

**June 30, 2005**

WLF ASKS D.C. CIRCUIT TO ALLOW PATIENTS ACCESS TO LIFESAVING DRUGS

(Abigail Alliance v. Crawford)

The Washington Legal Foundation (WLF) filed its opening brief today in the U.S. Court of Appeals for the District of Columbia Circuit in its lawsuit asking the court to strike down FDA regulations that prohibit terminally ill patients with no approved treatment options from obtaining new drugs while the drugs are undergoing clinical trials. On March 9, 2005, the D.C. Circuit denied the FDA's motion for summary affirmance of the district court's decision to dismiss the case.

WLF filed the lawsuit on July 28, 2003, on behalf of itself and the Abigail Alliance for Better Access to Developmental Drugs, a patient group. The lawsuit argues that FDA policies violate the Due Process Clause of the Constitution by depriving terminally ill patients of life and liberty without due process. The lawsuit is a component of efforts by the Abigail Alliance and WLF to bring about reforms of FDA processes for the benefit of dying patients.

The district court, while dismissing the case, ruled in favor of the plaintiffs with regard to the procedural issues in the case, concluding that further attempts to obtain relief from the FDA "would clearly have been futile." The judge further stated the FDA's previous rejection of the Abigail Alliance's proposal to the FDA to open up access to investigational drugs for patients with no other options "had a direct and immediate effect on the plaintiffs – it barred them [and their constituents] from access to potentially life-saving investigational drugs."

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 the FDA. The drugs remain unavailable to patients even though there is evidence of the drugs' safety and efficacy, and even though the patients have no alternative to the drugs other than to wait for their own death. 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.

J. Scott Ballenger, an associate in the Washington, D.C. office of Latham & Watkins, drafted the appeals court brief for WLF on a *pro bono* basis.

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, an honors student at

the University of Virginia. 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. 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 in the landmark case of *Washington Legal Foundation v. Friedman*, 56 F. Supp. 2d 81 (D.D.C. 1999), *appeal dis'm*, 202 F.3d 331 (D.C. Cir. 2000), in which the U.S. District Court for the District of Columbia agreed with WLF that the FDA's restrictions preventing drug manufacturers from disseminating accurate information about off-label uses were in violation of the First Amendment.

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For further information, contact WLF Senior Vice President for Legal Affairs David Price, (202) 588-0302. The brief and other case documents are available on WLF's web site, www.wlf.org.