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## REPORT

### Court Deals Crippling Blow to FDA

#### Federal Court Firmly Rejects FDA Prohibitions, Affirms Constitutional Right to Access Experimental Lifesaving Drugs

By John Otrompke, JD



Each year, thousands of Americans die while engaging in activities that involve some degree of risk. Although these activities provide no essential social benefit, society bears the cost of injuries and deaths that occur from people parachuting out of airplanes, skiing down steep mountains, and engaging in other dangerous but perfectly legal activities.

There is one “risky” activity, however, that the federal government has vehemently opposed and specifically outlawed. If diagnosed with a terminal disease, you may not “risk” trying a therapy that is not approved by the FDA. Even if there is a 100% certainty that you will die of a fatal illness, it is illegal for you to “risk” using a new therapy that the FDA has not approved. The FDA’s longstanding position is that it must “protect” terminally ill people from unproven medical treatments, whether the dying person desires such protection or not.

Fortunately, all this may soon change. In June 2006, a federal appellate court declared that the FDA’s draconian, utterly illogical position on experimental drugs is unconstitutional. The court ruled that terminally ill patients have a constitutional right to seek potentially lifesaving drugs—whether or not the FDA has given its final approval for their sale.

While the federal government is expected to appeal this decision all the way to the Supreme Court, this unprecedented ruling vindicates Life Extension’s 26-year position that FDA bureaucrats have no constitutional authority to deny Americans access to potentially lifesaving medications.

#### COURT’S COMMONSENSE RULING AFFIRMS LIFE EXTENSION POSITION

If you or a loved one were dying of a terminal illness, would you not feel you had the right to try an experimental medication to save your own life? Until recently, you did not have this right, according to the FDA and some court decisions that have affirmed the agency’s position.

However, all of that is about to change. The United States Court of Appeals for the District of Columbia Circuit has found for the rights of patients to access potentially lifesaving medical treatments. This monumental breakthrough could well mean the difference between life and death for many Americans.



According to this unprecedented appellate court ruling, for most of our history, individuals were free to take whatever medication they wanted without a doctor’s prescription. It was only in 1951 that Congress created a category of prescription drugs; and, in 1962, began requiring drug companies to conduct extensive tests to ensure the efficacy of their products. That led to long delays in the release of potentially lifesaving drugs, and to the deaths of countless patients who would gladly have borne the unknown risks for a chance at life.

#### The Right to Pursue Medical Treatment

In combination with traditional English and American legal ideas—such as the right to self-preservation and the uninterrupted enjoyment of

life, in the case, *Abigail Alliance for Better Access to Developmental Drugs, et al, v Andrew von Eschenbach, MD, et al*, the court found that mentally competent, terminally ill patients with no governmentally approved treatment options have the constitutional right, under the advice of a physician, to take potential treatments that have already been approved by the FDA to be tested experimentally in other human beings.

one's life, limbs, body, and health—the DC Court of Appeals found that the US Bill of Rights contains an “unenumerated” right for terminally ill patients with no viable treatment options to access experimental therapies that have already been approved for testing in other human beings.

If the US Supreme Court affirms this opinion, it would indeed be a major victory for patients' rights advocates such as the Life Extension Foundation. It would be the first time that a US court has ruled that patients have a constitutional right to access medical treatments under these circumstances. The Supreme Court has already found that patients have the right not to take potentially lifesaving treatments if they do not want to. If the federal trial court later determines that an order should prohibit the FDA from enforcing its restrictive, potentially lethal policies, it would indeed be a major erosion of the FDA's power and a tremendous opening for patients and patients' rights advocates to expand their own freedom.

## THE BIRTH OF A RIGHT?

The Abigail Alliance was named after Abigail Burroughs, a young woman who, like so many others, died while waiting for an effective cancer treatment to be developed and approved by the FDA. The Alliance petitioned the FDA for access to treatments that have already been approved for testing in other human beings. Because pharmaceutical companies say they have 300 potential cancer treatments in development right now, this could greatly increase the number of treatment options for patients who have no viable treatment options that have already been approved for sale by the FDA.

When the FDA turned down the Alliance's petition, the patients and their advocates took the matter to federal court. Although the federal trial court turned a deaf ear to the patients' claim, the court of appeals reversed this ruling, finding a constitutional right for the first time.

“Constitutional interpretation” is the process whereby courts find that our country's founding principles in fact protect many of the more recent principles that have come to constitute the landscape of our rights. Many of these principles, such as those underlying the right to decline medical treatment, have been established in just the last 30 or 40 years, even though they are not specifically mentioned in the US Constitution.

The right to seek life-sustaining medical treatment, according to the court, has always existed in our country, and is one of the rights retained by the people and protected by the Ninth Amendment. Moreover, according to the court, the FDA's statutory authority to limit patients' rights, in this case, is a rather new historical concept that violates the Constitution.

## Lengthy Drug Approval Process Threatens Patient Rights



Under the federal Food, Drug and Cosmetic Act, the FDA mandated that new drugs must go through three phases of clinical trials prior to their approval for sale to the public. On average, all three phases of drug testing combined take about seven years. If terminally ill patients were forced to wait for new drugs to complete this lengthy process of approval, many of them would die before new lifesaving therapies gained FDA approval.

The first phase (“Phase I”) of these clinical trials is intended to identify potentially harmful side effects of drugs. In the second phase, experimental drugs have already been approved for other human testing. According to the DC Court of Appeals, terminally ill patients should have access to experimental drugs that have already passed through Phase I trials.

In the Abigail Alliance case, the DC Court of Appeals reasoned that since the Supreme Court has already ruled that a patient has a fundamental right to refuse life-sustaining treatment, it only stands to reason that a person also has the right to access life-sustaining treatment. Thus, terminally ill patients who have exhausted all viable treatment options and have been directed by their physician to seek experimental drugs have a fundamental right to seek such therapies.

According to the court, the right of terminally ill patients to access potentially lifesaving treatments “falls squarely within the realm” of those rights held “implicit in the concept of ordered liberty.”

Terminally ill individuals thus have a fundamental right to access, under the direction of their physicians, experimental therapies that have completed Phase I trials, according to the DC Court of Appeals.

## EPILOGUE

Advocates of health freedom are anxiously watching to see how the DC Court of Appeals ruling will fare if and when it comes before the US Supreme Court.

Although patients have not always fared well in the courts on this issue, the approach adopted by the DC Court of Appeals could put the right to access experimental treatments in the category of some of the most unprecedented decisions in legal history. The Supreme Court may be challenged to determine if the right to access experimental treatment is a “fundamental right” demanded by “personal dignity and autonomy.”

The DC Court of Appeals noted that its decision does not mean that patients have a right to treatment with experimental stem cell therapies paid for by the government. Under the court’s decision, patients would have a right to try any therapies that had been approved by the FDA after Phase I trials for safety, including stem cell therapies, but the government is not necessarily obligated to pay for them.

The court also distinguished the Abigail Alliance case from certain cases of other federal courts from the 1980s in which patients sought access to laetrile, an experimental cancer drug. This is because laetrile had not cleared the FDA’s Phase I “safety hurdle,” and the FDA had not “eliminated the possibility that laetrile was a poison,” the court said.

Life Extension will continue to follow the case and alert members to its outcome and potential impact on health freedom.

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## The Work of the Life Extension Foundation

For 26 years, the Life Extension Foundation has taken the position that the federal government has no constitutional authority to deny seriously ill patients the right to try experimental, potentially lifesaving treatments for their health conditions. On multiple occasions, the Life Extension Foundation has gone to court in this ongoing battle. For more information, please visit [www.lef.org](http://www.lef.org) and [www.stopfda.org](http://www.stopfda.org).

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