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WLF AND ABIGAIL ALLIANCE FILE SUIT ON ACCESS TO LIFESAVING DRUGS *(Abigail Alliance v. McClellan)*

The Washington Legal Foundation (WLF) filed a lawsuit today against the Food and Drug Administration 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.

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 rights of terminally ill patients who have no other treatment options. The lawsuit argues that the regulations violate the right to privacy recognized by the U.S. Supreme Court and that they amount to a death sentence against those patients without due process of law.

“We are in a time of unprecedented innovation in cancer medicines, yet the regulatory process is forbidding sick people from making fundamental choices that could save their lives,” said WLF Senior Vice President for Legal Affairs David Price.

“We are seeing positive changes at the FDA, but not in the area of access to investigational drugs,” said Frank Burroughs, President of the Abigail Alliance for Better Access to Developmental Drugs. “It is vital that we move forward to give patients fighting for their lives every possible option.”

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.

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For further information, contact WLF Senior Vice President for Legal Affairs David Price, (202) 588-0302. A copy of the complaint is posted on WLF's web site, www.wlf.org