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COURT AGREES TO RECONSIDER WHETHER TERMINALLY ILL PATIENTS HAVE RIGHT OF ACCESS TO EXPERIMENTAL DRUGS

(Abigail Alliance v. von Eschenbach)

The U.S. Court of Appeals for the District of Columbia Circuit yesterday granted the federal government's petition for an *en banc* rehearing of its May 2006 decision that 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 May 2006 decision was a major victory in the Washington Legal Foundation's three-year effort to overturn FDA policies that deny such access. Yesterday's order means that WLF will have to reargue its case before all 10 judges who are members of the D.C. Circuit. The parties are required to file new briefs in early 2007, with oral arguments taking place in March 2007.

At the same time that the appeals court granted rehearing *en banc*, the three-judge panel that initially ruled in WLF's favor rejected the federal government's challenge to the "standing" of the two plaintiffs, WLF and the Abigail Alliance for Better Access to Developmental Drugs, a patients-right group. The panel held that even though many of the individuals on whose behalf the plaintiffs filed suit in 2003 have died in the ensuing three years, the plaintiffs continue to have "standing" to sue because "this is a classic case of a situation capable of repetition, yet evading review."

WLF filed suit against FDA in 2003 on behalf of itself and the Abigail Alliance. The district court dismissed the suit, ruling that the Constitution imposes no barriers to FDA efforts to regulate the treatment decisions of terminally ill patients and their doctors. WLF appealed from that decision. On appeal, WLF received invaluable pro bono legal assistance from Scott Ballenger, a partner in the Washington office of Latham & Watkins.

In May, a three-judge appeals court panel 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'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. The court said 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.

The majority decision, written by Judge Judith Rogers, was joined by Chief Judge Douglas Ginsburg. Judge Thomas Griffith dissented. All three judges will be among the 10 D.C. Circuit judges who will rehear the case *en banc*.

"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 learning of the rehearing decision. "We are confident that after hearing all the evidence, the *en banc* court will stand by the initial panel decision that greater access to drugs is warranted. Existing programs for expanded access and compassionate use of new drugs during this pre-approval period accommodate only a small number of patients – a fraction of those in desperate need," Samp said.

The Abigail Alliance for Better Access to Developmental Drugs 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. 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. 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.