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Court denies test drugs to dying patients

Terminally ill people do not have the right to get unapproved, potentially lifesaving treatments, an appeals panel rules.

By David G. Savage
Los Angeles Times Staff Writer

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WASHINGTON — People who are dying do not have the right to obtain unapproved drugs that are potentially lifesaving, even if their doctors say the treatment offers their best hope for survival, a U.S. appeals court here ruled Tuesday.

In an 8-2 decision, the court said federal drug regulators were entrusted by law with deciding when new drugs were safe for wide use.

The families of terminally ill patients, several of whom died after they were denied promising drugs that were still in tests, filed suit. They said that patients who were dying were far more willing to take risks and argued that they should not be forced to wait years for new treatments to win final approval from the Food and Drug Administration.

The judges said the families should take their pleas to Congress, not the courts.

However, the two dissenters said the ruling ignored the Constitution's protection for individuals and their right to life, and instead bowed to "a dangerous brand of paternalism" that put the government's interest first.

Leaders of the Abigail Alliance for Better Access to Developmental Drugs said they would appeal to the Supreme Court. The group was named in honor of Abigail Burroughs, a 21-year-old University of Virginia student who died of cancer in 2001. Her father, Frank, said she was denied the use of two investigational anti-cancer drugs that were recommended by her oncologist. These drugs later received FDA approval.

"We are talking about terminally ill patients and about drugs that were shown to work in earlier trials," said alliance co-founder Steve Walker, a St. Petersburg, Fla., geologist whose wife died of colon cancer.

In 2003, the alliance petitioned the FDA, urging it to change its rules so that drug companies could make available to dying patients "investigational drugs" that had won preliminary approval. There is a "different risk-benefit trade-off facing patients who are terminally ill and have no other treatment options," it said.

The FDA turned away the plea, saying it needed "to maintain a strong clinical trial system" to gather evidence before approving drugs for general use.

With the aid of the Washington Legal Foundation, a conservative nonprofit, the alliance sued the FDA. It said the Constitution should be read to "embrace the right of a terminally ill patient with no remaining approved treatment options to decide, in consultation with his or her own doctor . . . to seek access to investigational medications that the FDA concedes are safe and promising enough for substantial human testing."

The case touched on issues that had been debated fiercely in medical and legal circles.

Medical experts have long disagreed on whether the FDA moves too slowly or too quickly in approving new drugs. Some doctors have argued that clinical trials should be opened to more patients who might benefit from the new treatments.

And since the Roe vs. Wade ruling in 1973 that set out the right to abortion, many legal scholars have frowned on judges creating "new rights" from vague clauses in the Constitution. The suit over new drugs focused on the 5th Amendment, which says "no person shall be . . . deprived of life, liberty or property, without due process of law."

In 2004, a federal judge rejected the alliance's suit, saying there was "no constitutional right of access to unapproved drugs."

Last year, however, a three-judge panel of the U.S. appeals court sided with the group.

In a 2-1 decision, it said a "terminally ill, mentally competent adult patient" had a right to "potentially lifesaving investigational new drugs" which had been found to be safe for humans.

But before that decision could take effect, the full U.S. Court of Appeals for the District of Columbia voted to rehear the case. And Tuesday, it reversed its panel's ruling.

"We conclude there is no fundamental right 'deeply rooted in this nation's history and tradition' of access to experimental drugs for the terminally ill," said Judge Thomas B. Griffith, a Bush appointee, citing a Supreme Court decision that rejected the notion of a constitutional right to die. Griffith's opinion was joined by conservative and liberal members of the appeals court.

The two dissenters were Judge Judith W. Rogers, a Clinton appointee, and Chief Judge Douglas H. Ginsburg, a Reagan appointee.

"In the end, it is startling," Rogers wrote, that the Constitution has been read to include unnamed "fundamental rights" to marry, to control a child's education, to have sex in private and to have an abortion, "but the right to save one's life is left out."

Julie Zawisza, an FDA spokeswoman, said the agency was pleased with the ruling because it upheld the agency's "role in facilitating appropriate treatment access to investigational therapies while at the same time protecting the public at large by requiring that drugs are proven to be safe and effective before they may be marketed to U.S. consumers."

She also said that "on a limited basis," some patients and their doctors were permitted to obtain new drugs that were in clinical trials.