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COURT URGED TO CONSIDER WHETHER TERMINALLY ILL PATIENTS HAVE RIGHT OF ACCESS TO EXPERIMENTAL DRUGS

(Abigail Alliance v. von Eschenbach)

The Washington Legal Foundation (WLF) this week petitioned the U.S. Supreme Court to take up the issue of whether terminally ill patients have a “fundamental right” – protected by the U.S. Constitution – to access to experimental drugs that have not yet been fully approved by the Food and Drug Administration (FDA).

The request caps a five-year WLF effort to establish such a right. Because of FDA’s refusal to recognize such a right, WLF filed suit in 2003 on behalf of itself and the Abigail Alliance for Better Access to Developmental Drugs, a patients-rights group. 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 of this year, a divided appeals court sitting *en banc* reversed that decision. WLF is asking the Supreme Court to reinstate the panel decision.

WLF filed its 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 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 filing WLF's petition. "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.

If the Supreme Court agrees to hear the case, it is likely to issue a final ruling by next June. If WLF prevails in the High Court, the case will return to the district court, where FDA would have an opportunity to demonstrate that it has a "compelling interest" in restricting the constitutional rights of terminally ill patients.

Although the D.C. Circuit reversed its initial decision in WLF's favor, it unanimously rejected the federal government's challenge to the "standing" of the two plaintiffs, WLF and the Abigail Alliance. The appeals court held that even though many of the individuals on whose behalf the plaintiffs filed suit in 2003 have died in the ensuing four years, the plaintiffs continue to have "standing" to sue because "this is a classic case of a situation capable of repetition, yet evading review." Because standing has been clearly established, the Supreme Court may be less reluctant to grant review in the case.

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.