

GOVERNMENT & MEDICINE

## **Court to rule on dying patients' access to experimental drugs**

**Doctors worry that permitting early use could compromise the very process that helps them learn more about promising medications.**

By [Amy Lynn Sorrel](#), *AMNews* staff. Dec. 18, 2006.

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Should dying patients have special access to prescription drugs after just the first stage of clinical testing? The full U.S. Court of Appeals for the District of Columbia plans to take up that thorny question next year.

The Abigail Alliance for Better Access to Developmental Drugs argues that terminal patients should have the ability to take medications that have cleared phase I clinical trials and shown initial effectiveness and acceptable side effects.

But physicians say early access to these drugs poses ethical problems and could hurt the quality of the remainder of patients' lives.

The Abigail Alliance, with the **Washington Legal Foundation**, in 2003 sued the federal government to get initial access for certain patients.

The patient advocacy group, named after a 21-year-old who died of cancer, asks that the Food and Drug Administration allow pharmaceutical companies to sell experimental drugs to terminally ill patients who have no other approved treatment options.

A three-judge panel of the appeals court in May ruled that barring seriously ill patients from using potentially life-saving therapies impinges on their constitutional rights to self-preservation and to decide whether to seek medical treatment.

But in November the court accepted the FDA's appeal of the decision, and the full 10-judge bench is expected to rehear the case in March 2007.

"People who are fighting for their lives deserve every chance to live just like people now getting approved drugs," said Abigail Alliance President Frank Burroughs. "There is a way to see which drugs early on are extending and saving lives, but the FDA approval process is very cumbersome." Pharmaceutical companies have no incentive to participate in expanded access or compassionate use programs, he added.

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