News Release

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COURT URGED TO GRANT 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, sitting *en banc*, to grant terminally ill patients a constitutionally-based right of access to experimental drugs that have not yet been fully approved by the Food and Drug Administration (FDA).

In a brief filed in *Abigail Alliance and Washington Legal Found. v. von Eschenbach*, WLF argued that throughout American history the judiciary has recognized the right of individuals to engage in self-defense -- regardless whether the attacker is another person, an animal, or a disease. WLF argued that, based on that traditional self-defense right, the appeals court should recognize a constitutional right of terminally ill patients who lack effective treatment options to take experimental drugs, without interference from FDA. WLF argued that the decision to take such drugs should be left up to the patient, his or her doctor, and the drug's manufacturer.

In a historic decision last May, a three-judge D.C. Circuit panel ruled in WLF's favor on the issue. The D.C. Circuit granted FDA's rehearing petition in November and called for a new round of briefs from the parties. WLF will argue its case before the *en banc* court (that is, before all ten judges on the court) on March 1, 2007.

The three-judge panel's decision in May was a major milestone in a four-year WLF effort to overturn FDA policies that deny terminally ill patients access to experimental drugs, even when they are the only available treatment options. 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 has received invaluable pro bono legal assistance from Scott Ballenger, a partner in the Washington office of Latham & Watkins.

WLF's latest brief argued 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 encompasses a right, recognized throughout U.S. history, of 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 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.

If the ten-judge *en banc* court agrees with the earlier appeals court decision, 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 brief. "We are asking the courts to 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.

In its brief, WLF argued 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. WLF argued 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 a WLF victory would not mean that terminally ill patients could demand treatment from unwilling doctors and drug companies; rather, it would simply mean that FDA could stand in the way of treatment by willing providers only if it had 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. She 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.

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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.