

## **Abigail Alliance supports ACCESS Act**

Brownback legislation would save lives and protect research

ARLINGTON, Virginia, November 10, 2005 -- The Abigail Alliance for Better Access to Developmental Drugs is proud to stand with Senators Brownback and Inhofe in helping to save patient lives, protect clinical trials, and catalyze new innovation in data-collection methods affecting serious and life-threatening diseases. The ACCESS (Access, Compassion, Care, and Ethics for Seriously Ill Patients) Act, S.1956, is an important step toward making regulatory policy work for dying patients.

The new avenues of access provided in the ACCESS Act are similar to the conditional approval provisions of the Abigail Alliance's "Tier 1" citizens' petition, which was made in June of 2003 and still awaits a response. However, the Act improves on our original proposal substantially, taking into account the objections made by part of the cancer community.

### **Saving Patient Lives**

The Abigail Alliance represents the family and friends of thousands of patients who have lost an oft-repeated battle: they exhausted all possible treatment for their disease; they knew that a drug existed that could help extend their life; they were ineligible for any clinical trial studying the drug; and the pharmaceutical company sponsoring the drug could not provide an Expanded Use or Treatment IND program to allow them access. The ACCESS Act ends this problem. It allows patients to receive these investigational treatments, with the same important safeguards that are in place for other recipients of the same drugs.

### **Protecting Clinical Trials**

Clinical trials are essential to final confirmation of a treatment's efficacy and safety, and the ACCESS Act protects enrollment in clinical trials. It requires patients to have exhausted approved treatment options for their disease, including clinical trials and expanded use programs, before they are eligible for access to a drug under Tier 1.

### **Improving Clinical Trial Accrual**

The ACCESS Act also takes an important step in improving enrollment in clinical trials studying serious diseases: it bans the use of placebo and no-treatment arms on trials affecting this vulnerable population. This provision would force the research community and HHS to accelerate the woeful progress in defining modern data collection methods, including electronic health records and tumor registries. Modern methods would provide a more substantial body of evidence regarding current standards of care, and end the need to repeatedly measure disease progression and survival times of untreated patients. This ethically-questionable practice is among the largest barriers to patients who would otherwise willingly enroll in a clinical trial.

### **Placing Risk Calculations Where They Belong**

Current law and policy centralizes risk-benefit decisions regarding new treatments. One decision is made, based on statistical considerations such as average response rates and median survival times, and that decision affects all patients with the

disease regardless of their disease status or personal situation. This policy does not take into consideration the varying circumstances of different patients who, faced with only death, possess the intelligence and right to make an informed decision regarding all existing options. The ACCESS Act, while requiring FDA approval of likely benefit, returns this important decision to patients, in consultation with and under the care of their physicians. These patients are required to give their fully informed consent in writing before receiving treatment.

### **Providing for True Cost Recovery**

Most investigational drugs for life-threatening illnesses are sponsored by small, unprofitable bio-tech firms who rely on outside capital to survive. While it would be immoral for industry to reap windfall profits from these vulnerable patients, current policy does not even provide enough revenue to cover the fixed costs of creating and administering a large-scale expanded use program, including the necessary manufacturing capability. In addition, one affect of current policy is that data collected in these programs can only be held *against* the drug's approval, and cannot be used to support it. Therefore most companies, especially small ones, don't bother with these programs without substantial pressure from organizations such as ours. The ACCESS Act removes these strong disincentives to saving lives.

We recognize the economic inequity implications of providing commercial access to a drug that insurers may not cover, but we also recognize the incredibly charitable hearts of the American people, and the fundraising that occurs when a member of a community faces such a decision. This situation occurs today with many off-label uses of existing drugs, and those patients, supported by their families and communities, rise to the challenge. Our members, none of whom are exceptionally wealthy, would have been eager to raise those funds for their loved one if given the chance.

### **Remembering the Patients**

This year, the Abigail Alliance lost many close friends, including Kianna Karnes of Indiana, Kay Houk of Texas, and Beth Grubesich of Missouri, who all faced this battle and were denied the right to exhaust all existing options. We urge Congress to pass the ACCESS Act, so that we may prevent these tragedies in the future.

### **About the Alliance**

The Abigail Alliance for Better Access to Developmental Drugs was founded by 21-year-old Abigail Burroughs and her father Frank, prior to Abigail's death from head and neck cancer in June of 2001 and six months before the FDA's controversial refusal to approve Erbitux. Despite compelling evidence of its efficacy, Erbitux remains unapproved for head and neck cancer today, and the disease claims 11,000 lives every year.

The Abigail Alliance is a 501(c)3 organization that is supported entirely by individual donations, and neither solicits nor accepts financial support from the pharmaceutical industry.