

FOR IMMEDIATE RELEASE

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WLF AND ABIGAIL ALLIANCE SEEK REVIEW OF DRUG APPROVAL POLICIES *(In re Tier 1 Initial Approval Program)*

The Washington Legal Foundation (WLF) filed a petition today with the Food and Drug Administration on behalf of itself and the Abigail Alliance for Better Access to Developmental Drugs to urge the adoption of a program for greater availability of lifesaving medications.

The program proposed by WLF and the Abigail Alliance, known as Tier 1 Initial Approval, would enable the FDA to grant limited approval for promising drugs based on early evidence of effectiveness and safety. The petition also seeks regulatory changes to permit expanded availability of drugs to seriously ill patients at all stages of the FDA's clinical trial and review process.

At present, patients with life-threatening illnesses do not generally 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 "compassionate use" of new drugs during this pre-approval period accommodate only a small number of patients – a fraction of those in desperate need.

To prevent disruption of clinical trials that may lead to full approval of a drug, patients would be eligible for access to drugs under Initial Tier 1 Approval only if they have been denied participation in a clinical trial for the drug.

"The FDA needs to recognize that terminally ill patients with no other treatment options may have a different risk-benefit tradeoff from other patients when a promising new drug is in the pipeline," said WLF Senior Vice President for Legal Affairs David Price. "With the petition, we want to help the FDA better understand the needs of these patients, and we want to help the FDA understand that it has the authority under federal law to make the drugs available to these patients while the full approval process is underway."

The Abigail Alliance for Better Access to Developmental Drugs was founded in 2001 by Frank Burroughs, who is now its president. 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 petition is posted on WLF's web site, www.wlf.org.