The New York Times
nytimes.com

August 8, 2007

Court Rejects the Right to Use Drugs Being Tested

By ANDREW POLLACK

A federal appeals court ruled yesterday that patients with terminal illnesses do not have a constitutional right to use medicines that have not yet won regulatory approval.

The 8-to-2 decision by the Court of Appeals for the District of Columbia Circuit came in a closely watched and emotional case that pitted desperate patients willing to try unproven, even risky, therapies against those arguing that drugs should be proved safe and effective before they are made available.

The decision preserves the current regulatory system. If it had gone the other way "it would have undermined the entire drug approval process," said William B. Schultz, a former deputy commissioner of the Food and Drug Administration, who wrote an amicus brief arguing against the early access to drugs.

The case was filed against the Food and Drug Administration in 2003 by the Abigail Alliance for Better Access to Developmental Drugs, a group founded by a man whose daughter Abigail died from cancer after a long battle to receive treatment with experimental drugs that were eventually approved.

The group, joined by the Washington Legal Foundation, argued that forcing patients to wait years for a drug to go through the process of clinical trials deprived dying patients of their right to self-defense and violated the Fifth Amendment clause stating that people cannot be deprived of life, liberty or property without due process of law.

A district court ruled against the Abigail Alliance. That decision was reversed by an appeals court panel, but the full appeals court yesterday upheld the original district court decision.

Judge Thomas B. Griffith, writing for the majority, said a right to experimental drugs was not deeply rooted in the nation's history and tradition. Judge Griffith said the right of self-defense "cannot justify creating a constitutional right to assume any level of risk without regard to the scientific and medical judgment expressed through the clinical testing process."

In a dissent, Judge Judith W. Rogers wrote that it was “startling” that the “right to try to save one’s life is left out in the cold,” not protected by the due process clause of the Constitution, “despite its textual anchor in the right to life.”

Frank Burroughs, the founder of the Abigail Alliance, said his group was “dumbfounded that most of the justices tragically missed the merits of the case.” Mr. Burroughs vowed to appeal to the Supreme Court.

While critics often accuse the F.D.A. of letting unsafe drugs on the market, this case points to pressure on the agency from the opposite direction — patients who say it is too stringent in approving drugs for serious diseases. Many prostate cancer patients and advocacy groups, for instance, have recently criticized the agency for not approving a drug called Provenge.

The agency sometimes does lower the bar for approval of medicines for life-threatening diseases. And the companies developing such drugs can make them available before approval under some circumstances.

But Mr. Burroughs said such programs were inadequate. His organization advocates that drugs be made available to terminally ill patients as early as the conclusion of the first of three phases of clinical trials.

Some drug companies, doctors and other patient groups oppose that idea. Mr. Schultz, for instance, filed his brief supporting the current system on behalf of the National Organization for Rare Disorders, a patient advocacy group.

He and others say that if drugs were made available after only preliminary testing, drug companies would have little incentive to conduct full clinical trials to determine if a drug really works. That would allow companies to “profit from offering empty hope,” said Robert Erwin of the Marti Nelson Cancer Foundation, a patient advocacy group.

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