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Experimental Drug Case Gets Reprieve

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WASHINGTON -- Terminally ill patients seeking access to experimental, unapproved drugs won a legal reprieve Tuesday in a federal appeals court.

A three-judge panel reinstated a lawsuit filed on behalf of the patients and returned the case to district court, which had dismissed the case in 2004.

The Abigail Alliance for Better Access to Developmental Drugs and the Washington Legal Foundation sued the Food and Drug Administration in 2003, seeking access for terminally ill patients to drugs that have undergone preliminary safety testing in as few as 20 people but that have yet to be approved.

FDA approval of drugs generally requires extensive testing that can involve thousands of patients.

"Barring a terminally ill patient from the use of a potentially lifesaving treatment impinges on this right of self-preservation," Judge Judith W. Rogers wrote in the 2-1 opinion from the panel of the U.S. Court of Appeals for the District of Columbia Circuit.

Paul Kamenar, senior executive counsel for the Washington Legal Foundation, called the ruling a big defeat for the FDA.

"The FDA has long prohibited lifesaving medicines for terminally ill patients," he said. "We think this is a tremendous victory for patient groups and those who are in need of these kinds of medicines."

The FDA did not immediately return messages left seeking comment.

Donald Kennedy, a former FDA commissioner, called the lawsuit "Laetrile redux."

In the late 1970s, terminally ill cancer patients and their spouses sought access to Laetrile, a then- and still-unapproved drug, eventually suing the FDA _ and Kennedy _ in a case that landed in the Supreme Court.

In 1979, the Court ruled unanimously that there should be no exemption to the FDA's safety and effectiveness standards, which all drugs must meet, for medicines sought by terminally ill patients.

The U.S. District Court had dismissed the Abigail Alliance lawsuit in 2004, and the groups appealed shortly thereafter. Tuesday's opinion revives their case, but also means that years more of litigation are likely. The FDA can ask for the full appeals court to rehear the case. Otherwise, it returns to the lower court.

Judge Thomas B. Griffith, in a dissenting opinion, said the cases raises "a number of vexing questions," including whether patients could access any drug, including marijuana, that they and their doctors believe is potentially lifesaving.

"Would the majority's right guarantee access to federally funded stem cell research and treatment?" Griffith asked.

Tuesday's ruling comes amid heightened criticism of how the FDA handles access to drugs under its review.

Sen. Sam Brownback, R-Kan., introduced legislation last year that would require the agency to set up a program to expand access to experimental drugs for patients with serious or life-threatening conditions and diseases. The bill, SB 1956, was referred to committee in November.

Frank Burroughs, president of the Abigail Alliance, said providing access shouldn't be solely an FDA decision.

"The decision is the patient's decision, in consultation with their doctor, knowing at the time the known risks and benefits," said Burroughs, who founded the group after his daughter, Abigail, died of cancer in 2001.

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