

November 21, 2006 6:03 p.m. EST

Decision on Experimental Drugs is Vacated

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In a victory for the Food and Drug Administration, the U.S. Court of Appeals for the District of Columbia vacated an earlier decision that would have broadened patients' rights to experimental drugs.

The ruling last May came from a three-judge panel of the court, and the FDA quickly appealed. Now, the case will be re-heard by the entire court, according to Richard Samp, chief counsel of the **Washington Legal Foundation**. The foundation filed the original suit against the FDA, along with the Abigail Alliance for Better Access to Developmental Drugs, another nonprofit that favors aggressive access policies for experimental treatments.

The panel's broadly worded decision had said that the Constitution protected terminally ill, mentally competent patients' "informed access to potentially life-saving investigational new drugs" after successful initial clinical trials, if there are no other government-approved treatment options. If upheld, it potentially could have thrown into question much of the FDA's current regulation surrounding when patients can access drugs that haven't yet won agency approval to be marketed widely.

An FDA spokeswoman declined to comment. Mr. Samp said the plaintiffs are "confident that the entire court, once it looks carefully at the case, will reach the same decision the panel did."

There has long been a debate about access to experimental drugs. The FDA allows seriously ill patients to gain so-called "compassionate use" access to such treatments, and sometimes thousands of people take a drug through such programs before the medication has officially gone on the U.S. market. Some of the most aggressive patient groups, such as the Abigail Alliance, want even fewer restrictions on such access.

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