDA needs to be using modern scientific and statistical tools. The Abigail Alliance and many others have for some time supported pushing the FDA modernization effort forward, Critical Path Initiative (<http://www.c-path.org>). These changes can cut the extremely high drug development costs for cancer drugs and other drugs for life-threatening illnesses. The modern tools that exist today must be used by the FDA, since these tools reveal much earlier drug efficacy.

• **Some have issued misinformation to the public** saying that the Abigail Alliance is pushing for “a free for all” by incorrectly saying that all drugs would be available right after Phase I clinical trials begin. This too is incorrect. The Abigail Alliance is saying there needs to be early access to promising new cancer drugs and other drugs for serious life-threatening illnesses **as early as the completion** of Phase I trials, when there is **compelling evidence** of efficacy, as was the case with the gripping efficacy of Gleevec for CML leukemia and Erbitux for head and neck cancer by the end of these two Phase I trials.

• **It is often said by opponents** that only the FDA should decide what is best for the public. The Abigail Alliance and many others say that the decision to use investigational drugs should be the **decision of the patient in consultation with his or her doctor**. What does the public want? The public wants earlier access as is clearly revealed in a recent extensive poll by the National Consumers League (http://www.nclnet.org/news/2006/chronic_disease_survey_03062006.htm).