

PROVIDING HOPE: DEVELOPING A VIABLE REGULATORY
FRAMEWORK FOR PROVIDING TERMINALLY ILL PATIENTS
WITH ADEQUATE ACCESS TO INVESTIGATIONAL DRUGS

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“Don’t leave a stone unturned. It’s always something, to know you’ve done the most you could. But, don’t leave off hoping, or it’s of no use doing anything. Hope, hope, to the last!”¹

“If I die . . . I want my children to know I did everything I could.”² This is a common feeling among terminally ill individuals facing death. This desire to exhaust every option often causes people to fight to receive potentially toxic and dangerous treatments that are still in the investigational phase if the treatment provides even a glimmer of hope for survival or improvement in condition.³ Investigational treatments, however, expose patients to myriad risks that can be difficult to predict.⁴ Jolee Mohr’s mysterious death provides a sad illustration of the dangers of investigational drugs.⁵ Mrs. Mohr’s physician recruited her for a clinical trial to test the safety of an investigational arthritis treatment.⁶ After she received the investigational treatment, Mrs. Mohr experienced intractable vomiting and increased body temperature.⁷ She subsequently slipped into unconsciousness, and her family made the decision to remove life support after doctors confirmed that she had no hope of recovery.⁸

Limiting access to investigational drugs may help prevent tragedies similar to Mrs. Mohr’s. These limitations, however, reduce an individual’s access to treatments that may provide the only hope for the terminally ill. A

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1. CHARLES DICKENS, *NICHOLAS NICKLEBY* 634 (Wordsworth Editions 1995) (1839).

2. Musa Mayer, *When Clinical Trials are Compromised: A Perspective from a Patient Advocate*, 2 *PUB. LIBR. SCI. MED.* 1060, 1061 (2005), available at <http://medicine.plosjournals.org/perlserv/?request=get-document&doi=10.1371%2Fjournal.pmed.0020358>.

3. *Id.*

4. *See id.* See also Mellar P. Davis, *Should Experimental Therapies Be Made Available Off-Study for Terminally Ill Patients?*, 7 *THE LANCET ONCOLOGY* 531 (2006).

5. Rick Weiss, *Death Points to Risks in Research*, *WASH. POST*, Aug. 6, 2007, at A01.

6. *Id.*

7. *Id.*

8. *Id.*

Wall Street Journal editorial revealed the effects of limits on access to investigational drugs when it published its plea to address Kianna Karnes's attempt to access two investigational cancer therapies. While the entire nation focused on the outcome of the Terri Schiavo controversy, Kianna Karnes was nearing the end of her battle against kidney cancer that had spread throughout her body.⁹ The circumstances surrounding the battle for the lives of these two women, however, differed significantly. Kianna Karnes and her treating physicians believed that access to the right drugs would help prevent her death.¹⁰ Mrs. Karnes had sought, but was denied, access to two investigational drugs that had the potential to help her in her battle against cancer. Both drugs had shown promise in FDA trials for many years.¹¹ Mrs. Karnes, however, was unable to access the drugs through any of the available channels.

The sequence of events following the *Wall Street Journal's* editorial is tragic. Mrs. Karnes died the day after publication of the editorial at the age of forty-four, leaving behind four children.¹² To add to this tragedy, the manufacturers of the two investigational drugs contacted Mrs. Karnes's physician, and the FDA contacted her family immediately following the publication of the *Journal's* editorial.¹³ The *Journal* summarized the hopelessness of the situation by noting, "isn't it a national scandal that cancer sufferers should have to be written about in the *Wall Street Journal* to be offered legal access to emerging therapies once they've run out of other options?"¹⁴

The phenomenon of individuals seeking to access investigational drugs is not new. Patients hoping to exhaust every possible treatment before succumbing to death have sought access for several decades. The first criticisms of a "drug lag" arose shortly after the FDA began testing for efficacy in 1962.¹⁵ A 1973 study examined the effects of the new efficacy requirements and determined that compliance with the FDA's clinical trial process discouraged research and prevented the introduction of some effective drugs into the market.¹⁶ The debate continued when patient-advocates thrust

9. Editorial, *How About a 'Kianna's Law'?*, WALL ST. J., Mar. 24, 2005, at A14.

10. *Id.*

11. *Id.*

12. Editorial, *Kianna's Legacy*, WALL ST. J., Mar. 29, 2005, at A14.

13. *Id.*

14. *Id.*

15. Lois K. Perrin, Note, *The Catch-22 for Persons with AIDS: To Have or Not to Have Easy Access to Experimental Therapies and Early Approval for New Drugs*, 69 S. CAL. L. REV. 105, 115-16 (1995).

16. *Id.*

themselves into the regulatory process during the AIDS crisis of the 1980s.¹⁷ Critics of the FDA's policies during this crisis attacked the FDA's approval system as a whole, the methods used to test investigational drugs, and the inability of large populations of AIDS patients to access investigational drugs.¹⁸ Patient-advocates argued that the absence of conventional treatments allowed individual autonomy to trump the government's interest in safety.¹⁹ The FDA responded to these criticisms by expanding access to certain investigational drugs that have completed part of the trial process.²⁰ The debate between the competing interests of individual autonomy and safety is a critical component of the ongoing controversy surrounding access to investigational drugs.

In *Abigail Alliance v. von Eschenbach*,²¹ the United States Court of Appeals for the District of Columbia intensified the pressure on the FDA to increase access to investigational drugs by recognizing the right of a terminally ill patient to access certain investigational drugs.²² The D.C. Circuit held 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 determined by the FDA after Phase I trials to be sufficiently safe for expanded human trials warrants protection under the Due Process Clause."²³ The court applied *Washington v. Glucksberg*²⁴ to conclude that regulation of investigational drugs is the exception and not the rule in the United States because regulation for safety began in 1906 and regulation for efficacy began in 1962.²⁵ The court concluded that the rights to self-preservation and control over one's body have ancient roots in the common law.²⁶ Furthermore, the court concluded that the FDA failed to demonstrate that "government control of access to potentially life-saving medication 'is now firmly ingrained in our understanding of the

17. Marsha N. Cohen, *Getting New Drugs to People with AIDS: A Public Policy Response to Lansdale*, 18 HASTINGS CONST. L.Q. 471, 481 (1991).

18. *Id.*

19. Perrin, *supra* note 15, at 115.

20. *See infra* notes 56-65 and accompanying text.

21. 445 F.3d 470 (D.C. Cir. 2006), *rev'g* 2004 WL 3777340 (D.D.C. 2004), *vacated*, 469 F.3d 129 (D.C. Cir. 2006), *reh'g en banc*, 495 F.3d 695 (D.C. Cir. 2007), *cert. denied*, 128 S. Ct. 1069 (2008).

22. *Abigail Alliance*, 445 F.3d 470.

23. *Id.* at 486.

24. 21 U.S. 702 (1997) (establishing a two-part test used to examine an asserted liberty interest). *See infra* note 67 and accompanying text.

25. *Abigail Alliance*, 445 F.3d at 481-83.

26. *Id.* at 480.

appropriate role of government,' so as to overturn the long-standing tradition of the right of self-preservation."²⁷

After rehearing the case en banc, the District of Columbia Circuit held that terminally ill adult patients had no fundamental right to access investigational drugs.²⁸ The en banc majority traced drug regulation back to Colonial Virginia and even back to 15th century England to conclude that there is a history of evolving government regulation of drugs in response to changing science and technology.²⁹ Most importantly, the majority recognized the interests of terminally ill individuals and emphasized that the legislative and regulatory branches of government are best equipped to find the appropriate balance between individual liberty and community safety.³⁰

This note will explore the recent arguments presented by patient-advocates in support of a constitutionally protected liberty interest to access investigational drugs. Part I will explore the development of regulations governing the distribution of investigational drugs and demonstrate that limited access to investigational drugs should be permitted for certain individuals. Part II will explore potential constitutional foundations for a right of terminally ill patients to access certain investigational drugs and will demonstrate that current constitutional jurisprudence does not provide a strong framework for a right to access these drugs. Part III will examine potential statutory interpretations that would grant a right to access investigational drugs and the FDA's proposed method for increasing access. Part IV will point out the dangers of recognizing a constitutional right to access investigational drugs, show that such a right would likely become illusory, and conclude that increased access should occur through the legislative and regulatory process.

I. HISTORY OF THE REGULATION OF INVESTIGATIONAL DRUGS

Prior to the early 20th century, any regulation of drugs occurred at the state level and was inconsistent between states.³¹ As a result, adulteration and misbranding of drugs was common throughout the 19th century.³² The few

27. *Id.* at 483.

28. *Abigail Alliance*, 495 F.3d at 711.

29. *Id.* at 703-07.

30. *Id.* at 713.

31. See John P. Swann, *History of the FDA*, <http://www.fda.gov/oc/history/historyoffda/fulltext.html> (last visited June 22, 2008).

32. *Id.*

instances of federal regulation of drugs that did occur prior to the 20th century focused on the importation of drugs.³³ Congress's first attempt to correct the misbranding and adulteration problems occurred in 1906 with the passage of the Pure Food and Drug Act ("1906 Act").³⁴ The 1906 Act prohibited the sale of misbranded or adulterated foods or drugs in interstate commerce.³⁵ Furthermore, the statute required manufacturers to evaluate the strength, quality, and purity of drugs and to provide accurate drug content labels.³⁶ The statute focused on providing accurate labels to consumers instead of pre-market approval. The United States Pharmacopoeia and the National Formulary defined strength, quality, and purity. Any drugs not in compliance with these standards could not be sold unless the deviations from these standards were plainly stated on the label.³⁷ Enforcement of the 1906 Act focused on foods, which many believed posed a greater public health threat than drugs.³⁸ The United States Supreme Court rendered the 1906 Act ineffective when it ruled that "misbranding" as used in the statute included only statements of the "identity of the article" and not any therapeutic claims.³⁹ Therefore, the 1906 Act continued to permit access to any new drug for medicinal use because manufacturers were not restricted in the therapeutic claims that they could make.⁴⁰

Pressure continued to increase on Congress to remedy the ineffectiveness of the 1906 Act in the years following its enactment. The final push occurred in the 1930s with the introduction of Elixir Sulfanilamide, a drug targeted at pediatric patients. Elixir Sulfanilamide contained a highly toxic chemical similar to antifreeze.⁴¹ The distribution of Elixir Sulfanilamide caused more than one hundred deaths, including the deaths of a large number of children.⁴² In 1938, Congress responded to the disaster by passing the Food, Drug, and Cosmetic Act ("FDCA").⁴³ The most significant change in the regulatory

33. *Id.*

34. *Abigail Alliance v. von Eschenbach*, 445 F.3d 470, 481 (D.C. Cir. 2006), *vacated*, 469 F.3d 129 (D.C. Cir. 2006), *reh'g en banc*, 495 F.3d 695 (D.C. Cir. 2007), *cert. denied*, 128 S. Ct. 1069 (2008).

35. Perrin, *supra* note 15, at 109.

36. *Id.*

37. Swann, *supra* note 31.

38. *Id.*

39. *See United States v. Johnson*, 221 U.S. 488, 496-97 (1911).

40. *See Abigail Alliance v. von Eschenbach*, 445 F.3d 470, 481-82 (D.C. Cir. 2006), *vacated*, 469 F.3d 129 (D.C. Cir. 2006), *reh'g en banc*, 495 F.3d 695 (D.C. Cir. 2007), *cert. denied*, 128 S. Ct. 1069 (2008).

41. Swann, *supra* note 31.

42. *Id.*

43. *Abigail Alliance*, 445 F.3d at 482.

scheme was that the FDCA required extensive testing prior to granting governmental approval for new drugs.⁴⁴ The FDCA required the drug manufacturer to provide proof that a drug was safe before it was distributed in interstate commerce.⁴⁵

Drug regulation remained largely unchanged until 1962 when Congress responded to the Thalidomide tragedy by mandating, in the Kefauver-Harris Amendments to the FDCA, that the FDA review drugs for efficacy as well as safety prior to their distribution in interstate commerce.⁴⁶ The Amendments also provided the FDA with stricter control over drug trials.⁴⁷ The Thalidomide disaster is considered one of the greatest tragedies in the history of medicine. Many experts still believe, however, that it was unavoidable.⁴⁸ Thalidomide was widely used and praised as the most effective and safe sedative available.⁴⁹ The drug was also widely used to treat morning sickness in pregnancy, but was found to cause malformations in unborn children in 1962.⁵⁰ The dramatic effects of Thalidomide on unborn babies created a massive groundswell of support for increased regulation of prescription drugs in the United States.⁵¹ The 1962 Amendments are responsible for the current review process in effect today.

The FDA approval process is divided into three phases. Phase I trials enroll 10 to 100 individuals who are typically healthy. The average length of a Phase I trial is 1.5 years and costs approximately \$10 million. The goal of this phase of testing is to establish a maximum safe dose for the drug.⁵² Phase II trials enroll from 50 to 500 patients who suffer from the disease targeted by the drug. Researchers focus on the characteristics of patients who will be enrolled in the final phase of testing and make preliminary estimates of the effective doses of the drug and the duration of treatment. Phase II trials are approximately two years in length and cost \$20 million on average.⁵³ Phase III is the final stage of testing during which researchers seek to determine whether the treatment is effective and to discover side effects of the drug.

44. Perrin, *supra* note 15, at 109.

45. Swann, *supra* note 31.

46. Perrin, *supra* note 15, at 109.

47. *Id.*

48. See Ann Dally, *Thalidomide: Was the Tragedy Preventable?*, 351 THE LANCET 1197, 1197 (1998).

49. *Id.*

50. *Id.*

51. See Robert K. Plumb, *Deformed Babies Traced to a Drug*, N.Y. TIMES, Apr. 12, 1962, at 37.

52. Justin A. Zivin, *Understanding Clinical Trials*, SCIENTIFIC AMERICAN, Apr. 2000, at 71.

53. *Id.* at 73.

Phase III trials typically enroll from 300 to 300,000 patients depending on the drug being studied, last approximately three to four years, and cost \$45 million.⁵⁴ The testing process typically requires more than a decade to complete and a majority of drugs fail to complete the three-stage process.⁵⁵

The FDA currently provides several methods for limited access to investigational drugs. An investigational drug is a drug that has not yet been approved for distribution in interstate commerce under the FDCA. In 1987, the FDA adopted new regulations regarding the treatment use of investigational drugs (“Treatment IND”).⁵⁶ Under these regulations, a drug manufacturer or practicing physician may submit a treatment protocol⁵⁷ to the FDA for approval to distribute an investigational drug prior to completion of testing.⁵⁸ Application for Treatment IND occurs when an investigational drug demonstrates potential to aid patients with serious and life-threatening diseases.⁵⁹ However, drugs approved for Treatment IND must demonstrate some promise of safety and efficacy⁶⁰ and must be in Phase II trials.⁶¹ Most Treatment INDs are approved while in Phase III.⁶² Terminally ill patients seeking increased access argue that the Treatment IND method is not comprehensive enough because access to investigational drugs that have shown promise in early trials, such as investigational drugs that have completed Phase I testing or early Phase II testing, is still restricted.⁶³ The second method for access to investigational drugs is the compassionate use investigational new drug (“Compassionate Use”) or single-patient investigational new drug (“Single-Patient IND”).⁶⁴ Three requirements must

54. *Id.* at 75.

55. *Id.* at 70. For example, only five percent of all cancer drugs tested by clinical trials are ultimately approved for use. Furthermore, less than a third of drugs that successfully complete Phase I testing advance from Phase II to Phase III. Peter D. Jacobson & Wendy E. Parmet, *A New Era of Unapproved Drugs: The Case of Abigail Alliance v. von Eschenbach*, 297 J. AMER. MED. ASSOC. 205, 206 (2007).

56. Cohen, *supra* note 17, at 483.

57. MARK MATHIEU, *NEW DRUG DEVELOPMENT: A REGULATORY OVERVIEW* 262-63 (2d ed. PAREXEL 1990) (1987). A treatment protocol must contain:

the intended use of the drug; an explanation of the rationale for use of the drug . . . ; a brief description of the criteria for patient selection; the method of administration of the drug and the dosages; [and] a description of clinical proceedings, laboratory tests, or other measures to monitor the effects of the drug and to minimize risk.

58. Perrin, *supra* note 15, at 127.

59. MATHIEU, *supra* note 57, at 258.

60. See Swann, *supra* note 31.

61. Perrin, *supra* note 15, at 128.

62. *Id.*

63. See Cohen, *supra* note 17, at 483-84.

64. Larry Thompson, *Experimental Treatments? Unapproved but Not Always Unavailable*, FDA

be met for a terminally ill patient to obtain access under Compassionate Use: (1) the drug manufacturer must be willing to provide the investigational drug to the patient; (2) the patient must give informed consent; and (3) the treating physician must assume responsibility for treating the patient and agree to compile data about the effects of the investigational drug.⁶⁵

The FDA should be commended for its efforts to continually increase access to investigational drugs. These efforts, however, need to continue so that the FDA can provide terminally ill patients with more options in the safest manner possible. The current structure for obtaining access outside of the clinical trial process must be reviewed and refined to become more responsive to, and reduce the burden imposed on, terminally ill patients. Stories of terminally ill patients dying, such as Kianna Karnes, are far too common. The current exclusive focus on safety must be balanced against the terminally ill individual's right to access investigational drugs. The FDA should strive to find the appropriate balance between these two competing interests so that people are protected from dangerous drugs, but also have the ability to access appropriate investigational drugs.

II. CONSTITUTIONAL FOUNDATIONS FOR A RIGHT TO ACCESS INVESTIGATIONAL DRUGS

The Due Process Clause of the Fifth Amendment to the United States Constitution provides that “[n]o person shall be . . . deprived of life, liberty, or property, without due process of law.”⁶⁶ The United States Supreme Court has held that the Due Process Clause “guarantees more than fair process, and the ‘liberty’ it protects includes more than the absence of physical restraint.”⁶⁷ This liberty protects an individual's freedom from unwarranted government intrusion into the home, but the liberty is not limited thereto.⁶⁸ The Court has explained that “[f]reedom extends beyond spatial bounds. Liberty presumes an autonomy of self that includes freedom of thought, belief, expression, and certain intimate conduct.”⁶⁹ Examples of rights that the Court has defined as protected liberty interests under the Due Process Clause are the right to marry,

CONSUMER, Jan.-Feb. 2000, available at http://www.fda.gov/fdac/features/2000/100_exp.html.

65. *Id.*

66. U.S. CONST. amend. V.

67. *Washington v. Glucksberg*, 521 U.S. 702, 719 (1997).

68. *See Lawrence v. Texas*, 539 U.S. 558, 562 (2003).

69. *Id.*

to have children, to direct the education and upbringing of one's children, to marital privacy, to use contraception, to bodily integrity, and to abortion.⁷⁰

In *Washington v. Glucksberg*,⁷¹ the Supreme Court set forth a two-part test to determine whether an asserted right is a liberty interest protected by the Due Process Clause of the Fifth or Fourteenth Amendments.⁷² First, the Court stated that the Due Process Clause “protects those fundamental rights and liberties which are . . . ‘deeply rooted in this Nation’s history and tradition,’ and ‘implicit in the concept of ordered liberty,’ such that ‘neither liberty nor justice would exist if they were sacrificed.’”⁷³ Second, the Court required that the claim provide a “‘careful description’ of the asserted fundamental liberty interest.”⁷⁴ If the asserted interest passes the two-part test, any infringement by the State must pass strict scrutiny by being narrowly tailored and serving a compelling state interest.⁷⁵

In *Glucksberg*, four terminally ill patients and four physicians argued that a mentally competent, terminally ill adult has a liberty interest protected by the Due Process Clause of the Fourteenth Amendment to commit physician-assisted suicide.⁷⁶ The Court rejected this argument and held that the right to physician-assisted suicide is not a liberty interest protected by the Due Process Clause because history demonstrates an almost universal and continuous rejection of this asserted liberty interest.⁷⁷ The Court compared the asserted right of physician-assisted suicide with the right to refuse unwanted medical treatment, and while concluding that these two decisions are both “personal and profound,” pointed to the fact that the two decisions do not enjoy similar legal protection.⁷⁸ The Court explained that the implied right to refuse unwanted medical treatment “was not simply deduced from abstract concepts of personal autonomy,” but rather was grounded in the common-law right of protection from unwanted interferences with bodily integrity—i.e., the protection accorded by battery law.⁷⁹ The Court concluded that its “assumption was entirely consistent with this Nation’s history and

70. *Glucksberg*, 521 U.S. at 720.

71. 521 U.S. 702 (1997).

72. *Id.* at 720-21.

73. *Id.*

74. *Id.* at 721.

75. *See id.*

76. *Id.* at 707-08.

77. *Id.* at 723.

78. *Id.* at 725.

79. *Id.*

constitutional traditions.”⁸⁰ This comparison highlights the emphasis the Court placed on history related to the asserted interest when determining whether the asserted right was a protected liberty interest.

The Supreme Court addressed a competent individual’s right to refuse unwanted medical treatment in *Cruzan v. Missouri Department of Health*.⁸¹ Nancy Cruzan suffered major injuries in a car accident, and she subsequently slipped into a coma.⁸² Cruzan remained in a coma for three weeks, after which time doctors implanted in her a gastrostomy feeding and hydration tube.⁸³ Cruzan’s husband consented to the implementation of the tubes.⁸⁴ After all rehabilitative efforts failed and it became apparent that Cruzan had almost no chance of leaving the persistent vegetative state, Cruzan’s parents⁸⁵ requested that hospital employees terminate the artificial nutrition and hydration processes that kept Cruzan alive.⁸⁶ The hospital refused to terminate the artificial processes without court approval, and Cruzan’s parents sought and received approval from a Missouri state trial court.⁸⁷

The Supreme Court of Missouri reversed and held that the right to refuse unwanted medical treatment is not embodied in the right of privacy in either the Missouri Constitution or the United States Constitution.⁸⁸ The Missouri court did recognize the right to refuse medical treatment under the common law doctrine of informed consent, but held that a state policy in favor of preserving life prevented Cruzan’s parents from exercising choice in this situation.⁸⁹ Missouri’s requirement of “clear and convincing” evidence of the incompetent person’s intent to withdraw from treatment embodied the state’s policy in favor of the preservation of life.⁹⁰

The Supreme Court of the United States held that Missouri could require production of “clear and convincing” evidence of the incompetent individual’s desire to refuse life-sustaining medical treatment.⁹¹ The Court concluded that a state has an interest in safeguarding the personal element of the choice to

80. *Id.*

81. 497 U.S. 261 (1990).

82. *Id.* at 266. Persistent vegetative state is a condition in which a person exhibits motor reflexes but evinces no indications of significant cognitive function.

83. *Id.*

84. *Id.*

85. Cruzan’s parents were her co-guardians at this point. *See id.* at 268.

86. *Id.* at 267-68.

87. *Id.* at 268.

88. *Id.*

89. *Id.*

90. *Id.* at 280.

91. *Id.* at 280-81.

refuse medical treatment because of the “obvious and overwhelming finality” of the decision.⁹² The heightened evidentiary standard helps protect the incompetent individual from abuse.⁹³ To arrive at this conclusion, the Court assumed that a competent person has a protected liberty interest that permits refusal of unwanted medical treatment.⁹⁴

The Court inferred the right to refuse unwanted medical treatment from its prior decisions and the common law doctrines of battery and informed consent.⁹⁵ At common law, the harmful or offensive touching of one person by another with the intent to cause such contact is battery.⁹⁶ The principles of bodily integrity and individual autonomy also underlie the doctrine of informed consent.⁹⁷ Justice Cardozo explained that an individual has “a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient’s consent [] commits an assault, for which he is liable in damages.”⁹⁸ In light of the theories of battery and informed consent, the Court concluded that “the logical corollary of the doctrine of informed consent is that the patient generally possesses the right not to consent . . . to refuse treatment.”⁹⁹ The Court, however, has never explicitly held that the right of a competent adult to refuse unwanted medical treatment rises to the level of a liberty interest protected by the Due Process Clause.¹⁰⁰

Proponents of a right to access investigational drugs often cite a competent individual’s right to refuse unwanted medical treatment in support of a right to access investigational drugs. The argument can be summarized as follows: “If there is a protected liberty interest in self-determination that includes a right to refuse life-sustaining treatment . . . then the same liberty interest must include the complementary right of access to potentially life-sustaining medication. . . .”¹⁰¹ The focus of this analogy is the removal of

92. *Id.* at 281.

93. *Id.*

94. *Id.* at 279.

95. *Id.* at 269-70.

96. W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS § 9, at 39 (5th ed. 1984).

97. *Id.* at § 32, at 190.

98. *Schloendorff v. Soc’y of N.Y. Hosp.*, 105 N.E. 92, 93 (N.Y. 1914).

99. *Cruzan*, 497 U.S. at 270.

100. *See* *Washington v. Glucksberg*, 521 U.S. 702, 720 (1997) (stating that the Court has “strongly suggested” and “assumed” that the right to refuse unwanted medical treatment is a liberty interest protected by the Due Process Clause).

101. *Abigail Alliance v. von Eschenbach*, 445 F.3d 470, 484-85 (D.C. Cir. 2006), *vacated*, 469 F.3d 129 (D.C. Cir. 2006), *reh’g en banc*, 495 F.3d 695 (D.C. Cir. 2007), *cert. denied*, 128 S. Ct. 1069 (2008).

government from the individual's decision making process. Access proponents conclude that any government interference in the decision of whether or not to take an investigational drug is a violation of an individual's right to self-determination.¹⁰²

The argument that the right to access investigational drugs must be complementary to the right to refuse life-sustaining medical treatment seems to misperceive the basis for the right to refuse medical treatment. As previously mentioned, the right to refuse medical treatment is derived from the common law doctrines of battery and informed consent.¹⁰³ These doctrines focus on the individual's interest in bodily integrity and freedom from harmful or offensive touching. Therefore, the logical conclusion from these doctrines is that a person cannot be forced to undergo medical treatment.¹⁰⁴ There is no such logical conclusion from the common law doctrine of the right to access investigational drugs.

In *Abigail Alliance*, the United States Court of Appeals for the District of Columbia derived the right to access investigational drugs from the common law doctrines of necessity and self-defense.¹⁰⁵ The court concluded that these "ancient principles" of common law demonstrate a right of self-preservation that supports the right to access investigational drugs as an exercise of the right to self-preservation.¹⁰⁶ The doctrine of necessity arises when a person injures "an innocent person in order to avoid danger from another source."¹⁰⁷ Courts, however, have only applied the doctrine in a small number of cases and almost exclusively to situations where real or personal property is damaged.¹⁰⁸ Furthermore, in *United States v. Oakland Cannabis Buyers' Cooperative*,¹⁰⁹ the Supreme Court rejected a common law defense of necessity to the Controlled Substances Act and held that "the defense cannot succeed when the legislature has made a determination of values."¹¹⁰ The District of Columbia Circuit's en banc majority argued that Congress already

102. See *Abigail Alliance*, 445 F.3d at 484-85.

103. See *Cruzan*, 497 U.S. at 269-70.

104. *Id.* at 279.

105. See *Abigail Alliance*, 445 F.3d at 480-81.

106. *Id.* at 481.

107. KEETON ET AL., *supra* note 96, § 24, at 145.

108. *Id.* at 145-48.

109. 532 U.S. 483 (2001). The plaintiffs in the case, a group of patients seeking access to marijuana for medicinal purposes, argued that the common law necessity defense should be read into the Controlled Substances Act. *Id.* at 490.

110. *Id.* at 491.

eliminated the necessity defense in the FDCA by prohibiting “general access to experimental drugs. . . .”¹¹¹

The doctrine of self-defense is the privilege to use “all reasonable force to prevent any threatened harmful or offensive bodily contact, or any confinement”¹¹² Both the necessity and self-defense doctrines focus on the individual’s freedom from unwanted touching and the avoidance of harm. Although these common law doctrines do provide some support that a person should have the ability to protect herself from harm, they do not by themselves lead to a logical conclusion that a person has a liberty interest in accessing investigational drugs. The District of Columbia Circuit rejected Abigail Alliance’s argument that self-defense principles permit a terminally ill individual to assume “enormous risks’ in pursuit of *potentially* life-saving drugs.”¹¹³ Due to the emphasis on freedom from unwanted touching or bodily harm, the doctrines actually provide further support for a right to refuse unwanted medical treatment, rather than a right to access such treatment.

The approach used by the Supreme Court in *Lawrence v. Texas*¹¹⁴ provides a more expansive methodology to recognizing a liberty interest under the Due Process Clause. In *Lawrence*, John Lawrence and Tyron Garner were convicted of violating a Texas statute that prohibited “deviate sexual intercourse with another individual of the same sex.”¹¹⁵ Lawrence and Garner argued that the statute violated both the Equal Protection and Due Process Clauses of the Fourteenth Amendment. The Court overturned *Bowers v. Hardwick*¹¹⁶ when it held that the statute as applied to adult males violated the liberty interest protected under the Due Process Clause of the Fourteenth Amendment.¹¹⁷ In overturning *Bowers*, the Court focused on two elements of the Court’s decision: (1) the restrictive definition of the liberty interest, and (2) the Court’s emphasis on ancient history.

111. *Abigail Alliance v. von Eschenbach*, 495 F.3d 695, 708 (D.C. Cir. 2007), *cert. denied*, 128 S. Ct. 1069 (2008). The majority distinguished the asserted right to access investigational drugs from situations where self-defense principles are applicable, such as the abortion of a fetus if doing so is necessary to preserve the mother’s health or life, by arguing that “this case involves risk from drugs with no proven therapeutic effect” *Id.* at 709-10.

112. KEETON ET AL., *supra* note 96, § 19, at 124.

113. *Abigail Alliance*, 495 F.3d at 716 (emphasis in original).

114. 539 U.S. 558 (2003).

115. *Id.* at 563.

116. 478 U.S. 186 (1986) (holding that homosexuals do not have a liberty interest under the Due Process Clause to engage in homosexual sodomy).

117. *Lawrence*, 539 U.S. at 578.

The *Bowers* Court described the liberty interest at issue as the right of “homosexuals to engage in sodomy.”¹¹⁸ The *Lawrence* Court rejected this articulation of the asserted liberty interest. The Court explained that the sodomy statutes touch “upon the most private human conduct, sexual behavior, and in the most private of places, the home. The statutes do seek to control a personal relationship that . . . is within the liberty of persons to choose without being punished as criminals.”¹¹⁹ The Court looked beyond the statute to find the root of the liberty interest—the ability to structure a personal relationship. The ability to engage in homosexual sodomy was viewed as an outcome of the exercise of the liberty interest, not the liberty interest itself. The liberty interest was the ability to structure and control a personal relationship.¹²⁰ The outcome of this liberty interest may be a desire to engage in homosexual sodomy or some other action related to the personal relationship. A state cannot prohibit homosexual sodomy because such a prohibition would restrict the liberty interest of the individual to structure a personal relationship.

The Court relied heavily on the language in *Planned Parenthood v. Casey*,¹²¹ emphasizing the liberty to make decisions concerning marriage, procreation, contraception, family relationships, child rearing, and education.¹²² *Casey* described characteristics common to these liberty interests:

These matters, involving the most intimate and personal choices a person may make in a lifetime, choices central to personal dignity and autonomy, are central to the liberty protected by the Fourteenth Amendment. . . . Beliefs about these matters could not define the attributes of personhood were they formed under compulsion of the State.¹²³

The decisions concerning marriage, procreation, contraception, family relationships, children rearing, and education are all outcomes or variations of the fundamental right to structure and control a personal relationship. The Court concluded that persons in homosexual relationships should have the same freedom to make these decisions as persons in heterosexual relationships.¹²⁴

118. *Bowers*, 478 U.S. at 190.

119. *Lawrence*, 539 U.S. at 567.

120. *Id.*

121. 505 U.S. 833 (1992).

122. *Lawrence*, 539 U.S. at 573-74.

123. *Casey*, 505 U.S. at 851.

124. *Lawrence*, 539 U.S. at 574.

The *Lawrence* Court also departed from the *Bowers* Court's emphasis on the "ancient [historical] roots" of proscriptions against homosexual sodomy.¹²⁵ The *Lawrence* Court moved away from an exclusive focus on the history of the prohibition or the acceptance of such activity, and instead included history as one element in the examination of the alleged liberty interest.¹²⁶ The Court explained, "[H]istory and tradition are the starting point but not in all cases the ending point of the substantive due process inquiry."¹²⁷ The Court focused on other factors, such as the trends in recent history as related to homosexual conduct, the stigma imposed on individuals by criminal statutes, and trends in recent jurisprudence recognizing an individual's liberty to make certain decisions related to intimate elements of that person's life.¹²⁸ The *Lawrence* Court's use of history as one factor in the substantive due process inquiry significantly weakens the D.C. Circuit's recognition of the right to access investigational drugs. The D.C. Circuit used ancient common law principles to support its conclusion that regulation of investigational drugs does not have deep historical roots.¹²⁹ If the D.C. Circuit applied the *Lawrence* Court's analysis, the recent history of regulation of investigational drugs would significantly weaken the alleged ancient roots of the right to access.

The en banc majority in *Abigail Alliance* also relied on history, but arrived at the conclusion that drug regulation is the norm and not the exception.¹³⁰ In concluding that there is no tradition of protecting a right of access to drugs, the majority traced the regulation of drugs back to 15th century England and the Colony of Virginia's 1736 act relating to the "dispensing of more drugs than was 'necessary or useful' because that practice had become 'dangerous and intolerable.'"¹³¹ The difference between these two interpretations of the history of drug regulation lies in how one classifies the regulatory efforts. For example, the majority in the panel decision looked exclusively at the history of regulation of efficacy.¹³² The en banc majority, however, broadened its analysis of history to include all drug regulation efforts. This broadening of the scope of the historical examination revealed a long history of drug regulation in both England and the United States. These

125. *Id.* at 568-74 (quoting *Bowers v. Hardwick*, 478 U.S. 186, 192 (1986)).

126. *Id.* at 572.

127. *Id.* (citing *County of Sacramento v. Lewis*, 523 U.S. 833, 857 (1998) (Kennedy, J., concurring)).

128. *Id.* at 572-78.

129. *Abigail Alliance v. von Eschenbach*, 445 F.3d 470, 481 (D.C. Cir. 2006), *vacated*, 469 F.3d 129 (D.C. Cir. 2006), *reh'g en banc*, 495 F.3d 695 (D.C. Cir. 2007), *cert. denied*, 128 S. Ct. 1069 (2008).

130. *See Abigail Alliance*, 495 F.3d at 703-07.

131. *Id.* at 703-04.

132. *Abigail Alliance*, 445 F.3d at 482-84.

two contradictory conclusions about the history of drug regulation reveal the dangers of relying exclusively on the history of regulation or lack thereof in examining an asserted liberty interest.

The liberty interest examined in *Lawrence* is distinguishable from the interest in access to investigational drugs because the ability to access investigational drugs is not supported by an underlying constitutionally protected liberty interest. The liberty interest recognized in *Lawrence*¹³³ is based on the right to privacy in the marriage relationship announced in *Griswold v. Connecticut*¹³⁴ and its progeny. These liberty interests include the right to access contraceptives,¹³⁵ the right to access abortion,¹³⁶ and the right of persons less than sixteen years of age to access contraception.¹³⁷ All of these interests are some variation of the right to structure and control a personal relationship. An individual's decision to undergo treatment with investigational drugs would have fallen within the classification of "intimate and personal" choices described in *Casey*. However, there is not a long line of prior decisions leading to the conclusion that an individual has a right to access investigational drugs.

The arguments in support of the right of an individual to access investigational drugs are derived from a liberty interest that the Supreme Court has yet to explicitly recognize,¹³⁸ and which may have little or no legal tradition to support it. In rejecting the asserted liberty interest to physician-assisted suicide, the Supreme Court cited the reluctance of the Court to "expand the concept of substantive due process because guideposts for responsible decision making in this unchartered area are scarce and open-ended."¹³⁹ Furthermore, the Court limited the scope of the language in *Casey* when it explained that the fact "[t]hat many of the rights and liberties protected by the Due Process Clause sound in personal autonomy does not warrant the sweeping conclusion that any and all important, intimate, and personal decisions are so protected"¹⁴⁰

Patient-advocates concede that the right must be limited to certain drugs that have demonstrated some level of efficacy and have satisfied minimal

133. *Lawrence v. Texas*, 539 U.S. 558, 564 (2003).

134. 381 U.S. 479 (1965).

135. *See Eisenstadt v. Baird*, 405 U.S. 438, 454 (1972).

136. *See Roe v. Wade*, 410 U.S. 113 (1973).

137. *See Carey v. Population Services Int'l*, 431 U.S. 678 (1977).

138. *See Cruzan v. Mo. Dep't of Health*, 497 U.S. 261, 279 (1990).

139. *Washington v. Glucksberg*, 521 U.S. 702, 720 (1997).

140. *Id.* at 727-28.

safety concerns.¹⁴¹ The District of Columbia Circuit described the liberty interest as the “right of a terminally ill patient with no remaining approved treatment options to decide, in consultation with his or her own doctor, whether to seek access to investigational medications that the [FDA] concedes are safe and promising enough for substantial human testing.”¹⁴² This formulation of the asserted liberty interest appears to be too narrow, and many courts would be reluctant to recognize this narrow formulation of the interest.¹⁴³ Employing the *Lawrence* analysis, the asserted interest to access investigational drugs would need to be broadened to a more general right to access potentially life-saving medical treatment. The ability to access certain investigational drugs would be an outcome of this more general liberty interest in the preservation of life through access to medical treatment. The Court, however, has never recognized or suggested that an individual’s access to medical care is a protected liberty interest.¹⁴⁴ If an individual has a right to access investigational drugs, why should this right be limited to only those drugs that have passed Phase I testing? Furthermore, how would any changes in the current regulatory system affect the constitutional right, when the asserted liberty interest actually depends on a regulatory determination that the investigational drug is safe for testing?¹⁴⁵ The right to access investigational drugs would only have substance if the individual could obtain any investigational drug that a drug manufacturer was willing to provide. Therefore, it is unlikely that a court would find a right to access investigational drugs even when employing the more expansive analysis of *Lawrence*.

A constitutionally protected liberty interest in the access to certain investigational drugs would likely become illusory because of the complications that would arise in the exercise of such a right. There is serious doubt as to whether drug manufacturers would provide the investigational

141. See Letter from Frank Burroughs, President of Abigail Alliance, to Dr. Mark McClellan, Comm’r of Food and Drug Admin. (Oct. 7, 2003), available at <http://www.abigail-alliance.org/AbigailAllianceReplytoMusaMayerletter-Oct7.pdf>.

142. *Abigail Alliance v. von Eschenbach*, 495 F.3d 695, 701 (D.C. Cir. 2007), cert. denied, 128 S. Ct. 1069 (2008) (alteration in original).

143. The majority never reached the issue of whether the asserted liberty interest in access to investigational drugs satisfied the *Glucksberg* “careful description” requirement. Instead, the majority assumed *arguendo* that the description did satisfy this requirement. *Id.* at 702-03.

144. Wendy K. Mariner, *Equitable Access to Biomedical Advances: Getting Beyond the Rights Impasse*, 21 CONN. L. REV. 571, 582 (1989).

145. *Abigail Alliance*, 495 F.3d at 702 n.6.

medicines to terminally ill individuals.¹⁴⁶ Furthermore, the failure of the investigational drug may halt further clinical trials and expose the drug manufacturer to enormous liability.¹⁴⁷ Drug manufacturers already spend considerable amounts of money defending lawsuits arising from FDA-approved drugs, and it is doubtful that manufacturers would want to add to these costs by providing individuals with investigational drugs.¹⁴⁸ Furthermore, if a terminally ill patient chooses an investigational drug and suffers adverse health effects, who will be financially responsible for any subsequent medical care to treat the adverse conditions? The creation of a constitutional right to access investigational drugs would also remove the question from the very institutions best equipped to address it—Congress and the FDA.¹⁴⁹ Furthermore, the courts traditionally defer to the legislature in circumstances of scientific and medical uncertainty.¹⁵⁰ Constitutional protection places an issue beyond the reach of legislative and regulatory action in most instances.¹⁵¹ The many complications created by the exercise of the asserted liberty interest and the lack of support in recent constitutional jurisprudence suggests that the best approach to increasing access to investigational drugs for terminally ill patients is through changes in the current legislative and regulatory scheme governing the distribution of investigational drugs.

III. STATUTORY FOUNDATIONS FOR RIGHT TO ACCESS INVESTIGATIONAL DRUGS

Perhaps the strongest argument in support of a right to access investigational drugs is that safety concerns in the FDCA do not apply to terminally ill patients. When discussing whether it is possible for a person to treat himself unjustly, Aristotle explained, “For he suffers voluntarily, but no one is voluntarily treated unjustly. . . . It is not possible to treat oneself

146. Editorial, *Dying to Live*, 12 NATURE MED. 593 (2006).

147. *Id.*

148. *Id.*

149. The en banc majority of the District of Columbia Circuit recognized that “[o]ur Nation’s history and traditions have consistently demonstrated that the democratic branches are better suited to decide the proper balance between the uncertain risks and benefits of medical technology, and are entitled to deference in doing so.” *Abigail Alliance*, 495 F.3d at 713.

150. *Gonzales v. Carhart*, 127 S. Ct. 1610, 1636 (2007) (“The Court has given state and federal legislatures wide discretion to pass legislation in areas where there is medical and scientific uncertainty.”).

151. *See Washington v. Glucksberg*, 521 U.S. 702, 720 (1997).

unjustly.”¹⁵² The root of this idea is that “[n]o injustice has been done when an individual hurts him- or herself, if this person was beforehand fully aware of . . . a consequence . . . and if this person has accepted voluntarily to take the risk.”¹⁵³ Udo Schüklenk applied these arguments to the right of terminally ill patients to access investigational drugs to conclude:

When a person is faced with the inevitable outcome of disease progression, that is death, and this person is given the chance to try an experimental therapy with unknown outcome, then it is obvious that the worst possible outcome would again be the death of this person. All other outcomes would improve the baseline situation of this patient.¹⁵⁴

Schüklenk does acknowledge that there is a possibility that the investigational therapy could hasten disease progression, but argues that this risk is not much greater than that of individuals who enroll in clinical trials.¹⁵⁵ Therefore, if the inevitable outcome for a terminally ill patient is death, considerations of safety in the regulation of investigational drugs should not apply. This argument has not received widespread acceptance.

The Supreme Court examined the application of the FDCA to terminally ill patients in *United States v. Rutherford*.¹⁵⁶ A group of terminally ill cancer patients brought suit to enjoin the United States from prohibiting the interstate shipment of Laetrile, an investigational drug thought to be useful in the treatment of cancer.¹⁵⁷ Laetrile was not approved under the FDCA for distribution in interstate commerce.¹⁵⁸ The Court held that the FDCA is fully applicable to terminally ill patients and that the safety and efficacy standards of the FDCA apply equally to terminally ill patients and patients suffering from curable disease alike. In support of this, the Court relied on the fact that the FDCA contains no exceptions for terminally ill patients, and there is no evidence in the legislative history that Congress intended to create such an exception.¹⁵⁹ The Court concluded that questions of safety are inseparable from considerations of efficacy.¹⁶⁰ In support of its conclusion that the

152. UDO SCHÜKLENK, *ACCESS TO EXPERIMENTAL DRUGS IN TERMINAL ILLNESS: ETHICAL ISSUES* 24 (Mickey C. Smith ed., Pharmaceutical Products Press 1998).

153. *Id.* This premise assumes that the individual is competent to make the decision. The competency of the individual is beyond the scope of this note.

154. *Id.* at 28.

155. *Id.* at 178 n.70.

156. 442 U.S. 544 (1979).

157. *Id.* at 548-49.

158. *Id.* at 548.

159. *Id.* at 551-53.

160. *Id.* at 553.

FDCA's safety standards apply equally to terminally ill patients, the Court argued that "a drug is unsafe if it's potential for inflicting death or physical injury is not offset by the possibility of therapeutic benefit."¹⁶¹ Furthermore, "[a]n otherwise harmless drug can be dangerous to any patient if it does not produce its purported therapeutic effect. But if an individual suffering from a potentially fatal disease rejects conventional therapy in favor of a drug with no demonstrable curative properties, the consequences can be irreversible."¹⁶²

The Court does not adequately address the arguments made by Schüklenk. Proponents of a right to access investigational drugs seek access for patients who have exhausted all conventional treatments.¹⁶³ The Court based its conclusion on the premise that an individual may suffer severe consequences if he or she forgoes conventional treatment in favor of an investigational treatment.¹⁶⁴ Therefore, the Court's conclusion is less persuasive when a patient has exhausted all forms of conventional treatment. Schüklenk's argument—that any outcome other than death is an improved baseline situation of the patient—should apply in such a situation. A clinical trial for the same investigational drug would expose a terminally ill patient to some, if not all, of the same risks.¹⁶⁵ The structure of the current clinical trial system does not appear to significantly increase safety for terminally ill patients who have exhausted all conventional forms of treatment. If the terminally ill patient exhausts all conventional forms of treatment and participation in a clinical trial would expose the individual to the same risks as presented by personal use, the importance of safety for this individual is greatly reduced. The FDCA fails to adequately address this type of situation.

An alternative approach to directly attacking the FDCA is increased access through changes to the regulations promulgated under the FDCA. In response to the recent pressure to increase access to investigational drugs, the FDA has adopted this approach and, in December of 2006, issued proposed regulations to increase access.¹⁶⁶ The proposed regulations seek to clarify how

161. *Id.* at 556.

162. *Id.*

163. *Abigail Alliance v. von Eschenbach*, 445 F.3d 470, 472 (D.C. Cir. 2006), *vacated*, 469 F.3d 129 (D.C. Cir. 2006), *reh'g en banc*, 495 F.3d 695 (D.C. Cir. 2007), *cert. denied*, 128 S. Ct. 1069 (2008).

164. *See Rutherford*, 442 U.S. at 556.

165. Proponents of clinical trials argue that the strict guidelines for such trials protect the participant from unnecessary risk. The guidelines, however, often work to exclude terminally ill patients who have exhausted all conventional treatment. Paradoxically, the safety concerns designed to protect the patient actually produce the same result—death. Kianna Karnes's death is one example of this type of situation.

166. Expanded Access to Investigational Drugs for Treatment Use, 71 Fed. Reg. 75,147, (proposed Dec. 14, 2006).

patients can receive access to investigational drugs during clinical trials without meeting the exact criteria of the trial.¹⁶⁷ The proposals focus on expanded access for individual patients, intermediate-size patient populations, and larger populations under Treatment IND.¹⁶⁸ The proposals, however, do not create any new expanded-access programs and would permit companies to charge for the costs of manufacturing the drug. Such prices would be limited to costs of manufacturing to prevent companies from earning a profit under the new program.¹⁶⁹ The FDA's goal in permitting drug manufacturers to recover costs is to encourage smaller manufacturers to participate in expanded-access programs. The current prohibition on charging patients for the investigational drug prevents many smaller manufacturers from participating in these programs because they cannot afford to manufacture the drug.¹⁷⁰ The FDA explained that the changes are "intended to improve access to investigational drugs for patients with serious or immediately life-threatening diseases or conditions, who lack other therapeutic options."¹⁷¹ Critics of the proposed regulations argue that the rules do not make any significant changes and will result in a de minimis increase in access for terminally ill patients.¹⁷²

The FDA opposes providing blanket access to investigational drugs for fear that such access will trump safety concerns. FDA policies have traditionally focused on the scientific validation of potential therapies.¹⁷³ Therefore, current regulations restrict access until the manufacturer can provide proof of efficacy.¹⁷⁴ Furthermore, providing access to the investigational drug prior to approval would undermine the clinical trial system by reducing the number of patients willing to participate.¹⁷⁵ Few patients would volunteer for a clinical trial where they stand a chance of receiving a placebo. The FDA seeks to maintain a balance between access and safety despite this emphasis on scientific validation. The FDA has stated that

167. Jennifer Corbett Dooren, *FDA Pushes Access to Experimental Drugs*, WALL ST. J., Dec. 12, 2006, at A9.

168. Expanded Access to Investigational Drugs, 71 Fed. Reg. 75,147 (Dec. 14, 2006).

169. *Id.*

170. See Dooren, *supra* note 167.

171. Expanded Access to Investigational Drugs, 71 Fed. Reg. 75,147 (Dec. 14, 2006).

172. Washington G2 Reports, *FDA to Clarify Rules on Access to Experimental Drugs*, <http://www.g2reports.com/issues/news/news/breakingnews/28-1.html>.

173. Perrin, *supra* note 15, at 113-14.

174. *Id.*

175. See Susan Okie, *Access Before Approval—A Right to Take Experimental Drugs?*, 355 NEW ENG. J. MED. 437 (2006), available at <http://content.nejm.org/cgi/reprint/355/5/437.pdf>.

two of its most important regulatory goals are: (1) to protect the public from harm through product regulatory mechanisms, and (2) to maximize individual autonomy.¹⁷⁶ These goals operate in a closed system. Therefore, it is almost impossible to increase focus on both goals simultaneously. Any increase in individual autonomy will decrease the emphasis on safety and vice versa.¹⁷⁷

The unique situation of a terminally ill patient destroys the balance between the concerns of safety and individual autonomy because an individual who has exhausted all conventional treatments has no concern for safety. This places the FDA in a difficult position when trying to justify safety concerns because a terminally ill patient is likely to die while awaiting approval for an investigational drug. Safety measures as applied to that individual appear useless at best and harmful at worst. Although the FDA remains committed to safety in these situations, it has also recognized the need to provide access to certain terminally ill patients who have exhausted all other options.¹⁷⁸ The FDA continues to focus on increasing access by working to reduce review times.¹⁷⁹ This method of increasing access maintains the current review process but seeks to reduce review times by refining the process.¹⁸⁰

The FDA's response to the situation of terminally ill patients is inadequate. Scores of people will die while the FDA spends years determining how to reduce review times. Applying the normal safety concerns to terminally ill patients does not seem sensible. Some safety regulations are necessary to protect terminally ill patients from taking risks that expose them to significant dangers with no potential benefit,¹⁸¹ but the current balance between safety and individual autonomy gives too much weight to safety concerns to the detriment of terminally ill patients.

The most common arguments against increased access include the following: (1) the more access is increased, the harder it is to collect data on safety and efficacy; (2) access undermines the current clinical trial system because patients will seek direct treatment rather than enter a trial; and (3) access increases potential for fraud because drug companies would be permitted to market unproven drugs.¹⁸² Therefore, opponents of access argue that increased access will have an overall detrimental effect on the

176. *Id.*

177. *Id.*

178. Thompson, *supra* note 64.

179. *Id.*

180. *Id.*

181. See Davis, *supra* note 4; *Dying to Live*, *supra* note 146.

182. See Okie, *supra* note 175.

development of new life-saving drugs. The alternative to access is maintaining the current structure of clinical trials while increasing the use of trials until clinical research becomes a standard method of treating cancer.¹⁸³ This alternative would maintain the current accelerated approval process and compassionate-use program to provide access to investigational drugs in certain extreme situations where clinical trials are unable to provide care for the patient.¹⁸⁴

An alternative solution to the problem of access is to eliminate the current clinical trial system. Opponents of the current system argue that it is unethical because it knowingly denies the investigational treatment to some patients and gives other patients a placebo, thus providing no active treatment at all.¹⁸⁵ Therefore, even if a terminally ill patient qualifies for a clinical trial, there is no guarantee that the patient will receive the investigational drug. The fact that placebo trials are used on terminally ill patients makes the system particularly troublesome. A cancer patient who receives a placebo is likely to die despite her belief or hope that she is receiving the investigational drug.¹⁸⁶ Opponents of the system argue that the FDA should abandon placebo trials for terminally ill diseases because there is a significant difference between conducting such trials on the terminally ill and on generally healthy people.¹⁸⁷ Some opponents propose replacing placebo trials with large, open access trials that permit access for any individual who wants the new drug.¹⁸⁸ These trials would replace the placebo with statistical methods known as Bayesian statistics, which allow for statistically valid and reliable analysis without using randomized clinical trials.¹⁸⁹ The FDA already uses these statistical models to analyze results for medical device trials.¹⁹⁰

The only difference between clinical trial use and individual use of an investigational drug appears to be the benefits derived from each use. The clinical trial system can result in an outcome that is beneficial for a greater number of people by approving the distribution of an investigational drug that has demonstrated both its safety and efficacy. The clinical trial system, however, still exposes the patient to significant risks, and the requirements and

183. *Id.*

184. *Id.*

185. *How About a 'Kianna's Law'?*, *supra* note 9.

186. *Id.*

187. *Id.* The author makes a distinction between trials enrolling terminally ill patients and trials for drugs such as Vioxx, which are widely used on generally healthy people. *Id.*

188. *Id.*

189. *Id.*

190. *Kianna's Legacy*, *supra* note 12.

specifications of the trial severely restrict patient access to the investigational drug during the trial period.¹⁹¹ The stringent requirements result in a participation rate of two to five percent for potential patients.¹⁹² Individual use of an investigational drug promotes self-determination and may sustain and prolong the life an individual. Such use, however, may damage potential long-term benefits for the entire population of individuals suffering from that particular disease by reducing the amount of data on the safety and efficacy of the investigational drug.¹⁹³ We must continue to review and carefully monitor the current drug approval system and access mechanisms to determine which of the two approaches, or which combination thereof, will create the best equitable balance between access and safety.

IV. CONCLUSION

The right of a terminally ill patient to access certain investigational drugs has little support in either the Constitution or the Supreme Court's jurisprudence related to the alleged liberty interest in access. Courts have traditionally deferred to legislatures to make decisions concerning access and the availability of medical treatment.¹⁹⁴ Furthermore, any right to access investigational drugs is likely to become illusory unless drug manufacturers are mandated to provide the individual with the drug. Determining the appropriate scope of access to investigational drugs requires a delicate balancing of individual autonomy against the interest of the public in ensuring the safety of drugs. Elevating the access to investigational drugs to the level of a constitutional right would severely restrict the ability of Congress and the FDA to arrive at a proper balance between access and safety. Furthermore, constitutional protection of the right to access places the individual's interest above the larger community of persons suffering from the particular disease and those who will contract the disease in the future. Congress and the FDA must work to reduce review times and to provide simple and viable access programs for terminally ill patients with no remaining treatment options so that a person placed in the situation Kianna Karnes faced before her death has

191. University of Pittsburgh Medical Center, *Managing Your Health: Should You Take Part in a Clinical Research Trial?*, available at <http://www.upmc.com/HealthManagement/ManagingYourHealth/PersonalHealth/Men/?chunkiid=14431>.

192. *Id.*

193. See Mayer, *supra* note 2; Zivin, *supra* note 52.

194. See *Abigail Alliance v. von Eschenbach*, 495 F.3d 695, 713 (D.C. Cir. 2007), *cert. denied*, 128 S. Ct. 1069 (2008).

the ability to tell her children that she did everything possible to prolong her life. No drug regulatory system will ever be perfect, since no system can simultaneously grant access to every person who wants access to an investigational drug and protect society from the potential harmful effects of investigational drugs. Congress and the FDA must, however, strive to develop a regulatory framework that limits potential harm posed by investigational drugs while maintaining a fair system to provide access to individuals with no hope of recovery through conventional treatment.