

Right to Experimental Therapies: FDA New Drug Approval, Constitutional Rights, and the Public's Health

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Issue

Do terminally ill patients who have exhausted all other government-approved treatment options have a constitutional right to access investigational new drugs?

Abigail Alliance v. Eschenbach, 445 F.3d 470 (D.C. Cir. 2006)

Competing Interests

- Patients and patient advocates
- Pharmaceutical companies
- Government/FDA
- Physicians
- Future patients
- The public

Abigail Panel Decision

- “We conclude . . . that where there are no alternative government-approved treatment options, a terminally ill, mentally competent adult patient’s informed access to potentially life-saving investigational new drugs . . . warrants protection under the Due Process Clause.” 445 F.3d 470 (May 2, 2007).

Fundamental Rights

- Refuse medical treatment (*Cruzan v. Director, Missouri Dep't of Health*, 1990)
- Abortion (*Roe v. Wade*, 1973)
- Contraception (*Griswold v. Connecticut*, 1965)
- Sodomy (*Lawrence v. Texas*, 2003)
- *But not* assisted suicide (*Washington v. Glucksberg*, 1997)

Glucksberg Analysis

- “Deeply rooted in this Nation’s history and tradition”
- “Implicit in the concept of ordered liberty”
- “Careful description”

Washington v. Glucksberg, 521 U.S. 702
(1997)

Abigail En Banc Reversal

- “This case presents the question whether the Constitution provides terminally ill patients a right of access to experimental drugs that have passed limited safety trials but have not yet been proven safe and effective. The district court held that there is no such right.... [W]e affirm....”

495 F.3d 695 (Aug. 7, 2007)

Defining the Right

- Right to control one's body
- Right to access
- Right to self-preservation
- Right to refuse v. right to compel
- Right to be left alone
- Right to life v. right to property
- Right to life v. right to lives
- Right to medical self-defense

Abigail on Other Fronts

- ACCESS Act, S. 1956 (Nov. 3, 2005)
(Brownback, R - Kan.)
- FDA Proposed Guidelines, 71 Fed. Reg. 75147, 45168 (Dec. 14, 2006)
- “Saying No to Penelope,” Wall St. J., at A1
(May 1, 2007)

Selected Bibliography

- B. Benderly, *Experimental Drugs on Trial*, Sci. Am. (Oct. 2007)
- G. Anand, *Saying No to Penelope; Father Seeks Experimental Cancer Drug, But a Biotech Firm Says Risk is Too High*, Wall St. J. (May 1, 2007)
- P. Jacobson & W. Parmet, *A New Era of Unapproved Drugs; The Case of Abigail Alliance v. Von Eschenbach*, JAMA (Jan. 10, 2007)
- J. Groopman, *The Right to a Trial*, The New Yorker (Dec. 18, 2006)

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