

Sick patients need access to drugs sooner: court

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By Susan Heavey

WASHINGTON (Reuters) - The U.S. Food and Drug Administration's policy to withhold early-stage experimental drugs from terminally ill patient infringes their right to choose, a U.S. appeals court said on Tuesday, sending the case back to a lower court.

The FDA requires developing drugs to undergo a wide battery of tests, ranging from preclinical testing in the laboratory to large, advanced trials with people. Drug companies say the process can take up to 10 years.

But the U.S. Court of Appeals for the District of Columbia sided with two advocacy groups that filed the suit seeking patient access to new cancer drugs after initial tests show they are safe but before they receive FDA approval.

Judge Judith Rogers, writing for the majority, said terminally ill patients should be allowed to decide whether to accept the risks of taking a medication that might help them live longer.

"The key is the patient's right to make the decision about her life free from government interference," she wrote.

The ruling overturns a 2004 dismissal by the U.S. District Court for the District of Columbia, which will now have to review the case unless the FDA appeals.

In the lawsuit, filed in 2003, the **Washington Legal Foundation** and the Abigail Alliance argue patients have the constitutional right to available treatments.

"If death is certain and you have no options, it's the individual's option to decide," Abigail Alliance President Frank Burroughs told Reuters.

While some patients can take experimental drugs as part of a clinical trial or other programs, he added the lawsuit was critical because many patients are excluded.

The court agreed, saying patients are simply looking for the same access that others have.

In a dissenting opinion, Judge Thomas Griffith sided with the FDA regulatory process, saying government has the duty to ensure that drugs are safe and effective before they are sold.

"Although terminally ill patients desperately need curative treatments, their death can certainly be hastened by the use of a toxic drug," he wrote.

The FDA has moved to review drugs for cancer and other serious conditions faster than other medicines.

FDA Deputy Commissioner for Medical and Scientific Affairs Scott Gottlieb said the agency was "sympathetic" to terminally ill patients and was improving its efforts to make such therapies available.

The Washington Legal Foundation said it was hopeful it could work with the agency to develop a new policy.