

November 13, 2003

## WLF FILES RESPONSE IN LAWSUIT OVER ACCESS TO LIFESAVING DRUGS (*Abigail Alliance v. McClellan*, No. 03-cv-01601)

The Washington Legal Foundation (WLF) filed its response today to the federal government's motion to dismiss *Abigail Alliance v. McClellan*, a lawsuit against the Food and Drug Administration and the Department of Health and Human Services regarding access to investigational drugs for terminally ill patients with no other options. WLF also filed a cross-motion for summary judgment in the case, arguing that the record in the case shows the existence of a violation of the constitutional rights of those patients.

WLF brought the lawsuit on July 28, 2003, on behalf of itself and the Abigail Alliance for Better Access to Developmental Drugs to challenge FDA restrictions that prevent the terminally ill from obtaining new medicines that have shown safety and efficacy during clinical trials. The lawsuit was filed in the U.S. District Court for the District of Columbia and is pending on the docket of the Hon. Ricardo M. Urbina.

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.

In the lawsuit, WLF and the Abigail Alliance contend that these regulations violate the constitutional right to privacy and liberty recognized by the U.S. Supreme Court by denying terminally ill patients the ability to make the personal choice of whether to buy investigational drugs to attempt to prolong their lives. In filing its motion to dismiss on October 14, the federal government argued that such a right is foreclosed by earlier court decisions dealing with access to banned substances such as Laetrile or cannabis. WLF's response noted that these cases differ from WLF's lawsuit because they do not deal with investigational drugs, which the FDA has approved for administration to patients participating in clinical trials. WLF's lawsuit is limited to such drugs.

WLF argued in its response that the Supreme Court's so-called "right to die" cases recognize the fundamentally personal and intimate character of decisions regarding the end of life or the continuation of life, and support the lawsuit's contention that the Constitution does not permit the FDA to substitute its judgment for the personal choices of terminally ill patients who wish to take a risk on an investigational drug and thereby possibly extend their lives.

WLF and the Abigail Alliance earlier filed a citizen petition with the FDA on June 11, 2003, urging the agency to adopt a program for earlier availability of lifesaving drugs during the approval process. The FDA has acknowledged receipt of the petition, but has not otherwise responded to it. In the meantime, thousands of Americans have been dying every week for lack of access to medicines that could save or prolong their lives.

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. 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.

\* \* \*

For further information, contact WLF Senior Vice President for Legal Affairs David Price, (202) 588-0302. A copy of WLF's brief is posted on its web site, [www.wlf.org](http://www.wlf.org).