News Release

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COURT URGED NOT TO REHEAR RULING GRANTING TERMINALLY ILL PATIENTS ACCESS TO EXPERIMENTAL DRUGS

(Abigail Alliance v. von Eschenbach)

The Washington Legal Foundation (WLF) this week urged the U.S. Court of Appeals for the District of Columbia Circuit not to rehear its landmark May 2006 decision that granted terminally ill patients a right of access to experimental drugs that have not yet been fully approved by the Food and Drug Administration (FDA).

FDA in June filed a petition seeking rehearing before all ten members of the appeals court. FDA argued that WLF's victory poses a serious threat to FDA's ability to ensure the safety and effectiveness of prescription drugs sold in this country. In a brief responding this week to that petition, WLF argued that the constitutional right of access established by the appeals court is well-supported by numerous Supreme Court decisions recognizing a constitutional right to individual autonomy.

The May 2, 2006 decision by a three-judge panel of the appeals court was the culmination of a three-year WLF effort to overturn FDA policies that deny terminally ill patients access to experimental drugs, even when they are the only available treatment option. WLF filed suit against FDA in 2003 on behalf of itself and the Abigail Alliance for Better Access to Developmental Drugs, a patients-rights group. The appeals court decision overturned a district court decision that had dismissed WLF's suit. On appeal, WLF received invaluable pro bono legal assistance from Scott Ballenger, a partner in the Washington office of Latham & Watkins.

The appeals court ruled 2-1 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. The court held that the Fifth Amendment encompasses a right, recognized throughout American history, of individuals facing terminal illnesses to make fundamental decisions regarding whether to seek or not to seek medical treatment. The court said that if FDA wishes to prevent such patients from gaining access to 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.

FDA is asking all ten judges who sit on the D.C. Circuit to rehear the panel's decision. Unless the court grants the petition, the case will return to the district court, where WLF will prevail unless FDA can demonstrate that it has a "compelling interest" in restricting the constitutional rights of terminally ill patients. Alternatively, FDA could ask the U.S. Supreme Court to review the appeals court decision.

"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. 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," said WLF Chief Counsel Richard Samp after filing WLF's response to the rehearing petition. "We trust that the D.C. Circuit's decision will reverse that policy. Existing programs for expanded access and compassionate use of new drugs during this pre-approval period accommodate only a fraction of those in desperate need," Samp said.

The appeals court agreed with WLF that just as terminally ill patients have a constitutional right to die by refusing medical treatment, they also have a constitutional right to live by seeking access to all available treatment options. The court said that FDA has little reason to withhold promising drugs from patients based on safety concerns when the patients' illnesses mean that their lives are already in danger even without taking the experimental drugs. WLF noted that the decision does not mean that terminally ill patients can demand treatment from unwilling doctors and drug companies; rather, it simply means that FDA can stand in the way of treatment by willing providers only if it has exceptionally strong reasons for doing so.

The Abigail Alliance was founded in 2001 by Frank Burroughs. The group is named for Burroughs's daughter, Abigail, a college honors student. Abigail died of cancer on June 9, 2001, 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. The Abigail Alliance has numerous members and supporters who are suffering from terminal illness or who have lost family members to terminal illness. WLF is a public interest law and policy center with supporters in all 50 states. WLF often advocates before the FDA and litigates against it in support of the needs of sick Americans, including winning a landmark case that established a constitutional 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.