

Regulation of Drugs: A Death Sentence for the Terminally Ill?

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Tempt not a desperate man.

—William Shakespeare,
Romeo and Juliet¹

Introduction

THE U.S. FOOD and drug Administration (“FDA”) has long served as a regulator for new pharmaceuticals that are seeking introduction into interstate commerce. It ensures that pharmaceuticals that enter the market are safe and effective, thereby guaranteeing consumer benefit. The U.S. government justifies this sort of regulation on the grounds that it protects the aggregate community welfare.

The legislation that governs the FDA is largely reactive to public outcry concerning unsafe drugs. Public health crises throughout history ultimately fostered the creation of a paternalistic organizational structure that carefully monitors development of pharmaceutical products. Recently, however, the FDA has fallen victim to controversy surrounding its prevention of access to drugs that have not yet been deemed safe or effective. For example, patient advocacy groups have argued that FDA regulations discriminate against minority populations, such as the terminally ill, who are willing to take significant risks for a chance to live. For terminal patients, the cost of waiting for FDA approval² is significant, as waiting often proves fatal.³ This tension be-

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1. WILLIAM SHAKESPEARE, *ROMEO AND JULIET* act 5, sc. 3.

2. This is a process that can take on average eight years. See Peter M. Currie, *Restricting Access to Unapproved Drugs: A Compelling Government Interest?*, 20 J.L. & HEALTH 309, 309 (2007).

tween aggregate and individual interests has sparked controversy surrounding the FDA's role as protector of the collective public welfare.

A patient advocacy group known as Abigail Alliance for Better Access to Developmental Drugs ("Abigail Alliance")⁴ brought this tension to light through a lawsuit filed in 2003. In *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach* ("Abigail Alliance III"),⁵ the organization sought to enjoin the FDA from preventing the use of post-Phase I experimental drugs by terminally ill patients outside of the clinical setting.⁶ In a 2007 decision, the United States Court of Appeals for the District of Columbia held that terminally ill patients do not enjoy a fundamental right to obtain access to experimental drugs.⁷

This Comment focuses on the moral and political philosophy that guides current thought in bioethics and surrounds the tensions exemplified in *Abigail Alliance III*. It examines the relationship between patients, physicians, pharmaceutical companies, and the government—concluding that the duty owed by all of these interest groups is a responsibility to the betterment of the community. The unifying theme of this Comment is that utilitarian philosophy best exemplifies this duty. Part I begins with an overview of the FDA and clinical trials.⁸ Part II analyzes the court's reasoning in *Abigail Alliance III*. Part III offers an overview of deontological and utilitarian thought and further argues for the application of utilitarian principles. Finally, this Comment concludes that despite the potentially tragic consequences, utilitarian arguments favor limiting access to experimental drugs—even for terminally ill patients.

3. *Id.* at 309–10.

4. Part of the mission of Abigail Alliance is to create greater access to developmental drugs for patients suffering from "serious life-threatening illnesses." *The Abigail Alliance Mission*, ABIGAIL ALLIANCE, <http://abigail-alliance.org/mission.php> (last visited Nov. 22, 2011).

5. *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach* (*Abigail Alliance III*), 495 F.3d 695, 697 (D.C. Cir. 2007).

6. Patricia Marisa do Coito Cruz, Case Note, *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach: Is There a Right to Live?*, 25 T.M. COOLEY L. REV. 347, 357 (2008).

7. *Abigail Alliance III*, 495 F.3d 695.

8. "Although there are many definitions of clinical trials, they are generally considered to be biomedical or health-related research studies in human beings that follow a predefined protocol." *Understanding Clinical Trials*, CLINICALTRIALS.GOV, <http://clinicaltrials.gov/ct2/info/understand> (last visited Mar. 26, 2012).

I. An Overview of the FDA

“New drug approvals in the United States exemplify a broader set of governmental regulatory decisions that occur at the threshold between law and science, and involve complex and multidisciplinary problem solving.”⁹

A. The History of the FDA

The FDA is a scientific, regulatory, and public health agency.¹⁰ It regulates food products, human and animal drugs, therapeutic agents of biological origin, medical devices, cosmetics, animal feed, and radiation-emitting products for consumer, medical, and occupational use.¹¹ The FDA holds the distinction of being the “oldest comprehensive consumer protection agency” in the federal government, dating back to 1930.¹² Yet it is still a rather recent regulatory phenomenon, having developed over the past century alone.¹³ Regulatory reforms enforced by the FDA have largely resulted from public outcry in the wake of drug-related deaths and public health scares.¹⁴

The agency’s regulatory function arose from the enactment of the 1906 Pure Food and Drugs Act (“1906 Act”), which prohibited interstate commerce of “adulterated and misbranded” food and drugs.¹⁵ The 1906 Act was created in response to the dire state of the American meatpacking industry, depicted by Upton Sinclair in *The Jungle*.¹⁶ This Act primarily regulated labeling, as opposed to pre-mar-

9. Michael D. Greenberg, *AIDS, Experimental Drug Approval, and the FDA New Drug Screening Process*, 3 N.Y.U. J. LEGIS. & PUB. POL’Y 295, 297 (2000).

10. *FDA’s Origin*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm124403.htm> (last visited Nov. 4, 2011).

11. *Id.*

12. *History*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/WhatWeDo/History/default.htm> (last visited Nov. 4, 2011) (noting that the FDA’s historic roots trace back to 1848 with the appointment of Lewis Caleb Beck in the Patent Office and that it regulated agricultural products). In 1906, the FDA was known as the Bureau of Chemistry. See *FDA’s Origin*, *supra* note 10. In 1927, its name changed to the Food, Drug, and Insecticide Administration, and this led to the shortening of the name into the modern terminology. *Id.*

13. *History*, *supra* note 12.

14. Robert M. Harper, *A Matter of Life and Death: Affording Terminally-Ill Patients Access to Post-Phase I Investigational New Drugs*, 12 MICH. ST. U. J. MED. & L. 265, 267 (2008).

15. *History*, *supra* note 12. This Act was also known as the Wiley Act and was signed by President Roosevelt during the Progressive Era. *FDA History—Part I*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm054819.htm> (last visited Nov. 7, 2011).

16. *FDA History—Part I*, *supra* note 15.

keting approval, of food and drugs.¹⁷ Regulation of adulterated drugs and misbranding came into being in 1912, and the government began to seize pharmaceutical products accordingly.¹⁸

The 1938 Food, Drug, and Cosmetic Act (“1938 Act”) passed after an assessment that products regulated under the 1906 Act continued to be ineffective, and in response to the elixir sulfanilamide therapeutic disaster.¹⁹ Elixir sulfanilamide was prescribed to treat streptococcal infections; however, the solvent used in this untested product “was a highly toxic chemical analogue of antifreeze.”²⁰ Consumption of this substance caused over one hundred deaths, including those of women and children. The widespread public fury that resulted directly contributed to the passage of the 1938 Act.²¹

The 1938 Act represented the dawn of modern regulation. It provided a novel mechanism for overseeing the development of medical devices.²² It also mandated that drugs be adequately labeled, including satisfactory directions for safe use, and prescribed pre-market approval for all new drugs.²³ The burden now rested with the manufacturers to prove the safety and efficacy of any drug to the FDA before it could be sold on the market.²⁴

The Kefauver-Harris Amendment was passed in 1962 in response to the crisis surrounding thalidomide.²⁵ Thalidomide was prescribed as a sedative for pregnant women, but it ultimately caused serious physical abnormalities in newborn babies.²⁶ The resulting amendments mandated that a drug be safe and effective before marketing could take place; therefore, stricter controls were imposed for drug

17. *Id.* The Act focused on the regulation of foods and was less concerned with “adulterated or misbranded drugs.” *Id.*

18. *Id.*

19. *FDA History—Part II*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm054826.htm> (last visited Nov. 7, 2011).

20. *Id.*

21. *Id.*

22. *Id.*

23. *Id.*

24. *Id.*; see also Harper, *supra* note 14, at 269 (“[T]he Food, Drug, and Cosmetic Act of 1938 did not impose any obligation on the manufacturer to obtain FDA approval before releasing its drug into the marketplace. Rather, absent an FDA determination that the drug was not safe, the drug was automatically approved for commercial distribution.” (footnote omitted)). Subsequently in 1951, the Durham-Humphrey Amendment of 1951 was passed; it clarified what constituted a prescription or over-the-counter drug. *FDA History—Part III*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm055118.htm> (last visited Nov. 7, 2011).

25. *FDA History—Part III*, *supra* note 24.

26. *Id.* This drug was never approved in the United States. *Id.*

trials.²⁷ This was a significant departure from the predecessor acts and amendments, as FDA approval was not previously required.²⁸

Favor for deregulation only developed after the AIDS health crisis in the 1980s.²⁹ Initially, AIDS seemed to appear disproportionately in homosexuals and intravenous drug users, both unpopular political minorities. As such, societal attention to the disease and support for finding a cure were minimal.³⁰ Since the FDA had not officially recognized the disease at that time, desperately ill victims facing imminent death lacked an FDA approved treatment option—which translated to no hope for a cure.³¹ A movement arose around what many viewed as an inadequate response by the government to this pressing public health crisis.³² Soon thereafter, access to experimental therapy became a concern, and societal pressure on the FDA to provide and promote access to new drugs increased dramatically—resulting in the reform of the drug approval process.³³ Most notably, the FDA undertook measures to increase access to drugs that were not yet approved and to expedite approval for patients suffering from incurable illnesses.³⁴

Between 1987 and 1993, the FDA created exemptions to the Investigational New Drug Application (“IND”) process by permitting the use of investigational drugs as treatment for patients who were seriously ill.³⁵ The programs that were promulgated included “Subpart E” and the “accelerated approval” program, which expedited FDA review for qualifying new drugs.³⁶ Other regulations that accelerated access

27. *Id.* Informed consent was one of the provisions implemented by this new amendment. *Id.*

28. Harper, *supra* note 14, at 269–70.

29. Benjamin R. Rossen, *FDA’s Proposed Regulations to Expand Access to Investigational Drugs for Treatment Use: The Status Quo in the Guise of Reform*, 64 *FOOD & DRUG L.J.* 183, 189 (2009) (noting that AIDS was officially identified by the Centers for Disease Control in 1982).

30. *Id.* (“[D]espite the looming presence of a serious public health crisis, AIDS had not become a major political issue. Government research expenditures remained relatively small and FDA had not approved a single treatment for the disease.”).

31. *Id.*

32. *Id.* at 190 (noting that People with AIDS Health Group and the AIDS Coalition to Unleash Power aided the passage of a grassroots movement that pressed therapy access issues).

33. *Id.*

34. *Id.*

35. *Id.*

36. *Id.*

included the “parallel track” program, which was designed for early access specifically for AIDS patients.³⁷

The deregulation trend developed over the past twenty years as a result of political pressure, consumer activism, and industry.³⁸ In response to these combined forces, Congress enacted the FDA Modernization Act (“FDAMA”) in 1997. This Act sought to reduce the delay that accompanies the FDA approval process³⁹ in order to grant patients access to investigational drugs for “the diagnosis, monitoring, or treatment of a serious disease or condition in emergency situations.”⁴⁰ The FDAMA founded the fast track program.⁴¹ However, the FDA simultaneously maintained that a drug must first seek approval to be commercialized.⁴²

B. Regulation and Structure of Clinical Trials

If we knew what it was we were doing, it would not be called research, would it?⁴³

—Albert Einstein

The FDA is responsible for assuring that pharmaceutical drugs and medical devices are both safe and effective.⁴⁴ Accordingly, a pharmaceutical company seeking to market a new drug in the United States must first obtain FDA approval.⁴⁵ For the purposes of this Comment, the focus is on the clinical phases regulated by the FDA.⁴⁶ In

37. *Id.* Further discussion of the “parallel track” program can be found in *AIDS, Experimental Drug Approval, and the FDA New Drug Screening Process* by Michael D. Greenberg. See Greenberg, *supra* note 9.

38. *FDA History—Part V*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm125632.htm> (last visited Nov. 7, 2011).

39. See discussion *infra* Part B.

40. 21 U.S.C. § 360bbb(a) (2006) (effective January 15, 2007).

41. Harper, *supra* note 14, at 270.

42. Rossen, *supra* note 29, at 193.

43. Barbara A. Noah, *Bioethical Malpractice: Risk and Responsibility in Human Research*, 7 J. HEALTH CARE L. & POL’Y 175, 175 (2004) (quoting Albert Einstein).

44. *What Does FDA Do?*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194877.htm> (last visited Nov. 3, 2011) (“[The FDA is responsible for p]rotecting the public health by assuring that foods are safe, wholesome, sanitary and properly labeled; human and veterinary drugs, and vaccines and other biological products and medical devices intended for human use are safe and effective Advancing the public health by helping to speed product innovations[.] Helping the public get the accurate science-based information they need to use medicines, devices, and foods to improve their health.”).

45. *What Is the Approval Process for a New Prescription Drug?*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194949.htm> (last visited Nov. 3, 2011).

46. A brief description of the preclinical stages: At the outset, the role of the FDA in drug research is limited. *The Beginnings: Laboratory and Animal Studies*, U.S. FOOD & DRUG

large part, FDA oversight requires a sponsor, generally a pharmaceutical company, to submit an IND.⁴⁷ If the IND is approved, three distinct phases (also referred to as stages) of human testing commence.⁴⁸

A Phase I study involves the primary introduction of the new drug into human subjects.⁴⁹ At this stage the size of studies range from twenty to eighty subjects.⁵⁰ Phase I studies are “designed to determine the metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.”⁵¹ Thus, the primary aim of these studies is to determine preliminary safety of the drug for continued use in the *clinical* setting.⁵²

A Phase II study is designed to “evaluate[] the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common

ADMIN., <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143475.htm> (last visited Nov. 3, 2011). The developer must first ask the question: “If the body’s functioning is changed, will I have a useful drug?” *Id.* Preliminary research focuses on how the body functions, both normally and abnormally, or at its most basic levels. *Id.* This forms the concept about how a drug could be developed to prevent, cure, or treat a disease. *Id.*

Once the researcher has formed a concept of how a drug can be used, he has a target to aim for when conducting laboratory experimentation. *Id.* (noting that researchers add compounds to enzymes, cell cultures, or cellular substances that are cultivated in test tubes to measure chemical effect). This process can require testing dozens of compounds. *Id.* Similar results can follow computer simulations of enzymes and chemical structures or testing on microscopic organisms. *Id.*

Next, the compounds that have shown some desired effects are tested in living animals. *Id.* The preclinical trials aim to assess the toxic effects and the safety levels of the drug at different doses. *Id.* Where previous research has aimed to determine what “a drug does to the body,” animal testing aims to resolve “what the body does to the drug.” *Id.* (stating that scientists will measure the amounts of the drug absorbed in the blood; determine how the drug is metabolized; the toxicity and break down of metabolites; and the speed at which the drug and metabolites are excreted). However, when the drug is poorly absorbed, unsafe, or does not have the desired effect, it is often abandoned. *Id.* The Pharmaceutical Research and Manufacturers of America estimates that 5 in 5000 compounds make the voyage from preclinical to human testing. *Id.*

47. *Abigail Alliance III*, 495 F.3d 695, 697 (D.C. Cir. 2007) (noting that an IND must contain “detailed information establishing that human testing is appropriate”); *see also* 21 C.F.R. § 312.23 (2011).

48. This does not include the preclinical process described *supra* note 46. In some instances there may be a fourth phase of clinical testing. *Abigail Alliance III*, 495 F.3d at 698.

49. Investigational New Drug Application (IND), 21 C.F.R. § 312.21(a)(1) (2011).

50. *Id.*

51. *Id.* Phase I studies also assess “drug metabolism, structure-activity relationships, and mechanism of action in humans, as well as studies in which investigational drugs are used as research tools to explore biological phenomena or disease processes.” *Id.* § 312.21(a)(2).

52. *Abigail Alliance III*, 495 F.3d at 698.

short-term side effects and risks associated with the drug.”⁵³ These studies are “well controlled, closely monitored, and conducted in a relatively small number of patients, usually involving no more than several hundred subjects.”⁵⁴

A Phase III study is characterized by a large participant pool of “several hundred to several thousand subjects.”⁵⁵ At this stage, studies are designed to “gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling.”⁵⁶

Over the years, the FDA has reacted to public health crises by implementing reforms that serve to chip away at the testing regulations and requirements at each of these phases. “The FDA, acting in concert with Congress, has developed a variety of mechanisms for making investigational drugs available for treatment uses during the course of ongoing clinical trials.”⁵⁷ Regardless of the exceptions and exemptions created to circumvent the FDA process, the requirements of approval apply to all new drugs, including those used for treatment of terminal illnesses.⁵⁸ “These mechanisms are designed to strike a balance among the competing interests and concerns that are presented when patients and physicians wish to treat serious diseases with investigational drugs.”⁵⁹

II. Abigail Alliance

This is not just about me. I am trying to help so many others.⁶⁰
—Abigail Burroughs

Abigail Burroughs is the young face behind the movement towards compassionate access. Abigail was nineteen years old when she was diagnosed with head and neck cancer.⁶¹ She suffered through various types of chemotherapy and radiation treatments “to no avail.”⁶²

53. 21 C.F.R. § 312.21(b).

54. *Id.*

55. *Id.* § 312.21(c).

56. *Id.*

57. Brief for the Respondents in Opposition at 4, Abigail Alliance III, 495 F.3d 695 (D.C. Cir. 2007) (No. 07-444) [hereinafter “Brief for the Respondents in Opposition”].

58. *United States v. Rutherford*, 442 U.S. 544, 551–59 (1979).

59. Brief for the Respondents in Opposition, *supra* note 57, at 5.

60. Frank Burroughs, *Our Story*, ABIGAIL ALLIANCE, <http://www.abigail-alliance.org/story.php> (last visited Nov. 22, 2011).

61. Complaint at 19, Abigail Alliance for Better Access to Developmental Drugs v. McClellan, No. 03-1601 (RMU) (D.D.C. Aug. 30, 2004), 2004 WL 3777340 at *19.

62. *Id.*

At the end of her life, she was treated at Johns Hopkins by a renowned oncologist who attempted to use EGFR-targeted drug C225 (Erbix) from Imclone Systems, or (Iressa) from AstraZeneca to save her life.⁶³ Abigail's father, Frank Burroughs, founded Abigail Alliance⁶⁴ in March 2001.⁶⁵ Abigail Alliance—with its namesake's help—lobbied the pharmaceutical companies, Congress, and the media to obtain a chance at treatment.⁶⁶ Unfortunately, Abigail did not qualify for participation in Iressa clinical trials because the nature of these trials was limited both by size and type of patients.⁶⁷ Similarly, Abigail could not obtain Erbix—a drug intended for the treatment of colon cancer.⁶⁸ Abigail lost her fight against cancer at the age of twenty-one.⁶⁹

In 2003, Abigail Alliance submitted a proposal to the FDA to create new regulations that would enable terminally ill patients with no other treatment options to receive experimental drugs post-Phase I testing.⁷⁰ The complaint challenged an FDA policy that “prohibits mentally competent patients with no other treatment options from purchasing investigational drugs—medicines showing initial evidence of safety and efficacy in clinical trials, but not yet approved—even though their physicians recommend these drugs as their best hope of surviving or of prolonging their lives.”⁷¹

The Court of Appeals on this matter found that through the “‘treatment IND’” program, the FDA may approve the use of an investigational drug for terminally ill patients as long as: (1) there exists “‘no comparable or satisfactory alternative drug or other therapy,’” (2) the drug is currently “‘under investigation in a controlled clinical trial,’” (3) and “the drug’s sponsor ‘is actively pursuing marketing ap-

63. Burroughs, *supra* note 60.

64. The mission of Abigail Alliance is to help “create wider access to developmental cancer drugs and other drugs for serious life-threatening illnesses.” *The Abigail Alliance Mission*, *supra* note 4.

65. Complaint, *supra* note 61, at 19.

66. *Id.*; see also *The Abigail Alliance Mission*, *supra* note 4.

67. Complaint, *supra* note 61, at 19.

68. *Id.*

69. *Id.* Other individuals named in the complaint include: David Baxter, a young man who died of colorectal cancer shortly after he turned seventeen (Baxter was unable to participate in clinical trials because they are restricted to individuals over the age of eighteen); Alita Randazzo, a thirty-five year old woman who died of colorectal cancer; and Joel Oppenheim, who was diagnosed with multiple myeloma (Oppenheim's prior treatment history—specifically, with the drug dexamethadone—disqualified him from participation in the clinical trials). *Id.* at 20–25.

70. *Abigail Alliance for Better Access to Developmental Drugs v. McClellan (Abigail Alliance I)*, No. 03-1601 (RMU), 2004 WL 3777340, at *1 (D.D.C Aug. 30, 2004).

71. Complaint, *supra* note 61, at 1–2.

proval of the investigational drug with due diligence.’”⁷² However, under the existing law, the FDA maintains the ability to refuse any treatment request if: (1) the FDA believes that there exists “no ‘reasonable basis’ to conclude the drug is effective,” or (2) approving the request would “‘expose the patient[] . . . to an unreasonable and significant additional risk of illness or injury.’”⁷³

Accordingly, the crux of the issue is that the authority to approve or deny last-ditch efforts to save a life rests with the FDA alone. In practice, the FDA does not approve the use of drugs outside the clinical trials until the drug had passed Phase III, or, at the earliest, Phase II testing.⁷⁴

Abigail Alliance petitioned the FDA to adopt the Tier 1 Initial Approval proposal that would permit drug sponsors to make investigational drugs available to terminally ill patients with no other treatment options, once the drug was post-Phase I testing.⁷⁵ Abigail Alliance claims in Count I that:

FDA’s policy prohibiting the sale of investigational drugs to willing and mentally competent patients with no other treatment options interferes with the ability of Abigail Alliance’s patient-members and other terminally ill patients to choose the appropriate treatment for terminal illness, in violation of rights secured to those individuals by the rights to privacy and the liberty of the U.S. Constitution.⁷⁶

Abigail Alliance argues that the FDA’s “compassionate use” programs only aid the demands of “a fraction of those in desperate need.”⁷⁷

72. Abigail Alliance III, 495 F.3d 695, 699 (D.C. Cir. 2007).

73. *Id.*

74. *See generally* Brief for the Respondents in Opposition, *supra* note 57.

75. Complaint, *supra* note 61, at 27.

76. *Id.* at 30. Count II of the complaint states:

FDA’s policy prohibiting the sale of investigational drugs to willingly and mentally competent patients with no other treatment options operates as a death sentence for those patients, including the Abigail Alliance’s patient-members, in violation of the guarantee in the Fifth Amendment of the U.S. Constitution against deprivation of life without due process.

Id. at 32.

77. *Id.* at 15. The FDA responded by stating that senior officials had reviewed the submissions but stated that the inquiry by Abigail Alliance “‘raised several important questions about expanded access that [they] believe[d] deserve[d] further consideration,’ but questioned whether the specific proposal put forward by the Alliance ‘would have the intended desirable effects for patients.’” *Abigail Alliance III*, 495 F.3d at 700 (quoting Letter from Peter J. Pitts, Assoc. Comm’r for External Relations, U.S. Dep’t of Health & Human Servs., to Frank Burroughs, President, Abigail Alliance for Better Access to Developmental Drugs (Apr. 25, 2003)).

A. Constitutional Rights

The decision of *Abigail Alliance III* hinged on the absence of a fundamental right protected by the Due Process clause of the Fifth Amendment. Abigail Alliance argued that the FDA prohibition on the prescription of investigational drugs violates patients' "privacy and liberty rights, as well as their rights to life, pursuant to the due process clause of the 5th Amendment."⁷⁸ Specifically, it asserted that the court should find a fundamental right of access "implicit in the concept of ordered liberty."⁷⁹ Abigail Alliance further stressed that pharmaceutical companies have a derivative right to sell their products at fair market value to incentivize enforcement of that right.⁸⁰

The court framed the right at issue in the following way:

Whether the liberty protected by the Due Process Clause embraces 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 promoting enough for substantial human testing.⁸¹

The court then turned to the question of whether there in fact existed a fundamental right⁸² as framed above. Judicial recognition of a fundamental right begins with an analysis of whether or not the right is "‘deeply rooted in this Nation’s history and tradition’ [including the Nation’s practices], and ‘implicit in the concept of ordered liberty,’ such that ‘neither liberty nor justice would exist if they were sacrificed.’"⁸³ The court has also recognized a fundamental right where it pertains to "choices central to personal dignity and autonomy."⁸⁴

Here the court paid particular attention to two arguments set forth by Abigail Alliance:

78. *Abigail Alliance I*, No. 03-1601 (RMU), 2004 WL 3777340, at *9 (D.D.C. Aug. 30, 2004).

79. *Id.* (quoting *Palko v. Connecticut*, 302 U.S. 319, 325 (1937)) (internal quotation marks omitted).

80. See generally Brief for the Respondents in Opposition, *supra* note 57.

81. *Abigail Alliance III*, 495 F.3d at 701.

82. The Court has stated that "[t]he Clause . . . provides heightened protection against government interference with certain fundamental rights and liberty interests." *Washington v. Glucksberg*, 521 U.S. 702, 719 (1997). However, the Court is reluctant to expand the interpretation of fundamental rights. Such rights have been limited to "the rights to marry, 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." *Id.* at 720 (citations omitted).

83. *Glucksberg*, 521 U.S. at 720–21 (citations omitted).

84. *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 851 (1992).

(1) that “common law and historical American practices have traditionally trusted individual doctors and their patients with almost complete autonomy to evaluate the efficacy of medical treatments”; and (2) that FDA policy is “inconsistent with the way that our legal tradition treats persons in all other life-threatening situations.”⁸⁵

Significantly, the court did not address the broader question of “whether access to medicine might ever implicate fundamental rights.”⁸⁶ Because the claimed right (as strategically narrowed) was not deemed to be fundamental, rational basis review was applied to Abigail’s right of access claim.⁸⁷

Lastly, Abigail Alliance ineffectively argued that the right of access is protected in concepts of self-defense, necessity, and interference with rescue, encompassed in the protection afforded to “persons in peril.”⁸⁸

B. Abigail Alliance Does Not Succeed on Constitutional Grounds

The court’s inquiry was appropriately founded upon the notion that the government, specifically the FDA, has historically possessed the power to regulate drugs. While Abigail Alliance argued that the regulation of drug efficacy began in 1962, the court found that since the conception of the FDA congressional regulations were passed in response to safety concerns.⁸⁹ The court’s line of reasoning is appropriate where public outcry surrounding health crises has historically pressured the government to reform the regulations, regarding food and drugs, as preventative measures for the future.

The United States has continuously expressed an interest in the regulation of drugs. The Nation continually tailors its legislation in

85. *Abigail Alliance III*, 495 F.3d at 703.

86. *Id.* at 701 n.5 (“The dissent has recast the Alliance’s proposed right away from the terms used in its briefs and oral argument—a right to access investigational new drugs—into a right to ‘try to save one’s life,’ which has ‘its textual anchor in the right to life [expressed in the Fifth Amendment].’” (alteration in original) (quoting *Abigail Alliance III*, 495 F.3d at 714–15 (Rogers, J., dissenting))).

87. *Id.* at 712. Therefore, it was Abigail Alliance’s burden to demonstrate that there was no rational relation between the regulations and the governmental interest. *Id.* The court found that Alliance could not meet this burden. *Id.* This Comment primarily focuses on the analysis for a fundamental right as it speaks to the issue at large regarding whether individuals should have a right of access.

88. *Id.* at 703. The rights of self-defense and necessity, in addition to the tort of interference with rescue, are beyond the scope of this Comment. These rights are more abstract than direct comparison to health law cases that are on point.

89. *Id.* (“Thus, to succeed on its claim of a fundamental right of access for the terminally ill to experimental drugs, the Alliance must show not only that there is a tradition of access to drugs that have not yet been proven effective, but also a tradition of access to drugs that have not yet been proven safe.”).

light of modern concerns about “risks associated with drug safety and efficacy.”⁹⁰ As an example, the *Abigail Alliance III* court cited to an act dating back to 1736, which stated that the Colony of Virginia “addressed the dispensing of more drugs than was ‘necessary or useful’ because that practice had become ‘dangerous and intolerable.’”⁹¹ Similarly, in the early 1800s, the Territory of Orleans passed an act that required a pharmacist to have obtained a diploma and have passed an examination before dispensing drugs; legislation passed in South Carolina required pharmacists to obtain licenses.⁹² Alabama, Georgia, and Louisiana witnessed various prohibitions on the sale of deteriorated drugs and poisons.⁹³ Therefore, the court correctly concluded that even at the founding of this Nation “governments respond[ed] to the risks of new compounds as they became aware of and able to address those risks.”⁹⁴ While these trends are not attributable to the birth of the FDA, they demonstrate the reason why *Abigail Alliance*’s argument that regulation began in 1962 fell short of judicial recognition.

The court further explained that the absence of federal regulation surrounding drug development prior to the 1900s is attributable to the nonexistent need for regulation at that time.⁹⁵ In 1902, Congress began to respond to public health scares, largely in response to the use of a vaccine that proved deadly for the children of Missouri and New Jersey.⁹⁶ The Pure Food and Drugs Act followed.⁹⁷ Part of the court’s rationale in finding a history of drug regulation parallels and cites to the history of the FDA discussed *supra* Part I.⁹⁸

Even where *Abigail Alliance* urges the court to examine the recent history of the FDA, it is instructive to note that despite the public pressure that led to other early access programs, the FDA has never abolished the requirement of clinical trials. This demonstrates the importance of these regulations on the development of pharmaceuticals. It is not surprising that the court declined to find a fundamental right

90. *Id.*

91. *Id.* at 704.

92. *Id.*

93. *Id.*

94. *Id.*

95. *Id.* (explaining that the need for federal rulemaking developed after the Civil War with the expansion of interstate commerce).

96. *Id.* at 705.

97. *Id.*

98. *Id.* Interestingly, the court notes an objection to the 1938 Act, which parallels objections made by *Abigail Alliance*—the history of the Act demonstrates concerns about the absence of the right to self-medication. *Id.*

in light of the Nation's traditions, whereby the FDA reacts to health crises by creating regulations to better manage and protect against future harm. It would be a stretch to conclude that none of these regulations and government responses promoted the safety of the citizens and preserved the efficacy of drugs. Thus, the FDA rightly argued that regulation of the sale of adulterated and unsafe drugs is merely "a difference in degree, not a difference in kind."⁹⁹

After determining that the proffered right was not fundamental, the court subjected Abigail Alliance's claimed right of access to experimental drugs to mere rational basis scrutiny.¹⁰⁰ The governmental interest was appropriately set forth by the FDA: "Without a requirement of FDA approval, patients could be exposed to unreasonable risks from investigational drugs that may be neither safe nor effective."¹⁰¹ Conversely, Abigail Alliance recognized this inherent risk as articulated, but stressed that patients should be permitted to assume the risk and make deeply personal life decisions for themselves.¹⁰² The court looked to Supreme Court precedent to conclude that FDA approval requirements *are* rationally related to a legitimate state interest.¹⁰³ Therefore, for the purposes of its analysis, the court rejected the distinction between an audience of terminally ill individuals and a greater population: "[F]or the terminally ill, as for anyone else, a drug is unsafe if its potential for inflicting death or physical injury is not offset by the possibility of therapeutic benefit."¹⁰⁴ In conclusion, where the court did not find a fundamental right of access to experimental drugs, it rightly concluded that there was a rational basis between the state interest in regulation and the corresponding legislation. This interest transcended the classification of whether or not an individual suffers from a terminal illness.

The court's holding leaves this issue to be decided by the democratic process, thus encouraging the continuation of public debate and legal reform: "Consistent with that precedent, our holding today ensures that this debate among the Alliance, the FDA, the scientific and medical communities, and the public may continue through the

99. Brief for the Respondents in Opposition, *supra* note 57, at 13.

100. *Abigail Alliance III*, 495 F.3d at 712.

101. *Id.* (quoting Corrected En Banc Brief for the Appellees at 55–56, *Abigail Alliance III*, 495 F.3d 695, 699 (D.C. Cir. 2007) (No. 04-5350)) (internal quotation marks omitted).

102. *Id.*

103. *Id.* (citing *United States v. Rutherford*, 422 U.S. 544 (1979)).

104. *Id.* at 713 (quoting *Rutherford*, 422 U.S. at 555–56) (internal quotation marks omitted).

democratic process.”¹⁰⁵ As the public remains susceptible to a possible change in the FDA regulations, the following analysis will focus on whether or not, as a matter of public policy and philosophy, the terminally ill should be able to receive access to post-Phase I experimental medication.¹⁰⁶

III. Philosophical, Ethical, and Moral Arguments

The impulses of nature, then contain *hindrances* to the fulfillment of duty in the mind of man, and resisting forces, some of them powerful; and he must judge himself able to combat these and to conquer them by means of reason, not in the future, but in the present, simultaneously with the thought; he must judge that he *can* do what the law unconditionally commands that he ought.

—Immanuel Kant¹⁰⁷

There are two dominant philosophies in bioethics: utilitarianism and deontology (also known as Kantianism). These moral principles act as behavioral guidelines that dictate a standard for societal conduct. It is important to examine the conflicting ethical and philosophical tensions raised by early access to unapproved drugs to fully understand the perspectives of the researchers, patients, doctors, and the government. Arguments surrounding expanded access embody the notion of duties—specifically where the duty to provide access to investigational drugs, if found, should fall. As characterized by Kant, “[t]he notion of duty then must be an ethical one.”¹⁰⁸ Ethical decisions can be characterized based on the intentions of the parties and the consequences of their actions.

105. *Id.* at 713–14.

106. The law surrounding post-Phase I compassionate use could see a future of change, as the FDA is a largely reactionary mechanism that responds to public health crisis. First, this specific issue has never been heard by the Supreme Court. Next—as discussed *infra*—Abigail Alliance could potentially present its arguments before Congress in an attempt to “convince our Nation’s lawmakers that the current balance between safety and risk is scientifically or morally misguided and that terminally ill patients should have the early access to experimental drugs that the Alliance seeks.” Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach (*Abigail Alliance II*), 445 F.3d 470, 487 (Griffith, J., dissenting). In doing so, the democratic process would assess testimony by scientists, doctors, patients, advocacy groups, moralists, ethicists, and citizens on the matter, without circumventing the current power of the FDA. *See id.* at 470 (majority opinion). Since a large part of this analysis contains a complex moral question, I will present two approaches—a utilitarian and a deontological analysis—to better understand the tensions exacerbated by terminal illness.

107. IMMANUEL KANT, KANT’S CRITIQUE OF PRACTICAL REASON AND OTHER WORKS ON THE THEORY OF ETHICS 290 (Thomas Kingsmill Abbott trans., 6th ed. 1927).

108. *Id.*

For purposes of this Comment, the key distinction between the utilitarian and deontological approaches is one of the *absolute* good, as opposed to the relative good.¹⁰⁹ Dissenters of the utilitarian school of thought characterize the good as valuing personal freedoms, such as the access to investigational drugs to preserve life “higher than other goods or as having embraced a different view of the good life with a different schedule of the relative significance of costs and benefits.”¹¹⁰ This Comment concludes that when there is a moral decision to be made regarding access to investigational drugs, the communal good should supersede the individual desire of access. Therefore, societal interests and altruism should ultimately trump narrowly defined self-interests.

A. The Utilitarian Analysis

Ethics conforming to the utilitarian principal operate to maximize the net-well-being and to provide “the greatest good for the greatest number.”¹¹¹ One of the central missions of the FDA is to prospectively review and approve new drugs in the interest of public health.¹¹² The FDA regulations exist to ensure product safety and efficacy; in doing so, it is imperative that the FDA conducts a risk-benefit analysis to determine whether a drug is too harmful to reach the market.¹¹³ Regulations for clinical trials ensure the maximum consumer benefit from access to safe and effective approved products. When the process involves such an apparent utility to the community at large, proper regulation is necessary and should be followed—even where the failure to obtain access could harm an individual. In determining the difference between what we ought to do and what we should do, we must examine the chain of causes and effects (not only focusing on what is right or wrong).¹¹⁴ The following section applies a utilitarian moral approach to support restricted access of investigational drugs for terminally ill patients.

Utility is defined as:

109. *See id.*

110. H. TRISTRAM ENGELHARDT, JR., *THE FOUNDATIONS OF BIOETHICS* 83 (1986).

111. David T. McDowell, Note, *Death of an Idea: The Anencephalic as an Organ Donor*, 72 *TEX. L. REV.* 893, 925 (1994).

112. Currie, *supra* note 2, at 309.

113. *Id.*

114. JEREMY BENTHAM, *AN INTRODUCTION TO THE PRINCIPLES OF MORALS AND LEGISLATION* 12–13 (J.H. Burns & H.L.A. Hart eds., Athlone Press 1970) (1789) (“[An action conforms to the principles of utility] when the tendency it has to augment the happiness of the community is greater than any it has to diminish it.”).

[P]roperty in any object, whereby it tends to produce benefit, advantage, pleasure, good, or happiness . . . to prevent the happening of mischief, pain, evil, or unhappiness to the party whose interest is considered: if that party be the community in general, then the happiness of the community: if a particular individual, then the happiness of that individual.¹¹⁵

Then, the interest of the community is “the sum of the interests of the several members who compose it.”¹¹⁶ When an action occurs in confirmation with the utility of the community, it has a tendency to “augment the happiness of the community” that is greater than “any [tendency] it has to diminish it.”¹¹⁷ When one’s actions conform to the principle of utility, it is said that those actions ought to be done or should be done.¹¹⁸ In this context, there is no evaluation of what is right or wrong in accordance with an individual moral compass.

This utilitarian balancing occurred at the moment the Nation’s laws and policies surrounding scientific development were first conceived. Science adheres to and mutually affects these laws and policies.¹¹⁹ Robertson explains:

Because science is both a source of power and a threat to existing power structures, governments have a stake in seeing that science develops or that it doesn’t, and in extracting profits and power as it does. Science is too important to be left to scientists alone, but because of their expertise can never be totally severed from them.¹²⁰

This notion demonstrates that government regulation is necessary to maintain a fully functional scientific community that produces widely available new technologies.

Governmental regulations, like ethical considerations, should differ depending on the stage of scientific development. Different stages pose different potential harms; for example, science at its early stages focuses on legal and policy issues surrounding research and development.¹²¹ At early stage development, existing regulatory structures ensure the safety and validity of the technology to enable it to reach the market—the description of the FDA clinical trial phases discussed

115. *Id.* at 12 (“The community is a fictitious *body*, composed of the individual persons who are considered as constituting as it were its *members*.”).

116. *Id.*

117. *Id.* at 12–13.

118. *Id.* at 13.

119. See John A. Robertson, *Law, Science and Innovation: Introduction to the Symposium*, 38 J.L. MED. & ETHICS, 175, 176 (2010). This article provides an insightful analysis of ethical issues surrounding the development of embryonic stem cells. Embryonic stem cell access poses similar issues regarding compassionate access as does new drug development.

120. *Id.*

121. Robertson, *supra* note 119, at 176.

supra embody these regulations.¹²² Conversely, later stage regulation ensures wide communal access to new, safe, and effective treatments.¹²³

Even where early research raises significant questions of morality or public policy, continued regulation by the government is necessary. The scientific community has similarly stalled research because of the potential harmful effect on society.¹²⁴ Therefore, even where the FDA limits access to investigational drugs, review and consideration by the pharmaceutical company is necessary to prevent detrimental harm and further public health crises.

1. The Pharmaceutical Companies

At first blush, it would seem that pharmaceutical companies would favor Abigail Alliance's proposition—drugs made available through early access could be sold at market value with minimal testing. However, any potential for profit would pale in comparison to the risks that a pharmaceutical company would assume. For example, should terminal patients—a particularly vulnerable population—be exposed to drugs released absent the tight controls of a clinical trial, “unexplainable, adverse reactions to the drug could be revealed.”¹²⁵ The risks accompanying such side effects would also be greater due to decreased scientific controls¹²⁶ and an increased, unregulated sample size. These factors could result in premature termination of the study.¹²⁷

Were early access made available, the pharmaceutical companies would also risk exposure to significant legal liability should serious and unforeseen side effects arise. In this context, the level of safety is wildly uncertain and the population of individuals receiving investigational drugs is greatly expanded—thus increasing the likelihood of litigation. Manufacturers could face legal liability in areas such as

122. *See id.*

123. *Id.*

124. For example, the development and emergence of recombinant DNA techniques (that involved the ability of gene splicing in common organisms) created fear that engineered organisms that escaped the laboratory could cause potential epidemics and other disasters. This led the scientists, not the government, to halt development until protective mechanisms had been established. *Id.* at 176–77.

125. See Elizabeth Weeks Leonard, *Right to Experimental Treatment: FDA New Drug Approval, Constitutional Rights, and the Public's Health*, 37 J.L. MED. & ETHICS 269, 272 (2009).

126. For example, a patient's prior drug therapy, which would have prevented their participation in a clinical trial, could negatively interact with the current, experimental drug therapy.

127. Leonard, *supra* note 125, at 272.

product liability, failure to warn, fraud, and negligence.¹²⁸ In addition, small start-up companies may find it difficult to provide an adequate supply of investigational drugs to a larger patient population if such a fundamental right was found.¹²⁹ The totality of these risks would create a chilling effect on the production and development of new treatment options. Accordingly, society could face a decrease in innovation that might ultimately lead to many more deaths.

2. The Physicians

The interest of physicians must be considered because, in a situation where early access was an available treatment option, drugs would be obtained through the permission of the FDA, compliance with the pharmaceutical company, *and* with the prescription of a physician.¹³⁰ If one focuses on the utilitarian aspect of physician care, granting a fundamental right to investigational drugs could subject physicians to an increased risk of litigation resulting from the prescription of medication. In essence, the physician is the entity that evaluates the risks associated with various drugs—which are largely unknown—and the corresponding benefits of the same—which are also largely unknown.¹³¹ Physicians placed in this position are at a significant disadvantage in comparison to the researchers. They do not have access to the technology needed to monitor the patients, and identification of the onset of side effects could prove more difficult: “[R]esearch subjects have greater protections than do patients in such cases because research is independently reviewed and there are limits on the risks to which subjects may be exposed.”¹³² This could lead to a scenario in which a product appears to be favorable to both the physician and the patient, but is wholly ineffective—thus subjecting the patient to false expectations and exposing the physician to the fear of litigation. As Iltis appropriately comments: “Physicians face substantial risk of liability for deviating from the standard of care unless they can demonstrate that it was reasonable to believe it was in the patient’s best interest to do so.”¹³³ In comparison, clinical researchers are not bound by the same constraints, as they do not act in the subjects’ best

128. *Id.* at 273.

129. *Id.* at 272.

130. Leonard, *supra* note 125, at 273.

131. See Meghan K. Talbott, *The Implications of Expanding Access to Unapproved Drugs*, 35 J.L. MED. & ETHICS 316, 317 (2007).

132. Ana S. Iltis, *What the Doctor Didn't Say: The Hidden Truth About Medical Research* By Jerry Menikoff and Edward P. Richards, 36 J.L. MED. & ETHICS 419, 420 (2008) (book review).

133. *Id.*

interest. This distinction, while harsh, appropriately allocates the risk of litigation for investigational drugs.

3. The Government

The government's arguments in *Abigail Alliance III*—favoring the prohibition of access to post-Phase I investigational drugs—fall squarely within utilitarian philosophy. First, the FDA argues that there is concern about unregulated products entering the marketplace. If expanded access transcends the clinical trial setting, then further research and testing would occur after the widespread consumption of investigational drugs.¹³⁴

Second, after a drug enters the marketplace, it is difficult to enroll participants in studies and carry them out effectively.¹³⁵ As Leonard reasons: “Why would a patient who desperately wants a drug enroll in a traditional, ‘gold standard’ clinical trial and risk being assigned to a placebo or control group rather than buy the drug up-front?”¹³⁶ Failure to enroll can result in eliminating an available pool of potential subjects based on socioeconomic or other differences, which in turn could undermine researchers’ ability to achieve accurate results.¹³⁷ Concerns regarding the diminished importance of clinical trial results would be compounded if the drug manufacturer could receive a profit—it would provide a strong incentive for pharmaceutical companies to circumvent the FDA regulations.¹³⁸ The FDA aptly notes that in such a scenario, “the sponsor’s financial incentive to complete the scientifically rigorous and expensive clinical trial process [would be] directly reduced, and the sponsor may find it more attractive to sell the unapproved drug today than to vigorously pursue years of research for regulatory approval that most investigational drugs never obtain.”¹³⁹

Therefore, expanded access has the potential to undermine the clinical trial process¹⁴⁰ and the quality of collected data, an essential

134. *Abigail Alliance I*, No. 03-1601 (RMU), 2004 WL 3777340, at *12 (D.D.C. Aug. 30, 2004).

135. *Id.*

136. Leonard, *supra* note 125, at 274.

137. *Id.* at 275.

138. Brief for the Respondents in Opposition, *supra* note 57, at 6; *see also* Leonard, *supra* note 125, at 274 (“Manufacturers could sell drugs without the expense, effort, and risk of failure associated with conducting full trials.”).

139. Brief for the Respondents in Opposition, *supra* note 57, at 6.

140. For example, diethylstilbestrol was prescribed to women to avoid risks of miscarriage and as a prenatal vitamin, but was never systematically tested through controlled clinical trials. This drug ultimately led to cancer in the treated women’s daughters. Leo-

component of determining a given drug's safety and efficacy.¹⁴¹ Successful completion of Phase I determines that the drug is safe enough to be administered to a moderately larger, closely monitored population of Phase II testing—not that it is safe or effective for society at large.¹⁴² The result of early release would be that the product would enjoy some longevity in the market place with little understanding of actual benefits or potential toxicity.¹⁴³

Second, due to the serious nature of treatments for various terminal illnesses, possible adverse health consequences resulting from investigational drugs include hastened mortality.¹⁴⁴ One should carefully examine the argument for premature use in light of the specific qualities of drugs used to treat cancer: namely that this category of drugs are inherently toxic by design, and “their toxic effects often do not discriminate well between cancerous and non-cancerous cells.”¹⁴⁵

The Supreme Court illuminated this concern in *United States v. Rutherford*, where it declared that the Kefauver-Harris Amendments of 1962 demonstrated congressional intent to protect individuals suffering from fatal illnesses.¹⁴⁶ In *Rutherford*, the plaintiffs similarly argued that regulations did not have any reasonable application to terminally ill patients.¹⁴⁷ The Court expressly disagreed, stressing that “the concept of safety . . . is not without meaning for terminal patients. For the terminally ill, as for anyone else, a drug is unsafe if its potential for

nard, *supra* note 125, at 274. Similarly, autologous bone marrow transplant with high dose chemotherapy was a promising treatment option for breast and ovarian cancer. Accordingly, there was significant public pressure to make this treatment available even in the absence of complete scientific information. However, complete clinical trials demonstrated that it was no more effective than approved treatments. *Id.* Lastly, in the 1980s clinical researchers were unable to enroll volunteers for the clinical trial of azidothymidine because of the concerns about receiving a placebo and the availability of drugs through the grey market. *Id.* at 275.

141. Brief for the Respondents in Opposition, *supra* note 57, at 5; see also Expanded Access to Experimental Drugs for Treatment Use, 71 Fed. Reg. at 75,147, 75,150 (proposed Dec. 14, 2006) (to be codified at 21 C.F.R. pt. 312) (“[A] system of blindly permitting uncontrolled access to investigational drugs could make it difficult or impossible to enroll adequate numbers of patients in clinical trials.”).

142. Brief for the Respondents in Opposition, *supra* note 57, at 3.

143. Abigail Alliance I, No. 03-1601 (RMU), 2004 WL 3777340, at *12 (D.D.C. Aug. 30, 2004).

144. *Id.*

145. *Id.* at *4.

146. *United States v. Rutherford*, 442 U.S. 544, 553 (1979) (“Both [Committee] Reports note with approval the FDA’s policy of considering effectiveness when passing on the safety of drugs prescribed for ‘life-threatening disease.’”).

147. *Id.* at 555.

inflicting death or physical injury is not offset by the possibility of therapeutic benefit.”¹⁴⁸ Therefore, there is no reason to question the FDA’s ability to regulate drugs for the terminally ill as opposed to any other patient population.

Lastly, the government’s authority to regulate access to these drugs would be significantly diminished by the recognition of the requested fundamental right.¹⁴⁹ Identifying a right of access to life-saving drugs outside FDA approval could lead to an acceptance of the same right for patients who are not terminally ill but need treatment for other illnesses.¹⁵⁰ This possibility leads one to ask: At what point is the line drawn? Who defines what a terminal illness is?

It is easy to see how this slippery slope could threaten the FDA’s very legitimacy and existence in general.¹⁵¹ This is a substantial price to pay where preliminary determinations of safety and efficacy for many products “often prove unfounded, and drugs that initially appear promising are frequently found ineffective or even affirmatively dangerous to life and health.”¹⁵² In this context, it is important to remember that a majority of drugs do not complete the clinical trials. For cancer treatment, approximately five percent of drugs are ultimately approved by the FDA and reach the market. “Thus, when investigational drugs are fully tested by the FDA’s clinical trial process, the expectations regarding safety and efficacy that led the sponsor to initiate the process commonly prove to be unfounded.”¹⁵³

Even in light of the compelling and tragic cases that move the audience to argue in favor of expanded access, regulation is nonetheless essential to the population at large. The FDA provides a public utility that, if undermined, would lead every citizen of the United States to question both the safety and efficacy of the products that they consume. The court in *Abigail Alliance III* ultimately came to the correct decision—a conclusion that possesses foresight and appropriately takes into account the potential outcome of extending a fundamental right in this context. It is important to note that even absent the recognition of a fundamental right, legislation could be passed to grant early access. Such legislation would be appropriate in nature

148. *Id.* at 555–56.

149. Leonard, *supra* note 125, at 273.

150. *Id.*

151. *Id.*

152. Brief for the Respondents in Opposition, *supra* note 57, at 3.

153. *Id.* at 4 (“Successful clinical trials are the exception, not the rule.”).

and scope because it would protect against the slippery-slope finding that all individuals are entitled to receive life-sustaining drugs.

4. The Potential Liability of Physicians and Pharmaceuticals is a Legitimate Concern

Litigation as a theme reoccurs in this Comment, specifically in the context of the threat of an outpouring of lawsuits serving to chill the actions of both physicians and pharmaceutical companies. It is important to note instances in which clinical trials have been suspended because of serious injury to a participant.¹⁵⁴

In 1999, Jesse Gelsinger, an eighteen year-old boy afflicted with a mild form of an inherited liver disease, sustained multiple-organ failure and died in response to a dose of a viral vector that was designed to insert healthy genes into his liver cells.¹⁵⁵ The fatal treatment was considered to be risky for an individual who was coping relatively well with such a disorder.¹⁵⁶ The Gelsinger family sued the University of Pennsylvania and the director of the bioethics program, among others, alleging “that the information provided in the informed consent documents was incomplete and that the research team deliberately misled the family about the safety of the protocol by withholding information about previous adverse events associated with the gene therapy procedure.”¹⁵⁷

Similarly, Ellen Roche, a twenty-four year-old healthy participant, died while participating in a 2001 study that sought to understand the physiological mechanism of asthma.¹⁵⁸ Roche’s inhalation of the chemical provided to her ultimately led to the failure of her lungs and kidneys.

For purposes of this Comment these examples are limited—however, they demonstrate that the occurrences of side effects should not be lightly overlooked as they can have significant and concrete consequences for biomedical research. As such, society should favor the propagation of research that can treat many as opposed to the prolonged life of one.

154. Noah, *supra* note 43, at 177.

155. *Id.*

156. *Id.*

157. *Id.* at 178.

158. *Id.* This led to the suspension of all federally-funded research at Johns Hopkins University. *Id.* at 179.

B. Deontological View

The deontological principals focus on individual morality; these principals are not justified in terms of their consequences. Kantian philosophy is grounded on the “moral status of persons in the capacity for autonomous rational agency; roughly, the capacity to make one’s own choices about what to do.”¹⁵⁹ In contrast to the utilitarian ideals, there exists a strong argument for individual choice and interests.¹⁶⁰

The deontological perspective treats the concept of justice as *fairness*, because “persons accept in advance a principle of equal liberty and they do this without a knowledge of their more particular ends.”¹⁶¹ Under the deontological framework, however, the “question of attaining the greatest net balance of satisfaction never arises in justice as fairness; this maximum principle is not used at all.”¹⁶² Therefore, deontology, from philosophers such as W.D. Ross, distinguishes between what is good and what is right—arguing that “some people fail to notice the distinction between ‘right’ and ‘morally good’, and that others, while distinguishing the meaning of these terms, think that only what is morally good is right.”¹⁶³ A morally good act results from decisions that have a good motive.¹⁶⁴ Conduct that is right need not be achieved through a good motive.¹⁶⁵ In that sense, moral obligations exist even when an action does not effectuate the greater good. This theory creates duties both for the respect of humanity and the ability of self-determination.

1. The Patient’s Perspective: Consideration of the Individual

The arguments made by Abigail Alliance are deeply rooted in the deontological perspective—that is, the right of an individual to re-

159. Maria Merritt, *Bioethics, Philosophy, and Global Health*, 7 *YALE J. HEALTH POL’Y L. & ETHICS* 273, 286 (2007).

160. Consider this example:

One might think of a community attempting to bring its members to realize a higher level of health and to lower certain health care costs by stopping smoking and engaging in exercise programs. What of the sedentary smokers who do not judge that such is worth the effort? The achievement of the communal view of the good will often fall prey to the free choice of individuals not to aid its prospering.

ENGELHARDT, *supra* note 110, at 83.

161. JOHN RAWLS, *A THEORY OF JUSTICE* 31 (Belknap Press 1971).

162. *Id.* at 30.

163. DAVID ROSS, *THE RIGHT AND THE GOOD* 3 (Phillip Stratton-Lake ed., Oxford Univ. Press 2002) (1930).

164. *Id.* at 4.

165. *Id.* at 3.

ceive medical treatment as a citizen of the United States.¹⁶⁶ The central contention is that terminally ill patients who have no approved treatment options have a right to decide for themselves whether or not they wish to take an investigational drug that the government concedes is safe for human testing.¹⁶⁷

This argument presents a challenge to the FDA restrictions on the grounds that they violate principles of autonomy and privacy.¹⁶⁸ In a society that has protected the right to privacy, the right to die, the right to bodily integrity, and the right to bear children, the right to live should be considered fundamental.¹⁶⁹ Deontology would command dignity and respect for life choices without the consideration of the implications of individual choices on the society at large. However, in terms of public policy, recognition of the deontological persuasion could have a disastrous effect on the health care industry:

If we truly value bodily autonomy and patient self-determination, why limit the question to terminally ill patients? Why not recognize any person's interest in ingesting potentially palliative, curative, or harmful drugs, free from government interference? On autonomy grounds alone, there does not seem to be a basis for the distinction.¹⁷⁰

Imbedded in arguments regarding personal autonomy is the notion that patients should be able to assume the risk of negative safety and efficacy consequences associated with the use of investigational drugs outside of clinical trials. The predicament is that terminally ill patients who have a very low life expectancy—and have exhausted all of their viable FDA approved treatment options—are willing to tolerate various associated high or unknown risks in an effort to survive.¹⁷¹ Abigail Alliance argues that these patients are competent and can produce rational and intentional actions in the absence of controlling influences.¹⁷²

In order for patients to make competent and informed decisions concerning their health and treatment options, they must have an un-

166. See generally Petitioner's Reply Brief, *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 552 U.S. 1159 (2008) (No. 07-444). This argument is fully explained in the litigation opinion briefs, opinions, and supporting materials.

167. Brief of Appellants at 43, *Abigail Alliance III*, 495 F.3d 695 (D.C. Cir. 2007) (No. 04-5350), 2005 WL 1826286 at *43.

168. *Id.*

169. *Id.*

170. Leonard, *supra* note 125, at 272.

171. See Currie, *supra* note 2, at 309–10.

172. See Alice K. Marcee, *Expanded Access to Phase II Clinical Trials in Oncology: A Step Toward Increasing Scientific Validity and Compassion*, 63 *FOOD & DRUG L.J.* 439, 450 (2008).

derstanding of the potential risks and benefits associated with such decisions.¹⁷³ However, at this stage in clinical testing, there is an utter lack of information surrounding the potential risks and benefits associated with this avenue of treatment; therefore, the ability of patients to give truly informed consent is jeopardized.¹⁷⁴ The motivation for entering into clinical trials or receiving expanded access is the idea that the patient will directly benefit from the investigational drug.¹⁷⁵ This behavior is known as therapeutic misconception;¹⁷⁶ it is generally attributed to the patient's desperate willingness to enter these risky situations.¹⁷⁷ This misconception does not resonate with the purpose of early clinical trials, which concentrate on the collection of evidence as to the toxicity of drugs, rather than focusing on positive responses in patients.¹⁷⁸

In response to the compelling deontological arguments about personal autonomy, I contend that it is important to examine the status of terminally patients as "medically vulnerable."¹⁷⁹ Traditionally, protection has been provided to individuals held to be in particularly vulnerable positions, including: pregnant women, prisoners, the mentally disabled, and children.¹⁸⁰ Such classification mandates additional protection. Safeguards, such as institutional review boards, protect

173. *Id.* at 451.

174. *Id.* ("The five elements [of informed consent] must be met: voluntarism, capacity, disclosure, understanding, and finally, a decision."). This problem with informed consent exists for individuals involved in the early stages of clinical research, where it differs with respect to expanded access is that there is a lack of careful monitoring and a larger population of individuals consenting to experimental treatment—therefore the problem is magnified.

175. *Id.*

176. Therapeutic misconception is well documented and is exemplified by patients that are unable to comprehend the distinction between clinical care and participation in research. Iltis, *supra* note 132, at 420 ("Risks that may be imposed on research subjects may not be imposed on patients, and harms for which patients may sue may not give subjects the same valid legal claims. These differences may be startling to patients who are enrolled in clinical trials but continue to see themselves primarily as patients, e.g., they are enrolled in a trial because they are receiving or may be receiving medical treatment from their doctor in the trial, and they see research participation as part of being a patient.").

177. Marcee, *supra* note 172, at 451.

178. *Id.*; see also Iltis, *supra* note 132, at 419 (discussing a research study whose primary purpose of is not to "benefit[] the subjects but rather to help answer a research question: it is *doing those very things that causes the study to be a research study.*").

179. Jerry Menikoff, *The Vulnerability of the Very Sick*, 37 J.L. MED. & ETHICS 51, 51 (2009) (noting that the "medically vulnerable" extend to individuals with serious illnesses that will likely cause death, where the existing treatment options are unsatisfactory and the patient is informed about a clinical trial that purports to have promising new treatment for that illness).

180. *Id.*

these populations from coercion and undue influence. In this instance, the patient's particular vulnerability results from the desperation to find treatment for their life-threatening illness.¹⁸¹

Abigail Alliance's patient population is composed of individuals who are not able to participate in clinical trials because they do not meet the requirements¹⁸²—this fact furthers the argument that they are incredibly vulnerable to potential adverse effects of the drugs.¹⁸³ While there is a strong deontological argument for expanded access, the gravity of the potential harm favors a utilitarian approach. This approach has the potential to protect not only society at large, but the terminally ill population as a whole.

2. Locke's Theory of Property

Under the "Lockean" approach, "the original author, having exerted mental labor to create work, is entitled to exclusive rights in it."¹⁸⁴ Thus, the creator should be entitled to manage the use and sale of his product as he pleases. Ultimately, this is one of the central arguments of intellectual property law. Following this approach, it should be the drug company and not the FDA that determines the sale of the investigational drug. However, there is a distinction between ownership to copyright and, for example, consummation of drugs that could adversely affect the body. Drugs that can present dire consequences should be regulated, notwithstanding the identity of their creator.

That being said, it is also in the best interest of pharmaceutical companies to regulate the drugs that they produce and accordingly strive to avoid negative publicity. Pharmaceutical companies may be reluctant to provide these products internally, even in the presence of FDA approval. Such dissemination could prevent the future retail and distribution of the drug. Arguably, the physicians and the pharmaceuticals are in the best position to make this decision about the administration of a drug, even though it could still lead to limited or no distribution.

The Supreme Court has no enforcement mechanism. Even if Abigail Alliance had obtained a favorable verdict, without incentive,

181. *Id.* at 56.

182. For example, they are not of the requisite age.

183. Pharmaceutical companies first attempt to enroll patients seeking expanded access; however, this is often not possible because of the heavy controls placed on the structure of the clinical trial to minimize the risk of the drug's adverse effects.

184. Barbara Friedman, *From Deontology to Dialogue: The Cultural Consequences of Copyright*, 13 *CARDOZO ARTS & ENT. L.J.* 157, 161 (1994) (providing further background of intellectual property and morality, particularly deontology).

pharmaceuticals may have been reluctant to comply with the court order and provide experimental drugs to terminally ill patients without a minimum baseline of protection.¹⁸⁵ As discussed *supra*, the pharmaceutical companies would likely be unable to recover market value for the distribution of the experimental drugs. In addition, pharmaceutical companies might fear tort litigation and the potential termination of the clinical trial due to harmful or deadly side effects. This would limit their ability to manufacture various drugs.¹⁸⁶

Even if the court had ruled in favor of Abigail Alliance, under a theory of Lockean intellectual property rights, the pharmaceutical would likely attempt to retain ownership and management of the drug as it deems fit in light of considerations regarding costs, delay to the market, and a heightened degree of risk to both the future of the drug and the patient. In conclusion, the legal system based around compassionate access must still preserve and develop an environment that is favorable to innovation. Maintaining pharmaceuticals' ability to control distribution, quality, and quantity of their products will facilitate and encourage favorable development in both new science and technology.

Conclusion

Every drug for cancer and other serious life-threatening illnesses that the Abigail Alliance has pushed for earlier access to in our ten-year history is now approved by the FDA! There is not one drug that we pushed for earlier access to that did not make it through the clinical trial process. Many lives could have been saved or extended, if there had been earlier access to these drugs!¹⁸⁷

—Frank Burroughs, Founder

Currently, the proposed reform—namely the Compassionate Access Act—seeks “to amend the Federal Food, Drug, and Cosmetic Act to create a new conditional approval system for drugs, biological products, and devices that is responsive to the needs of seriously ill patients, and for other purposes.”¹⁸⁸ However, it has not been acted on since 2010. As such, the debate over early access to drugs for terminal patients persists:

185. Ashley Ochs, Comment, *A Study in Futility: Abigail Alliance for Better Access to Developmental Drugs Will Not Expand Access to Experimental Drugs for the Terminally Ill*, 39 SETON HALL L. REV. 559, 581 (2009).

186. *Id.* at 581.

187. ABIGAIL ALLIANCE, <http://abigail-alliance.org/> (last visited Nov. 22, 2011).

188. H.R. 4732, 111th Cong. (2d Sess. 2010).

On the one hand, when existing treatments have been tried and have proven ineffective, patients who are suffering from serious disease have an understandable interest in trying potentially effective investigational drugs, particularly when the patient's illness is life-threatening. On the other hand, allowing patients to obtain and use unproven drugs carries a host of risks and potential detriments for the public health.¹⁸⁹

Clinical trials offer a hope of future treatment or a cure to patients suffering from illnesses that are currently untreatable. The research conducted and data garnered from these trials have the ability to drastically transform the current practice of medicine in the United States. Yet, research is not meant to be a form of treatment; rather, it is intended as a bridge to successful medical application.¹⁹⁰

Research studies involving clinical testing are not aimed at benefiting research participants in a manner that would hinder or detriment the collection of data addressing an imperative research question. In many instances, the research structure involves procedures that in fact are *not* in the best interests of the subjects.¹⁹¹ For example, it is a frequent occurrence to give one condition a placebo drug, which will have no beneficial impact and could prevent the subject from seeking additional treatment. Where a subject's interest is not the focus of the research study, there should be heavy protections surrounding the individual—even if such regulations come at a high price to individuals seeking an exception to the same.

Expanding access to post-Phase I drugs circumvents the rationale behind research studies at the expense of a possible detriment to society. It goes against the grain of regulation that historically developed to combat the issue of unsafe drugs reaching the market and causing catastrophic effects. It permits a judge to create a standard of care in a field where the physician and paramedical company are vastly more knowledgeable. Accordingly, while the outcome of *Abigail Alliance III* temporarily took compassionate access out of the hands of the judicial branch, the issue remains ripe for legislative decision—and the legislature should and likely will favor utilitarian arguments against expanded access.

And yet, despite the propriety of employing utilitarian principles in this context, one cannot help but wonder: Is there a better way? It is

189. Brief for the Respondents in Opposition, *supra* note 57, at 5.

190. Noah, *supra* note 43, at 176.

191. Iltis, *supra* note 132, at 419. This includes subjecting healthy individuals to research trials or mandating that participants who have an illness obtain a placebo treatment. *Id.* at 420.

difficult to ignore the plight of terminal patients in dire need of a cure and deny them potential treatment options. One cannot simply overlook the possibility that, in some circumstances, turning to an experimental treatment as a last resort might save a particular patient's life. However, the utility of FDA regulation of experimental drugs should not be taken lightly. As it stands, "it is unlawful to procure experimental drugs not only because they have not been proven effective, but because they have not been proven *safe*."¹⁹² Although restricting access to experimental drugs may produce tragic results in certain individual cases, the FDA's overarching goal of ensuring safety to the public at large remains paramount and must not be compromised.

192. Brief for the Respondents in Opposition, *supra* note 57, at 13 (emphasis added).