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# 'Right to unapproved drugs' case heads for US appeals court - 05/02/2007

On March 1, in a landmark case, the Food and Drug Administration will ask a US Court of Appeals to overturn the backing it gave in May 2006 to a lawsuit which calls for terminally-ill patients to have the constitutional right to be treated with unapproved drugs.

The lawsuit, which was originally brought in July 2003 by patient group the Abigail Alliance for Better Access to Developmental Drugs and the Washington Legal Foundation (WLF), claims that current FDA policy violates the "constitutional privacy and liberty rights" of "mentally competent patients with no other treatment options" by prohibiting them from purchasing investigational drugs, "even though their physicians recommend these drugs as their best hope of surviving or of prolonging their lives."

The US District Court for the District of Columbia threw the suit out in 2004 but, in a groundbreaking decision last May, the Court of Appeals for the DC Circuit ruled that it should be reinstated. "Barring a terminally ill patient from the use of a potentially lifesaving treatment impinges on the right of self-preservation," commented one of the judges, Judith Rogers.

Then, in November, the court agreed to the FDA's request to rehear the case completely. Following that, on December 11, the agency announced plans to make experimental drugs more widely and easily available and to clarify when, and how much, manufacturers could charge for such drugs - it is currently illegal for them to sell an unapproved drug. The agency's proposals are currently going through a 90-day public comment period, and are expected to become final some time this year.

In a new brief filed with the court ahead of the March 1 hearing, the WLF says a terminally ill patient's constitutional right to take experimental drugs is a right to engage in self-defence and the FDA should not interfere; such decisions should be left to the patient, doctor and manufacturer.

Promising new medications currently remain unavailable to the vast majority of patients with life-threatening illnesses during the years of clinical testing and review required by the agency, "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 the WLF's chief counsel, Richard Samp. "Existing programs for expanded access and compassionate use of new drugs during this pre-approval period accommodate only a fraction of those in desperate need," he added.

However, there are huge ethical issues involved. If the lawsuit is successful, it will mean new drugs no longer having to go through the full three phases of clinical trials before becoming available to the public, reports the *Washington Times*, which also quotes observers as stating that the drug industry is not supporting the lawsuit because of the potential liability if an experimental drug should harm a patient. But the WLF says a victory for the lawsuit "would not mean that terminally ill patients could demand treatment from unwilling doctors and drug companies; rather, it would simply mean that FDA could stand in the way of treatment by willing providers only if it had exceptionally strong reasons for doing so."

In fact, the proposed new guidelines explicitly state that the FDA "cannot compel a drug manufacturer to provide access to investigational drugs for treatment use."

The case will be heard before all 10 judges of the DC Circuit Appeals Court on March 1. If they agree with the May 2006 decision, it will return to the District Court. However, many observers believe this unprecedented battle will go all the way to the Supreme Court.

â€¢ The Abigail Alliance was founded in 2001 by Frank Burroughs, when his daughter, Abigail, died of cancer "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," it says. *Lynne Taylor*