



A Right to Access Unapproved Experimental Drugs? Abigail Alliance Battles the FDA for a New Constitutional Right

(previously published in the *Mississippi Medical News*)

By: Kathryn R. Gilchrist and Sara Love Swaney

ADAMS AND REESE LLP

In November 2001, Frank Burroughs founded the Abigail Alliance for Better Access to Developmental Drugs in response to the death of his 21-year-old daughter, Abigail, who had unsuccessfully tried to obtain the drugs cetuximab (Erbix) and gefitinib (Iressa) to treat her squamous cell carcinoma of the head and neck. Abigail's oncologist at Johns Hopkins recommended either of the two drugs because her tumor was rich in epidermal growth factor receptors and both drugs inhibit those receptors. A rare cancer called for a rare treatment. Abigail did not meet inclusion criteria for the gefitinib trials, and the cetuximab trial was restricted to patients with colon cancer.

Ordinarily, investigational drugs may be used only within a controlled drug trial, but under the "compassionate use" policy the FDA may approve the use of an investigational drug outside of clinical trials for life-threatening diseases when (1) there is no comparable treatment alternative, (2) clinical trials of the drug are underway, and (3) formal FDA approval is underway. The FDA may also deny compassionate use if the scientific evidence does not provide a reasonable basis to conclude that the drug may be effective for its intended use.

Abigail Alliance took issue with the FDA policy and criticized it for unduly restricting the scope of the compassionate use program. The Alliance claimed that the FDA's policy imposed market limits on drugs still in development and effectively led to an inadequate supply of compassionate use drugs. When the FDA did not respond to the Alliance's complaint, the Alliance filed a lawsuit against the FDA in federal court.

In a surprising decision last May (2006), a three judge panel of the U.S. Court of Appeals for the District of Columbia held that terminally-ill, mentally competent adults, with no reasonable alternative to government-approved treatment options, have a constitutional right to access potentially life-saving drugs. The court said that FDA's bar on allowing terminally ill patients to use the investigational new drugs at issue impinges on the "right of self-preservation." The FDA requested a rehearing before the full nine-judge panel of the DC Circuit Court of Appeals, and the court granted their petition to rehear the case. The decision could come down any day.

If the court affirms the panel decision, and says there is a right to unapproved experimental drugs, this case would fundamentally challenge the government's system for evaluation drugs and could reshape the regulation and sale of pharmaceuticals for the future. Further, even if the panel decision isn't upheld, (i.e., the D.C. court ultimately concludes there is no right to experimental drugs), many healthcare professionals believe Abigail Alliance's campaign will nonetheless result in greater access to experimental drugs. Regardless of the outcome, many observers applaud Abigail Alliance for highlighting the struggle to balance the desires of sick people for cutting edge treatments with society's need for scientific evidence of safety and efficacy.

The lawsuit is only one component of Abigail Alliance's campaign to change FDA policy. In November of 2005 Senator Sam Brownback (R-Kan.) introduced a bill called the ACCESS (Access, Compassion, Care and Ethics for Seriously-Ill Patients) Act, S.1956. Under Senator Brownback's proposal, an experimental drug could obtain "Tier 1" approval on the basis of Phase One testing and preclinical evidence (from testing in animals, computer modeling, or pharmacologic studies) and could be marketed for seriously ill patients who had exhausted other treatment options. The bill alarmed the clinical research community because of a fear that the market would be flooded with drugs that were not known to be effective, and the 109th Congress ended without any action taken on the legislation.

More recently, however, on December 11, 2006, the FDA itself announced proposed regulations designed to expand access to experimental drugs (see 71 Fed. Reg. 75, 147 (Dec. 14, 2006)). The regulations address many of the Alliance's demands, but thus far the Alliance has not commented publicly.

The case of *Abigail Alliance v. von Eschenbach* presents a host of challenging contemporary health policy tensions: drug safety at the limits of scientific knowledge, the role of markets versus that of regulators, appropriate medical care for terminally ill patients, and individual rights versus the protection of public health. As we wait to hear a decision from the DC Circuit Court, we should ponder the broad public policy and clinical implications at issue in *Abigail Alliance*.

Kathryn R. Gilchrist is an attorney with Adams and Reese LLP's healthcare practice group. Sara Love Swaney is co-chair of the Student Health Law Association at University of Mississippi Law School where she is a second year student.