



January 14, 2008

## **COURT DECLINES TO CONSIDER WHETHER TERMINALLY ILL PATIENTS HAVE RIGHT OF ACCESS TO EXPERIMENTAL DRUGS**

*(Abigail Alliance v. von Eschenbach)*

The U.S. Supreme Court declined today to take up the issue of whether terminally ill patients have a “fundamental right” – protected by the U.S. Constitution – of access to experimental drugs that have not yet been fully approved by the Food and Drug Administration (FDA). The decision was a setback for the Washington Legal Foundation (WLF), which filed the petition for review on behalf of itself and the Abigail Alliance for Better Access to Developmental Drugs, a patients-rights group.

The court's action marks the latest chapter in a five-year WLF effort to establish rights for terminally ill patients. Because of FDA's refusal to recognize such a right, WLF filed suit in 2003 on behalf of itself and the Abigail Alliance. In May 2006, a panel of the U.S. Court of Appeals for the District of Columbia Circuit ruled in WLF's favor on the issue. But in August 2007, a divided appeals court sitting *en banc* reversed that decision. WLF asked the Supreme Court to hear the case and reinstate the panel decision. The Court's one-sentence order denying review indicated that Chief Justice John Roberts recused himself from considering the petition. It provided no explanation for the Chief Justice's action.

WLF has pledged to continue its advocacy in support of patients' rights. WLF has not yet determined whether that advocacy will include renewed litigation in a different judicial circuit.

WLF filed its Supreme Court petition with invaluable *pro bono* assistance from attorneys with the Washington, D.C. office of Latham & Watkins, including J. Scott Ballenger, Allyson M. Maltas, Christopher S. Turner, and Davis B. Tyner.

WLF's petition urged the Supreme Court to hold that once FDA has determined, after Phase I trials, that a potentially life-saving investigational new drug is sufficiently safe for expanded human trials, terminally ill patients have a constitutional right to seek treatment with the drug if there are no other FDA-approved drugs available to the patient. WLF argued that the Fifth Amendment's Due Process Clause encompasses a right, recognized throughout American history, of all individuals facing terminal illnesses to

make fundamental decisions regarding whether to seek or not to seek medical treatment. WLF argued that if FDA wishes to prevent such patients from gaining access to investigational drugs that have completed Phase I trials, it bears the burden of demonstrating that its restrictions are “narrowly tailored” to serve a compelling governmental interest.

“Under FDA regulations, the vast majority of patients with life-threatening illnesses do not have access to promising new medications during the years of clinical testing and review required by FDA,” said WLF Chief Counsel Richard Samp after reading the Supreme Court's order denying review. “The drugs remain unavailable even though there is evidence that they are safe and effective and even though patients have no alternative to the drugs other than to wait for their own deaths. We are asking the courts to reverse that policy,” Samp said.

The May 2006 appeals court decision in WLF's favor was a high water mark in WLF's effort to establish constitutional rights for terminally ill patients. The court said that the right of patients, in consultation with their doctors, to choose a course of treatment free from government interference is as well established in our nation's history as other constitutional rights previously recognized by the Supreme Court, such as the right to refuse medication, the right to educate one's children outside the public school system, and the right to teach one's children in a language other than English.

The Abigail Alliance was founded in 2001 by Frank Burroughs. The group is named for Burroughs's daughter, Abigail, who died of cancer after she was stymied in her efforts to obtain new cancer drugs that her oncologist believed could save her life, but which were still in clinical trials. WLF is a public interest law and policy center with supporters in all 50 states. It devotes a substantial portion of its resources to defending free enterprise, individual rights, and a limited and accountable government. WLF has frequently advocated before the FDA and litigated against it in support of the needs of sick Americans, including winning a landmark case that established the First Amendment right to disseminate truthful information about off-label uses of FDA-approved products.

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For further information, contact WLF Chief Counsel Richard Samp, (202) 588-0302. WLF's brief and other case documents are available on WLF's web site, [www.wlf.org](http://www.wlf.org).