



Highlights of Abigail Alliance Accomplishments

- In 2009, with much Abigail Alliance time invested and unfortunately with the FDA falling far short of the reform measures needed, FDA issued new regulations that may slightly increase the number of people per year who gain access to developmental drugs and vaccines. While the FDA failed to implement substantive changes in its programs, the agency did acknowledge that its programs don't work very well and hoped that clarifying its policies and procedures would result in a small increase in the availability of investigational drugs to patients with serious and life-threatening diseases and no remaining approved treatment options. Of course, this is in the plus column and would not have happened without our efforts. We will continue to work to get more substantive and effective changes from the FDA.
- The Abigail Alliance continued to be the rallying point for individuals and organizations that understand the vital need for much needed change. More friends and allies have been added in 2009, as the Abigail Alliance continues to work to help patients with cancer, Alzheimer's, ALS, MS, Parkinson's, and other serious and life-threatening illnesses.
- The Abigail Alliance continues to elevate the visibility of the critical need for better access to developmental drugs, with coverage of the issue in all forms of media, including medical journals.
- We continue to provide patients with information, emotional support and one-on-one assistance in their efforts to gain access to the investigational medical treatments they and their doctors deem to be the most medically appropriate for their situation.
- In 2002 the Abigail Alliance developed the 'Tier 1 Initial Approval' ('Tier 1') proposal that would greatly increase access to developmental drugs for tens of thousands of cancer patients and others with life threatening illnesses. In 2005 this effort resulted in the introduction of the Access, Compassion, Care, and Ethics for Seriously Ill Patients Act (ACCESS Act). The ACCESS Act has been improved and was reintroduced in June 2008 as S.3046 and H.R. 6270. The sponsors of the bill plan to reintroduce the bill with bipartisan support in the current Congress this fall or early in 2010.
- The Abigail Alliance is the only organization working to make expanded access programs more common and more accessible for patients with cancer and other life-threatening illnesses.
- Beginning in 2001 the Abigail Alliance successfully got the NIH to start keeping www.clinicaltrials.gov more up to date. Back in 2001 the Abigail Alliance also began to address the fact that many companies were not listing their clinical trials on www.clinicaltrials.gov. In 2001 the compliance rate was 25 to 30 percent. The Abigail Alliance working with the FDA and the NIH stayed on top of this problem. In 2009 it was announced that the compliance rate was now close to 100 percent.
- We continue to promote ways to better inform the public about clinical trials. Because of the efforts of the Abigail Alliance, the NIH now does a better job of promoting the vital website www.clinicaltrials.gov where patients and families can find detailed information about ongoing clinical trials..
- Working one on one with individual patients, sponsors and the FDA, we have been able to get some patients who were benefitting from an investigational drug in a clinical trial, back on the drug after they were dropped from the study due to protocol rules or other procedural issues. We have also helped patients gain access to promising investigational drugs through FDA's compassionate use program (called single-patient access).
- We continue to press for faster FDA review and approval of new life saving and extending drugs.
- With other organizations, we continue to push the FDA's 'Critical Path Initiative' towards reality, and are weighing in regularly in the media and communications with the FDA, the pharmaceutical and biotech industries, other patient groups and the clinical research community on the need to accelerate the scientific modernization of our drug development process. Our recommendations are focused on catching FDA's regulatory science up with the rapidly expanding scientific knowledge of disease biology, and the need to better align our clinical research methods with the medical needs of the patients participating in clinical trials.
- In 2007 we began working with the FDA Deputy Commissioner for Policy on improving the advisory committee selection process to better represent patients, and to provide more balanced advice to the FDA regarding its approval criteria and decisions. So far this has resulted in some positive changes for patients, but considerable work remains to be done in this area to bring the perspectives of real patients more clearly into FDA's view.
- After four years of effort, three prominent doctors and friends of the Abigail Alliance have been invited to apply for Special Government Employee status at FDA, which will enable them to serve as members of the FDA's Oncologic Drug Advisory Committee.

- From the efforts of the Abigail Alliance, in October 2009 the FDA opened up eligibility (increased access) of the Phase III trial for the lung cancer vaccine Lucanix.
- In November 2009 we joined a study with BIO (biotechnology industry trade group) regarding better expanded access and the related ethical issues.
- In late 2009 was part of the FDA beginning to allow the kinds of drug testing needed for development of effective Hepatitis C virus treatment for people with hemophilia.

