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COURT RULES THAT TERMINALLY ILL PATIENTS HAVE “FUNDAMENTAL RIGHT” TO EXPERIMENTAL DRUGS

(Abigail Alliance v. Eschenbach)

In a major victory for the Washington Legal Foundation (WLF), the U.S. Court of Appeals for the District of Columbia Circuit ruled yesterday 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 decision is the culmination of a three-year WLF effort to FDA policies that deny such access.

WLF filed suit against FDA in 2003 on behalf of itself and the Abigail Alliance for Better Access to Developmental Drugs, a patients-rights group. 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.

The appeals court 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. Unless FDA appeals the decision, the case now returns to the district court, where WLF will prevail unless FDA can demonstrate that it has a “compelling interest” in restricting the constitutional rights of terminally ill patients. FDA has two appeal options. It could petition all nine active

judges on the court of appeals to rehear the case *en banc*. Alternatively, it could ask the U.S. Supreme Court to review the decision.

"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 reviewing the Court decision. "We are hopeful that today's decision will reverse that policy. 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 appeals court agreed with WLF that just as terminally ill patients have a constitutional right to die by refusing medical treatment, they also have a constitutional right to live by seeking access to all available treatment options. The court said that FDA has little reason to withhold promising drugs from patients based on safety concerns when the patients' illnesses mean that their lives are already in danger even without taking the experimental drugs. WLF noted that the decision does not mean that terminally ill patients can demand treatment from unwilling doctors and drug companies; rather, it simply means that FDA can stand in the way of treatment by willing providers only if it has exceptionally strong reasons for doing so.

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 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.