

THE RIGHT TO ACCESS EXPERIMENTAL DRUGS: WHY THE FDA SHOULD NOT DEPRIVE THE TERMINALLY ILL OF A CHANCE TO LIVE

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INTRODUCTION

Abigail Burroughs, a twenty-one-year-old honor student at the University of Virginia, died of cancer on June 9, 2001.¹ Eighteen months earlier, doctors diagnosed her with cancer of the head and neck, treating her with chemotherapy and radiation therapy.² By March 2001, this standard therapy for Abigail's type of cancer had failed to yield significant improvement, and Abigail was hospitalized at Johns Hopkins University Hospital.³ Abigail's treating oncologist urged the Burroughses to attempt to obtain two different drugs, including Erbitux, which targets the same growth receptors that Abigail's cancer cells expressed.⁴ However, Abigail could not obtain Erbitux because it was approved only for clinical trials of treatment for colon cancer; she also failed to qualify for a clinical trial involving a second drug, Iressa.⁵ Abigail was "stymied in her efforts to obtain new cancer drugs that her oncologist believed could save her life," despite the fact that the drugs were available to others in clinical trials.⁶ In May 2001, Abigail was finally admitted to a clinical trial for a new cancer drug, Tarceva, but by then was "too ill to travel from Virginia to the Texas testing site."⁷ Abigail died two weeks later.⁸

Frank Burroughs, Abigail's father, described the entire experience of trying to find treatment for his daughter as a "horrible, horrible nightmare."⁹ He formed the

* J.D., William & Mary Law School, 2008; B.S., University of Virginia, 2005. I would like to thank my family for their support in helping me become the person I am today. My parents devoted their lives to the education and upbringing of my siblings and me, and without them, we would have very little to show for ourselves in this world.

¹ Complaint at 2, *Abigail Alliance for Better Access to Dev. Drugs v. McClellan*, 2004 U.S. Dist. LEXIS 29594 (D.D.C. 2004) (No. 03-1601).

² Robert Cohen, *Ruling May Upend Drug Safety Precautions*, STAR-LEDGER (Newark, N.J.), Feb. 12, 2007, at 1.

³ Abigail Alliance, *The Abigail Story*, <http://abigail-alliance.org/story.htm> (last visited Feb. 14, 2008).

⁴ *Id.*

⁵ Cohen, *supra* note 2.

⁶ Complaint, *supra* note 1, at 2.

⁷ Cohen, *supra* note 2.

⁸ *Id.*

⁹ *Id.*

Abigail Alliance, an organization that hopes to expand access to “experimental drugs outside the clinical trial setting” for terminally ill cancer patients.¹⁰ Frank summed up the organization’s purpose by saying “[p]eople just want a chance to live when they are facing death.”¹¹ In order to accomplish its mission, the Abigail Alliance filed a lawsuit to “enjoin the Food and Drug Administration (FDA) from continuing to enforce a policy that violates the constitutional privacy and liberty rights of terminally ill patients.”¹²

In *Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach (Abigail I)*,¹³ the Court of Appeals for the D.C. Circuit held that a “terminally ill, mentally competent adult” patient has a right under the Due Process Clause¹⁴ to access experimental drugs that have passed FDA Phase I trials when no alternative, FDA-approved treatments exist or are successful.¹⁵ For simplicity, this narrowly defined right will be referred to in this Note as the “right to access treatment.” The Abigail Alliance sought this right to access treatment because U.S. law currently bars the sale of new drugs that have only passed FDA Phase I trials.¹⁶ The finding of a right to access treatment was reversed by the Court of Appeals for the D.C. Circuit on rehearing en banc in August 2007 (*Abigail II*).¹⁷ This Note argues that the court’s recent denial of a fundamental right to access treatment is wrong and will use *Abigail I* as a guideline to illustrate why recognition of the fundamental right to access treatment for terminally ill, competent adults is constitutionally supported and should be incorporated into the FDA’s approach to regulating new drugs.

With this background of how the case in *Abigail I* arose, this Note will explore the initial holding of the Court of Appeals for the D.C. Circuit, the historical and legal context surrounding the right to access treatment, and how the ruling impacts the FDA’s policy regarding access to experimental drugs. The first Part of this Note examines *Abigail I* and outlines what the right to access treatment means, as explained by the Court of Appeals for the D.C. Circuit in its initial holding. The court used the precedent established in *Washington v. Glucksberg*¹⁸ and *Planned Parenthood of Southeastern Pennsylvania v. Casey*¹⁹ to determine whether the right to access

¹⁰ *Id.*

¹¹ *Id.*

¹² Complaint, *supra* note 1, at 1.

¹³ 445 F.3d 470 (D.C. Cir. 2006), *rev’d en banc*, 495 F.3d 695 (D.C. Cir. 2007), *cert. denied*, 76 U.S.L.W. 3189 (U.S. Jan. 14, 2008) (No. 07-444).

¹⁴ U.S. CONST. amend. V (“[N]or shall any person . . . be deprived of life, liberty, or property, without due process of law . . .”).

¹⁵ *Abigail I*, 445 F.3d at 486.

¹⁶ 21 U.S.C. § 355(a) (2000).

¹⁷ *Abigail Alliance for Better Access to Dev. Drugs v. Von Eschenbach (Abigail II)*, 495 F.3d 695 (D.C. Cir. 2007), *cert. denied*, 76 U.S.L.W. 3189 (U.S. Jan. 14, 2008) (No. 07-444).

¹⁸ 521 U.S. 702 (1997).

¹⁹ 505 U.S. 833 (1992) (plurality opinion).

treatment is a fundamental right found in the Due Process Clause.²⁰ The second Part outlines common law and American legal history that may support a right to access treatment. This Part also examines the history of the FDA's creation and illustrates why the FDA's purpose is compatible with recognition of this right. The third Part analyzes the right to access treatment in the context of modern substantive due process jurisprudence. Supreme Court precedent often requires the government to defer to individual choice over state interest with regard to personal medical choices.²¹ The fourth Part introduces the FDA's current approach to regulating new drug manufacturing and also outlines some of the practical problems the system imposes on terminally ill individuals, for whom conventional treatments either do not exist or are ineffective. The fifth and final Part proposes a solution that would reconcile the recognition of a fundamental right to access treatment with the FDA's tradition of promoting public safety.

The purpose of this Note is not to extensively discuss administrative policy, though some initial recommendations are included for how to accommodate both public safety and the right to access treatment. The FDA should allow earlier access to post-Phase I experimental drugs and increase safety at the end of the drug testing process. The FDA should use the invitation extended by *Abigail I* to review its entire regulatory process of testing experimental drugs as a whole. Rather than front-loading expensive testing for safety and efficacy before any new drug can be marketed to any population, terminally ill or otherwise, the phases of testing should be spaced out in longer increments, with expanded access and marketing as the drug progresses through clinical trials. This may also help in preventing some of the criticism aimed at the FDA resulting from drugs being too widely available after initial testing, such as in the controversy surrounding Vioxx.²²

The FDA could still prohibit access outside the clinical trial setting to any experimental drug until Phase I testing for basic safety is complete. Then, in accordance with the right to access treatment, patients should have access to experimental drugs only when they are terminally ill and are not extensively worried about long-term side effects of an experimental drug. To qualify for experimental drugs, patients must have the mental competence to understand and assume the great risks involved with experimental drugs, including failed efficacy or even hastened death. The FDA should continue to limit access to new drugs by the general population until testing for efficacy and extended safety screening occurs. The right to treatment outlined in *Abigail I* can thus be accommodated without sacrificing public safety.

²⁰ *Abigail I*, 445 F.3d at 476.

²¹ See, e.g., *Cruzan v. Dir., Mo. Dep't of Health*, 497 U.S. 261 (1990) (upholding the right to refuse life-sustaining treatment).

²² See Anna Wilde Mathews, *FDA Is Criticized over Its Handling of Drug Safety*, WALL ST. J., Sept. 23, 2006, at A3.

In consideration of this country's present and historical respect for the natural right of an innocent person to preserve his own life, and in consideration of the individualist, entrepreneurial spirit that successfully drives the market place decisionmaking, the FDA should revise its policies and allow for greater access for the terminally ill to post-Phase I experimental drugs.

I. ABIGAIL ALLIANCE

The Abigail Alliance sought "access to potentially life-saving post-Phase I investigational new drugs on behalf of mentally competent, terminally ill adult patients who have no alternative government-approved treatment options."²³ Because the Abigail Alliance claimed a right warranting protection under established substantive due process jurisprudence in a case that was "of first impression,"²⁴ the court in *Abigail I* searched Supreme Court precedent for a method of analysis from which to proceed.²⁵ The court discovered two methods of analysis: one established in the 1960s and 1970s, most recently affirmed in *Casey*,²⁶ the other from the Court's 1930s jurisprudence, but most recently applied in *Glucksberg*.²⁷ The *Abigail I* court started with the *Glucksberg* analysis, reasoning that it was the more restrictive of the two and that if a new right to access treatment existed under the *Glucksberg* approach, it would certainly exist under the *Casey* method.²⁸

The Court in *Glucksberg* had two criteria for analyzing a claimed right.²⁹ "First, we have regularly observed that the Due Process Clause specially protects those fundamental rights and liberties which are, objectively, 'deeply rooted in this Nation's history and tradition.'"³⁰ In examining this first criteria, the *Abigail I* court explored the right to access treatment in the context of the common law to determine its historical grounding.³¹ For example, William Blackstone wrote that a person has the right to "his life, his limbs, his body, [and] his health" as well as right of self-

²³ *Abigail I*, 445 F.3d at 472.

²⁴ *Id.* at 475.

²⁵ *Id.* at 475–76.

²⁶ *Id.* at 476.

²⁷ *Id.*

²⁸ *Id.* at 477. In addition to being the more recent precedent, *Glucksberg* had a majority holding supported by three currently sitting Justices, while the *Casey* plurality was supported by only two current Justices, making *Glucksberg* the precedent more likely to be used for deciding future cases. See *Washington v. Glucksberg*, 521 U.S. 702, 704 (1997); *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 843 (1992) (plurality opinion).

²⁹ *Glucksberg*, 521 U.S. at 720.

³⁰ *Id.* at 720–21 (quoting *Moore v. City of E. Cleveland*, 431 U.S. 494, 503 (1977) (plurality opinion)).

³¹ *Abigail I*, 445 F.3d at 480.

defense and self-preservation.³² The right to self-preservation is so strong that a person may generally

defend himself against another by force intended or likely to cause death or serious bodily harm, when he reasonably believes that (a) the other is about to inflict upon him an intentional contact or other bodily harm, and that (b) he is thereby put in peril of death or serious bodily harm or ravishment, which can safely be prevented only by the immediate use of such force.³³

The court also described how U.S. tort law generally imposes liability on people who interfere with a third person giving aid for a bodily injury to a wounded person.³⁴ The court drew an analogy between a terminally ill individual fighting off a disease and a person fighting off a deadly attacker.³⁵

The court also described the history of laws inhibiting or regulating access to treatment.³⁶ The U.S. government did not regulate drug manufacturers for safety reasons until 1906 and did not regulate for efficacy until 1962.³⁷ Federal law strictly prohibits the introduction and sale of new drugs into interstate commerce without FDA approval, which includes submitting proof of safety and efficacy.³⁸ The Kefauver-Harris Amendments gave the FDA the power to require more stringent testing for safety and efficacy, greater power to inspect manufacturing and advertising practices, and the power to require more complete disclosure of all testing results for an experimental drug, including drugs proven to have adverse effects.³⁹ The court noted that very little in the FDA's history indicated that the primary purpose of the agency was to regulate which patients could have access to experimental drugs and

³² WILLIAM BLACKSTONE, 1 COMMENTARIES *125, *127, *130.

³³ RESTATEMENT (SECOND) OF TORTS § 65(1) (1965).

³⁴ *Abigail I*, 445 F.3d at 480–81.

³⁵ *See id.* at 480.

³⁶ *Id.* at 481–83.

³⁷ *Id.* at 481–82.

³⁸ 21 U.S.C. §§ 355(a)–(b)(1) (Supp. III 2003):

(a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug.

(b)(1) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a) of this section. Such person shall submit to the Secretary as a part of the application (A) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use

³⁹ *Abigail I*, 445 F.3d at 482.

that the focus was instead on preventing fraud and reckless disregard for general public safety.⁴⁰ In sum, the court concluded that there was evidence of a “long-standing tradition of the right of self-preservation.”⁴¹

In addition to finding that a fundamental right must be rooted in the nation’s history, the Court in *Glucksberg* had a second prong in its test requiring that the right be “‘implicit in the concept of ordered liberty’ such that ‘neither liberty nor justice would exist if [it was] sacrificed.’”⁴² The *Abigail I* majority considered *Cruzan v. Director, Missouri Department of Health*⁴³ for support that a right to access treatment is implicit in ordered liberty.⁴⁴ The court explained that “[i]f there is a protected liberty interest in self-determination that includes a right to refuse life-sustaining treatment, even though this will hasten death, then the same liberty interest must include the complementary right of access to potentially life-sustaining medication, in light of the explicit protection accorded ‘life.’”⁴⁵ The court, by analyzing the right to access treatment in comparison with the right to refuse treatment, wisely invoked *Cruzan* as a recent Court decision that successfully found a previously unrecognized fundamental right under the Due Process Clause.⁴⁶ The question is whether a right to refuse life-saving treatment is analogous to a right to access treatment.⁴⁷

The court in *Abigail I* ensured that it proceeded with caution in defining the contours of the right to access treatment. The test in *Glucksberg* “required . . . a ‘careful description’ of the asserted fundamental liberty interest.”⁴⁸ The court in *Abigail I* noted that the plaintiffs did not seek access to post-Phase I drugs for the entire U.S. population or to overturn the Controlled Substances Act, which claims broad authority to regulate potentially harmful substances.⁴⁹ The court emphasized that the plaintiffs were seeking a narrowly-tailored right, anticipating criticism that the court invented a new right under substantive due process jurisprudence.⁵⁰ The court exercised “reasoned judgment”⁵¹ by focusing on the narrow right to access treatment as opposed to finding, for example, a broad, expansive “right to treatment,” which

⁴⁰ *Id.* at 483.

⁴¹ *Id.*

⁴² *Washington v. Glucksberg*, 521 U.S. 702, 721 (1990) (quoting *Palko v. Connecticut*, 302 U.S. 319, 325–26 (1937)).

⁴³ 497 U.S. 261 (1990).

⁴⁴ *Abigail I*, 445 F.3d at 484.

⁴⁵ *Id.* at 484–85.

⁴⁶ *Id.*

⁴⁷ *See infra* Part III.

⁴⁸ *Washington v. Glucksberg*, 521 U.S. 702, 721 (1990).

⁴⁹ *Abigail I*, 445 F.3d at 478.

⁵⁰ *See, e.g.*, Editorial, *A Court Makes up a Right*, WASH. POST, May 3, 2006, at A22.

⁵¹ *See Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 849 (1992) (discussing the cautious, but open-minded approach courts should take in evaluating claims of new fundamental rights).

could be construed to impose affirmative duties on the government to subsidize the cost of experimental treatments for terminally ill patients.⁵²

The court examined and distinguished cases from other circuits that addressed variations on the right to access treatment sought by the Abigail Alliance.⁵³ The court acknowledged that in *Rutherford v. United States*, the Tenth Circuit held that the right to access treatment being sought by the Abigail Alliance did not exist.⁵⁴ The *Rutherford* court, comparing the right to access treatment with a right to refuse life-saving treatment, noted that

[i]t is apparent in the context with which we are here concerned that the decision by the patient whether to have a treatment or not is a protected right, but his selection of a particular treatment, or at least a medication, is within the area of governmental interest in protecting public health.⁵⁵

In explaining why the right to access treatment did not exist, the *Rutherford* court noted that “[i]t is apparent from the record that the proponents did not conduct the research and the laboratory testing required under the prevailing procedures, and it thus must be held that they did not meet their burden” to convince the FDA that the proposed drug accommodated public safety.⁵⁶ According to this court, *all* patients must, to some minimum degree, seek to accommodate the FDA’s concern for public safety in seeking to access experimental drugs.⁵⁷

The *Abigail I* court implied that the same result in *Rutherford* would be reached even with the existence of a fundamental right to access treatment because the government’s interest in protecting the entire population, *terminally ill or otherwise*, with *basic* safety precautions may be a compelling interest allowing government action to override the right to access treatment.⁵⁸ Though the government has a valid interest in promoting public safety for all patients generally, it does not necessarily follow that the *Rutherford* court’s complete deference to all FDA safety and efficacy procedures, at the expense of any recognition of the interest of *terminally ill* patients in accessing experimental drugs, is the only way to satisfy this governmental interest.⁵⁹

⁵² *Abigail I*, 445 F.3d at 478.

⁵³ *Id.* at 486.

⁵⁴ 616 F.2d 455 (10th Cir.), *cert. denied*, 449 U.S. 937 (1980).

⁵⁵ *Id.* at 457.

⁵⁶ *Id.*

⁵⁷ *See id.*

⁵⁸ *Id.*

⁵⁹ *See id.* (noting that “[i]n this case, the government’s interest may prove to be weaker because the Alliance seeks only access to investigational new drugs that the FDA, after Phase I human trials, has deemed sufficiently safe”).

The opponents to *Abigail I* criticized the majority's finding of a new right under the Due Process Clause as an act of judicial activism.⁶⁰ They attempted to recast the right to access treatment as a question of

whether the Due Process Clause of the Constitution mandates access to experimental drugs that have cleared Phase I of FDA testing, such that Congress cannot protect terminally ill patients from the risks experimental drugs present unless it uses a means narrowly tailored toward achieving a compelling interest in limiting access.⁶¹

The opponents were bothered about mandating access and corresponding obligations on the government to provide treatment, but the only mandate of the right to access treatment is for the government to remove itself as an obstacle for terminally ill patients with nothing left to lose who choose to seek potentially life-saving experimental drugs. The dissent also was mistaken in considering the risks of experimental drugs in a vacuum.⁶² Instead, the risks should be considered in the context of a terminally ill patient who is facing an almost certain death because of failed or non-existent conventional treatments.

The opponents to *Abigail I* more wisely attacked the right to access treatment through its roots in the common law history⁶³ upon which the majority relied for justification of the right.⁶⁴ The dissent in *Abigail I*, relied heavily on *United States v. Oakland Cannabis Buyers' Cooperative*, which involved patients seeking medicinal marijuana based on the common law defense of necessity.⁶⁵ The Court in *Oakland* noted that “[u]nder any conception of legal necessity, one principle is clear: [t]he defense cannot succeed when the legislature itself has made a ‘determination of values.’”⁶⁶

⁶⁰ *Id.* at 488 (Griffith, J., dissenting) (“Instead of allowing the elected branches to resolve these debates, the Alliance argues that the Constitution mandates its desired outcome, regardless of the particular balance already struck by Congress and the Executive.”); *Abigail II*, 495 F.3d 695, 700 (D.C. Cir. 2007), *cert. denied*, 76 U.S.L.W. 3189 (U.S. Jan. 14, 2008) (No. 07-444) (“Having thus been rejected by the FDA, the Alliance turned to the courts . . .”). The “opponents to *Abigail I*” include the dissent in *Abigail I* and the majority in *Abigail II*. Both opinions were written by Judge Griffith.

⁶¹ *Abigail I*, 445 F.3d at 491 (Griffith, J., dissenting).

⁶² *See id.* at 488–90 (discussing the general new drug applications and the extensive and time-consuming FDA testing phases that drugs must go through to ensure general safety and effectiveness).

⁶³ *See, e.g., Abigail II*, 495 F.3d at 703–07.

⁶⁴ *Abigail I*, 445 F.3d at 491–92.

⁶⁵ *Id.* at 492, 296; *United States v. Oakland Cannabis Buyers' Coop.*, 532 U.S. 483 (2001).

⁶⁶ *Id.* at 491 (citation omitted).

The problem with comparing the right to access treatment in *Abigail I* with the right to access medicinal marijuana is that the right to access treatment is restricted to only those instances in which lives are imminently threatened.⁶⁷ The right to access treatment is only for terminally ill patients and only for treatments that are considered potentially life-saving—otherwise the missing element of life-saving necessity blunts the importance of a constitutional right.⁶⁸ Congress, through the Controlled Substances Act, affirmatively declared that marijuana is a substance with no medicinal properties,⁶⁹ while the experimental drugs at issue are being tested in clinical trials because there is a possibility that they have medicinal, life-saving value.

The *Abigail II* opinion lists various state law provisions regulating drug safety.⁷⁰ However, these statutes regulated the safety of poisons and adulterated drugs for the *population at large*, not potentially life-saving drugs for the *terminally ill*. The majority would have us believe a statute regulating the sale of deteriorating drugs and the sale of poisons evidences an intent to regulate all drugs in all contexts.⁷¹ The opponents to *Abigail I* were successful in pointing out that there is very little statutory history ever explicitly defending or encoding a right to access treatment.⁷² If the Abigail Alliance was seeking deregulation of all drugs, surely the majority's argument would be relevant. But ignoring the context of the right to access treatment (terminally ill patients seeking a last chance to extend their lives with drugs having a basic level of safety testing) makes these historical notes irrelevant to the discussion.

The opponents, however, have more trouble disentangling the right upheld in *Cruzan* from the right to access treatment sought by the plaintiffs. The dissent in *Abigail I* began by summarizing how the majority depended on *Cruzan*: “The [*Cruzan*] Court's assumption that there is a right to refuse lifesaving treatment in some circumstances was predicated upon ‘the common-law rule that forced medication was a battery[] and the long legal tradition protecting the decision to refuse unwanted medical treatment.’”⁷³ The dissent then tried to disentangle freedom to refuse unwanted medical treatment from a right to access treatment by arguing that “a tradition protecting individual *freedom* from life-saving, but forced, medical treatment does not evidence a constitutional tradition of providing affirmative *access* to a potentially harmful, and even fatal, commercial good.”⁷⁴

⁶⁷ See *Abigail I*, 445 F.3d at 486 (majority opinion).

⁶⁸ See *id.* (summarizing the issue at hand as involving only “potentially life-saving drugs”). The extent to which a drug must demonstrate this potential would be a concern going forward. See *id.* (discussing government's interest in public health).

⁶⁹ 21 U.S.C. § 812 (2000).

⁷⁰ *Abigail II*, 495 F.3d 695, 703-06 (D.C. Cir. 2007), *cert. denied*, 76 U.S.L.W. 3189 (U.S. Jan. 14, 2008) (No. 07-444).

⁷¹ *Id.* at 704.

⁷² *Abigail I*, 445 F.3d at 491-92 (Griffith, J., dissenting).

⁷³ *Id.* at 495 (citing *Washington v. Glucksberg*, 521 U.S. 702, 725 (1997) (discussing *Cruzan*)); see also *Cruzan v. Dir., Mo. Dep't of Health*, 497 U.S. 261, 269 (1990).

⁷⁴ *Abigail I*, 445 F.3d at 495.

The dissent never explained why a patient refusing life-saving treatment has a right under the Due Process Clause to take risks with his life, but a patient is not allowed to take risks with his life through actions that are likely the only possible way to save it. If the former is based on a long standing tradition that forced medical care constituted battery,⁷⁵ why cannot the latter be based on the tradition that blocking someone from receiving medical help constitutes a tort?⁷⁶

One way to think about the *Abigail I* and *II* opinions is to ask whether the plaintiffs are more similar to the patient in *Cruzan*, who wanted to be free from government interference in choosing a medical procedure, or more similar to the patient in *Glucksberg*, who requested a traditionally unprotected liberty that is strongly antithetical to the state's interest in promoting the preservation of life. The *Abigail II* court did not realize that, at their core, the rights recognized in *Abigail I* and *Cruzan* seek to prevent an interferer (the government) from overriding what the patient determines, in good faith, is in her best medical interest.⁷⁷ And unlike the right to suicide sought in *Glucksberg*, which may be considered an attempt to protect a bad faith medical choice made out of despair to end life,⁷⁸ the right to access treatment embraces a patient's hope to prolong life.

The dissent wondered whether the right to access treatment opens a sort of Pandora's box of practical problems:

If a terminally ill patient has such a right, are patients with serious medical conditions entitled to the benefit of the same logic and corresponding access? If an indigent cannot afford potentially life-saving treatment, would the Constitution mandate access to such care under the right recognized by the majority? Can a patient access any drug (*i.e.*, marijuana for medicinal purposes) if she believes, in consultation with a physician, it is potentially life-saving? . . . Perhaps most significantly, what potential must a treatment have in order for the Constitution to mandate access?⁷⁹

These questions indicate that the dissent mistook a broad right to treatment with the narrowly-tailored right to access treatment sought by the plaintiffs.⁸⁰ The right should only be held by terminally ill patients, not chronically ill patients, because for them the FDA's policies restricting access to experimental drugs have the most

⁷⁵ *Id.*

⁷⁶ *See Abigail I*, 445 F.3d at 480–81 (majority opinion).

⁷⁷ *See, e.g., supra* notes 32–35, 46 and accompanying text.

⁷⁸ *See Glucksberg*, 521 U.S. at 711–712.

⁷⁹ *Abigail I*, 445 F.3d at 499 (Griffith, J., dissenting) (citation omitted).

⁸⁰ *See supra* notes 13–15 and accompanying text.

serious consequences: premature death.⁸¹ The right to access treatment only seeks to remove the government as an obstacle to treatment, not guarantee a provider of treatment.⁸² Access in this case should be likened to prescription drug access: one should be allowed to buy a prescription drug, in consultation with and under the recommendation of a doctor, if he or she privately contracts with a supplier to provide it. This analogy also answers the other questions the dissent posed.⁸³

The right to access treatment described and defended in *Abigail I* has solid grounding in the fundamental right of self-defense. As the next Part explains, the extension of the right of self-defense to the cause of the Abigail Alliance is based in a deep respect for the right of any innocent individual to use dangerous methods to defend against a life-threatening attack.

II. HISTORICAL NOTIONS OF LIBERTY AND HOW THE FDA CAME TO BE

In order to comply with *Glucksberg*, the court in *Abigail I* had to find historical support for the existence of a right to access treatment.⁸⁴ The court found support in the commentaries of William Blackstone, who wrote that “[f]or whatever is done by a man, to save either life or member, is looked upon as done upon the highest necessity and compulsion.”⁸⁵ Samuel Pufendorf, Thomas Hobbes, and John Locke, along with Blackstone, all believed that self-preservation was a natural right.⁸⁶ It is reasonable to think that, based on the writings of these influential men, the drafters of the Bill of Rights believed that a “right of self-preservation” would be an inviolable natural right of man, even though the right was never explicitly enumerated in the Bill of Rights.⁸⁷ A broad right of self-preservation supports the narrowly-tailored right to access treatment and shows how this right is at least minimally rooted in America’s legal tradition.

Certain tort cases in American legal history embody a right of self-preservation in the common law and strengthen the historical support for the right to access

⁸¹ *Cf. Abigail I*, 445 F.3d at 474 (noting the three stages of FDA testing take seven years and terminally ill patients “have no other [timely] options”).

⁸² *See id.* at 486 (discussing that the right to access treatment seeks only to provide “the same right of access enjoyed by those terminally ill patients lucky enough to secure a spot in Phase II trials”).

⁸³ A patient in consultation with his or her doctor should be allowed to pursue any drug which they together decide is in the best medical interest of the patient. The likelihood that doctors would collude with patients to fraudulently obtain treatments that are not actually reasonably believed to be life-saving is beyond the scope of this Note.

⁸⁴ *Abigail I*, 445 F.3d at 479.

⁸⁵ 1 WILLIAM BLACKSTONE, COMMENTARIES *126.

⁸⁶ *See* J.D. Droddy, *Originalist Justification and the Methodology of Unenumerated Rights*, 1999 L. REV. M.S.U.-D.C.L. 809, 858.

⁸⁷ *Id.* at 859; *see also* U.S. CONST. amend. IX (“The enumeration in the Constitution, of certain rights, shall not be construed to deny or disparage others retained by the people.”).

treatment. The court in *Abigail I* highlighted some of these cases in which “a person is faced with death, [and thus] necessity often warrants extraordinary measures not otherwise justified.”⁸⁸ In *Ploof v. Putnam*, the court considered whether the defendant committed trespass or negligence when his servant unmoored a ship tied to his dock by the plaintiff.⁸⁹ The plaintiff moored his ship to the defendant’s dock out of concern for the safety of his family because of a sudden and violent storm that threatened them with imminent, possibly fatal harm.⁹⁰ The court considered whether the plaintiff had a legal right to be moored to the defendant’s dock because of the doctrine of necessity: “Th[e] doctrine of necessity applies with special force to the preservation of human life. . . . One may sacrifice the personal property of another to save his life or the lives of his fellows.”⁹¹ This reasoning suggests that tort actions should not apply to individual actions taken out of self-preservation, even when the action itself trespasses upon another’s property.

In *Vincent v. Lake Erie Transportation Co.*, the court considered another case involving the doctrine of necessity.⁹² The plaintiff, a wharf owner, sued the defendant, a ship owner, for negligence.⁹³ This case is similar to *Ploof* because it involved one party mooring his ship to the opposing party’s dock without the owner’s consent.⁹⁴ The mooring party, the defendant in this case, invoked the doctrine of necessity to support his legal right to moor his ship to the plaintiff’s dock; he was trying to avoid having to sail into a coming storm.⁹⁵ The court considered the importance of a right of self-preservation when it wrote:

[A] starving man may, without moral guilt, take what is necessary to sustain life; but it could hardly be said that the obligation would not be upon such person to pay the value of the property so taken when he became able to do so. And so public necessity, in times of war or peace, may require the taking of private property for public purposes; but under our system of jurisprudence compensation must be made.⁹⁶

The court would not require the defendant to unmoor his ship so as to avoid trespassing on the plaintiff’s wharf and therefore require the defendant to put his life and

⁸⁸ *Abigail I*, 445 F.3d at 480.

⁸⁹ 71 A. 188, 189 (Vt. 1908).

⁹⁰ *Id.* at 188.

⁹¹ *Id.* at 189.

⁹² 124 N.W. 221 (Minn. 1910).

⁹³ *Id.* at 221.

⁹⁴ *See id.*

⁹⁵ *Id.*

⁹⁶ *Id.* at 222.

property in imminent danger.⁹⁷ The defendant, however, had to compensate the plaintiff for the damaged wharf.⁹⁸ The *Vincent* holding is another example in the American legal tradition of valuing self-preservation of life over the destruction of another's property without the owner's consent. *Vincent*, however, may also represent the principle that though a right of self-preservation may exist, it should not be without cost to those parties acting to preserve their own life.⁹⁹ This precedent is helpful in determining who should bear the costs in enforcing a right to access treatment and supports the proposition that this right only allows access and does not require government funding of these treatments.¹⁰⁰

There is little other American case law that extensively weighs the right of self-preservation against material concerns; though the few cases that have considered the matter have all found self-preservation the greater good.¹⁰¹ The right to access treatment is just one expression of a right of self-preservation: instead of facing violent storms, terminally ill patients face fatal diseases. In a modern context, the Court in *Glucksberg* found that there was never common law or statutory approval of suicide or physician assisted suicide such that there could be support for a constitutional right to suicide.¹⁰² The cases dealing with a right of self-preservation have one important feature not present with the right to suicide at issue in *Glucksberg*: the person seeking to protect a personal choice concerning his well-being was trying to extricate himself from a perilous, life-threatening position.¹⁰³ The Court in *Glucksberg* cited Blackstone's *Commentaries* as evidence that there never was, and there is not currently, a fundamental right to act to destroy one's life.¹⁰⁴ The holding in *Glucksberg* comports with the right to access treatment; though there may be no historical support for a right to destroy one's life, there is historical support for a right to preserve one's life, even if it means imperiling a third party's property.¹⁰⁵

⁹⁷ *Id.* at 221.

⁹⁸ *Id.* at 222.

⁹⁹ *See id.*

¹⁰⁰ *But see Abigail I*, 445 F.3d 470, 499 (D.C. Cir. 2006) (Griffith, J., dissenting) (considering whether a right to access treatment would require that terminally ill patients, especially the indigent, gain access to experimental drugs without having to personally pay for the treatment), *rev'd en banc*, 495 F.3d 695 (D.C. Cir. 2007), *cert. denied*, 76 U.S.L.W. 3189 (U.S. Jan. 14, 2008) (No. 07-444).

¹⁰¹ George C. Christie, *The Defense of Necessity Considered from the Legal and Moral Points of View*, 48 DUKE L.J. 975, 988 (1999).

¹⁰² *Washington v. Glucksberg*, 521 U.S. 702, 711 (1997).

¹⁰³ *See Christie*, *supra* note 101, at 994–95.

¹⁰⁴ *Glucksberg*, 521 U.S. at 711–12. The Court noted that Blackstone believed suicide was “self-murder” and that “the law has . . . ranked [suicide] among the highest crimes.” *Id.* at 712 (quoting 4 WILLIAM BLACKSTONE, COMMENTARIES *189).

¹⁰⁵ *Compare* 4 WILLIAM BLACKSTONE, COMMENTARIES *189 (declaring suicide a high crime), *with* 1 WILLIAM BLACKSTONE, COMMENTARIES *130 (supporting a right of self-preservation generally).

The history of the FDA may shed some light on the strength of the government interests likely to be at issue when considering whether a right to access treatment exists.¹⁰⁶ The FDA's emergence can be explained by a series of twentieth-century pieces of legislation, with each law "emerg[ing] in the wake of public outcry over sensational events involving drug safety."¹⁰⁷ The government began regulating drugs in 1906 with the Pure Food and Drug Act.¹⁰⁸ The Act focused on drug purity, making it a misdemeanor to adulterate or misbrand a drug.¹⁰⁹ The focus of this law was preventing situations in which drug manufacturers had clearly manufactured fraudulent treatments.¹¹⁰ The government should have the legal authority to shut down drug manufacturers who are proven to be only selling snake oil treatments, and this is not at issue in this Note. This goal should be a continuing, or even increased, focus of the modern FDA.¹¹¹ The 1906 act "did not, however, limit individual access to new drugs or regulate therapeutic claims by drug manufacturers."¹¹²

Federal law again increased governmental scrutiny of drug manufacturing in response to 107 deaths caused by the use of Elixir Sulfanilamide, which was marketed without ever being tested for safety or efficacy.¹¹³ Congress passed the Food, Drug, and Cosmetic Act of 1938 to ensure drug manufacturers tested new drugs for safety, though the law did not require testing for efficacy.¹¹⁴ The law required drug manufacturers to file a New Drug Application (NDA) which would demonstrate at least some scientific assurance of safety.¹¹⁵ The drug manufacturer could market its new drug unless the FDA decided the drug was unsafe.¹¹⁶ The restrictions at this point were still at their most basic, requiring that the manufacturer give at least some consideration to the safety of its consumers but not requiring any evidence of efficacy.¹¹⁷

The final major piece of legislation that defined the modern FDA was the Kefauver-Harris Amendment of 1962, which itself was a response to the birth defects

¹⁰⁶ See generally *Rasmussen v. Fleming*, 741 P.2d 674, 683–86 (Ariz. 1987) (listing the legitimate state interests that may limit the right to refuse life-saving treatment, including preserving life, safeguarding the integrity of the medical profession, preventing suicide, and protecting innocent third parties).

¹⁰⁷ C. Frederick Beckner, III, Note, *The FDA's War on Drugs*, 82 GEO. L.J. 529, 529 (1993).

¹⁰⁸ Richard J. Nelson, Note, *Regulation of Investigational New Drugs: "Giant Step for the Sick and Dying"?*, 77 GEO. L.J. 463, 467 (1988).

¹⁰⁹ *Id.*

¹¹⁰ See *id.* at 468.

¹¹¹ See *infra* Part V.

¹¹² *Abigail I*, 445 F.3d 470, 481 (D.C. Cir. 2006), *rev'd en banc*, 495 F.3d 695 (D.C. Cir. 2007), *cert. denied*, 76 U.S.L.W. 3189 (U.S. Jan. 14, 2008) (No. 07-444).

¹¹³ Beckner, *supra* note 107, at 528–29, 529–30 n.7.

¹¹⁴ *Abigail I*, 445 F.3d at 482.

¹¹⁵ *Id.*

¹¹⁶ *Id.*

¹¹⁷ See *id.*

caused by the morning sickness drug Thalidomide.¹¹⁸ The amendment used the Interstate Commerce Clause to prevent the manufacture of any new drug without meeting FDA approval based on seven factors, including safety and efficacy.¹¹⁹ The amendment gave the FDA expanded powers, which allowed the agency “to approve human clinical trials, regulate drug advertising, inspect drug-manufacturing facilities, and promulgate good manufacturing practices, . . . [and] require[] drug manufacturers to disclose to the FDA any information they received regarding the adverse consequences of approved drugs.”¹²⁰

The legislative progression that structured the modern FDA suggests that agency’s mission concerns protecting unknowing consumers from careless or conniving drug manufacturers. It is true that “[e]xperimental drugs present a variety of potential risks and benefits to patients”¹²¹ and that the purpose of the FDA’s regulation of experimental drugs is to “determine[] and balance[] those risks and benefits” because “[s]ome drugs may harm patients; others may help.”¹²² The court in *Abigail I* was not trying to undo these protections for unknowing consumers who prefer to trust in the FDA’s judgment but merely tried to allow consumers for whom these protections had little practical value the option of pursuing treatments they believe are in their best interest—self-preservation.¹²³ This is consistent with the early American legal tradition in which individuals were allowed to take dangerous actions that promoted self-preservation.¹²⁴

Another way to analyze *Abigail I* is to determine to what extent each individual in society can decide what actions promote his own self-preservation when these actions are balanced against legitimate governmental interests. The current limits on similar medical rights, like the right to refuse life-saving treatment, will provide an appropriate template for this consideration in the next Part.

III. CURRENTLY RECOGNIZED TRADITIONAL NOTIONS OF ORDERED LIBERTY AND THEIR IMPLICATIONS FOR A RIGHT TO ACCESS TREATMENT

Traditional notions of ordered liberty found in the Fourteenth Amendment’s Due Process Clause, as first enunciated in *Griswold v. Connecticut*,¹²⁵ are important

¹¹⁸ David Leo Weimer, *Safe—and Available—Drugs*, in *INSTEAD OF REGULATION* 239, 245 (Robert W. Poole, Jr. ed., 1982).

¹¹⁹ 21 U.S.C. § 355(d) (2000).

¹²⁰ *Abigail I*, 445 F.3d at 482–83.

¹²¹ *Id.* at 486 (Griffith, J., dissenting).

¹²² *Id.*

¹²³ *See id.* at 472 (majority opinion) (explaining that the plaintiffs were seeking to enjoin an FDA policy barring early access to investigational drugs for terminally ill patients, not requiring these patients to have state subsidized access or forbidding the FDA from issuing recommendations).

¹²⁴ *See supra* notes 88–100 and accompanying text.

¹²⁵ 381 U.S. 479 (1965).

parts of the legal context surrounding the right to access treatment. *Griswold* relied on “penumbras” in the Bill of Rights, which are “formed by emanations from those guarantees that help give them life and substance.”¹²⁶ The Court then declared that a Connecticut law prohibiting married couples from using contraceptives was in violation of a “right of privacy older than the Bill of Rights.”¹²⁷ Essentially, the Court reasoned that the penumbras of the First, Third, Fourth, Fifth, and Ninth Amendments implicitly encoded a “right of privacy” in the Constitution that prevents the state from regulating how married couples may engage in private sexual activity because this activity has been recognized as a fundamental right in American legal history.¹²⁸ The Court did not give a detailed description of how English or American common law and statutory law regulated marital sexual privacy, yet still found the activity to be protected.¹²⁹

The importance of allowing an individual to make health-related choices affecting bodily integrity permeates modern substantive due process jurisprudence. In *Eisenstadt v. Baird*, the Court considered the constitutionality of laws making the distribution of birth control to an unmarried woman illegal in light of the infringement on an individual’s right of privacy.¹³⁰ The Court wrote that “[i]f the right of privacy means anything, it is the right of the *individual*, married or single, to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child.”¹³¹ Like *Griswold*, the Court struck down a law when it directly regulated the sexual activity and procreative choices of human beings.¹³²

The Court in *Roe v. Wade* held that the right of privacy in the penumbras of the Fourteenth Amendment Due Process Clause supported a right for a woman to terminate her pregnancy.¹³³ The reason that personal medical decisions are frequently the subject of due process privacy rights is because these issues are often a matter significantly affecting quality of life and thus “so fundamentally affect[] a person.”¹³⁴

The phrase “so fundamentally affecting a person”¹³⁵ would have no meaning if it did not include matters of life or death, considering that one must be alive to enjoy any other right. The right to access treatment, because it protects a terminally ill patient’s last chance to preserve her own life, is thus a matter of life and death, and it so affects a person’s private concern for her health that it could neatly fit in the due process jurisprudence created by *Griswold*, *Eisenstadt*, and *Roe*.

¹²⁶ *Id.* at 484.

¹²⁷ *Id.* at 486.

¹²⁸ *Id.* at 484–86.

¹²⁹ *See id.*

¹³⁰ 405 U.S. 438, 440, 443 (1972).

¹³¹ *Id.* at 453.

¹³² *Id.* at 452–53.

¹³³ 410 U.S. 113, 153 (1973).

¹³⁴ *See Eisenstadt*, 405 U.S. at 453.

¹³⁵ *Id.*

Aside from the importance of privacy as applied to personal medical decisions, the importance of privacy as an unapplied, abstract idea is vital to the meaning of the Due Process Clause. The Court explained:

The makers of our Constitution undertook to secure conditions favorable to the pursuit of happiness. They recognized the significance of man's spiritual nature, of his feelings and of his intellect. They knew that only a part of the pain, pleasure and satisfactions of life are to be found in material things. They sought to protect Americans in their beliefs, their thoughts, their emotions and their sensations. They conferred, as against the Government, the right to be let alone—the most comprehensive of rights and the right most valued by civilized man.¹³⁶

The government should respect choices, even risky ones, an individual makes as long as the choices are made in a good faith effort to preserve one's privacy or health. This is not to say that a right of privacy embodied in the right to access treatment would allow a terminally ill patient to take drugs for which *no* basic testing for safety has occurred.¹³⁷ The idea of privacy, as expressed in *Roe*, could clearly support a right to access treatment: if a patient's privacy is so strong that women are protected from government interference when they make medical decisions like whether to have an abortion, which potentially harms innocent third parties, privacy could also shield medical decisions that are made in good faith to prolong a patient's life.

Although the fundamental right of privacy as expressed in cases like *Eisenstadt* could protect a right to access treatment, the cases that most heavily rely upon a right of privacy are from a past era of substantive due process jurisprudence.¹³⁸ The Court in *Casey*, however, considered whether five provisions of a Pennsylvania statute violated a woman's right to make a medical decision to have an abortion and effectively reexamined how broadly the Due Process Clause should be interpreted.¹³⁹ The Court reaffirmed *Roe* and determined that “[c]onstitutional protection of the woman's decision to terminate her pregnancy derives from the Due Process Clause”

¹³⁶ *Id.* at 453 n.10 (quoting *Olmstead v. United States*, 277 U.S. 438, 478 (1928) (Brandeis, J., dissenting)).

¹³⁷ Such a policy may be so reckless as to be analogous to patients who wish to commit suicide in pursuit of their happiness. The Supreme Court has clearly proclaimed that such recklessness is not constitutionally protected. *See* *Washington v. Glucksberg*, 521 U.S. 702, 711 (1997).

¹³⁸ *Griswold*, *Eisenstadt*, and *Roe* were decided in 1965, 1972, and 1973, respectively. *See supra* notes 125, 130, 133.

¹³⁹ *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 844 (1992).

and that the “controlling word in the cases before us is ‘liberty.’”¹⁴⁰ The Court, in determining how the right to an abortion fit amongst other rights previously upheld under the Due Process Clause, noted that the law grants “constitutional protection to personal decisions relating to marriage, procreation, contraception, family relationships, child rearing, and education, . . . [matters] involving the most intimate and personal choices a person may make in a lifetime, choices central to personal dignity and autonomy, [that] are central to the liberty protected by the Fourteenth Amendment.”¹⁴¹ One common theme among these rights is that they involve individuals making decisions in their pursuit of happiness which do not pose a threat of harm to any constitutionally recognized legal entity.¹⁴² The Court, having reaffirmed its commitment in *Roe* to the idea of a right of privacy, decided that the right was not absolute and was subject to certain regulations.¹⁴³ The state’s interest in protecting fetal life can at some point during a pregnancy—after viability—eclipse the liberty interest of an individual.¹⁴⁴ The reasoning of the Court suggested that the more narrowly-tailored a proposed right under the Due Process Clause, such that it does not interfere with an appropriate state interest, the more likely it is consistent with the right of privacy.¹⁴⁵

In a case more factually similar to the one brought in *Abigail I*, the Court expanded on the principles espoused in *Casey* in its analysis of the case of a woman in a vegetative state named Nancy Cruzan.¹⁴⁶ In *Cruzan*, the Court considered whether Nancy’s guardians had the right to withdraw her life support under the Constitution.¹⁴⁷ The Court summarized the right from unwanted medical treatment by stressing that “[t]he principle that a competent person has a constitutionally protected liberty interest in refusing unwanted medical treatment may be inferred from our prior decisions.”¹⁴⁸

The right to access treatment sought by the Abigail Alliance may be inferred from *Cruzan*. The Court in *Cruzan* found that individual medical choices, when clearly and competently expressed, can override government actions that may prolong an

¹⁴⁰ *Id.* at 846.

¹⁴¹ *Id.* at 851 (citation omitted).

¹⁴² The right to access treatment does not threaten harm to any innocent third party but may threaten harm to the terminally ill patient who uses experimental drugs for which safety testing, though substantially done, is not complete. *See Abigail I*, 445 F.3d 470, 473 (D.C. Cir. 2006), *rev’d en banc*, 495 F.3d 695 (D.C. Cir. 2007), *cert. denied*, 76 U.S.L.W. 3189 (U.S. Jan. 14, 2008) (No. 07-444).

¹⁴³ *Casey*, 505 U.S. at 851–53, 869.

¹⁴⁴ *See id.* at 869.

¹⁴⁵ The Court, recognizing the Due Process Clause has “boundaries [that] are not susceptible of expression as a simple rule,” advised that courts should be cautious and exercise “reasoned judgment” when interpreting due process rights. *Id.* at 849–50.

¹⁴⁶ *Cruzan v. Dir., Mo. Dep’t of Health*, 497 U.S. 261, 266 (1990).

¹⁴⁷ *Id.* at 267–68.

¹⁴⁸ *Id.* at 278.

individual's life.¹⁴⁹ The state traditionally succeeds in interfering with an individual's choice of medical treatment when it erred on the side of prolonging life.¹⁵⁰ This is because "[t]he state's interest in preserving life is the most significant interest asserted by the state."¹⁵¹ The Abigail Alliance sought to allow terminally ill patients to make individual choices that, though involving risk, are good faith attempts to prolong life.¹⁵² If there is a right to refuse unwanted medical treatment because traditional notions of privacy protect patients from government interference and government interference is at its strongest when it errs on the side of prolonging life, then personal medical decisions to use experimental drugs that are made in an attempt to prolong life are amongst the strongest and most fundamental interests a person can have. The right to access treatment, thus, should be protected under the Due Process Clause.

The majority in *Abigail I*, responding to criticism from the dissent that *Cruzan* does not imply a right to access treatment, explained how the Court may extrapolate from substantive due process case law precedent: "Were it impermissible to draw any inferences from a broader right to a narrower right . . . nearly all of the Supreme Court's substantive due process case law would be out of bounds."¹⁵³ The Court should easily embrace a right to access treatment if it chooses to embrace a right to refuse life-saving treatment. Logically the right to refuse life-saving treatment and the right to access treatment are inextricably linked, and either both exist or neither do.

IV. THE FDA'S CURRENT APPROACH AND ITS PRACTICAL PROBLEMS

A. Paternalism

As previously mentioned, the FDA's structure is based on legislation regulating the manufacture of new drugs that passed in phases between the early and late twentieth century before "external controls" existed.¹⁵⁴ The current system, however,

¹⁴⁹ See *id.* at 278–79.

¹⁵⁰ See, e.g., *id.* at 281–82 (holding that Missouri could set a high evidentiary requirement for proof of an individual's choice of withdrawal of treatment).

¹⁵¹ *Rasmussen v. Fleming*, 741 P.2d 674, 683 (Ariz. 1987).

¹⁵² *Abigail I*, 445 F.3d 470, 472 (D.C. Cir. 2006), *rev'd en banc*, 495 F.3d 695 (D.C. Cir. 2007), *cert. denied*, 76 U.S.L.W. 3189 (U.S. Jan. 14, 2008) (No. 07-444).

¹⁵³ *Id.* at 481 n.12. The court listed examples:

See, e.g., *Griswold* (inferring specific right to use contraception from general right to be free from intrusion into "sacred precincts of marital bedrooms"); *Roe* (identifying specific right to terminate a pregnancy from broader right to privacy); *Moore* (extrapolating from broader constitutional protection for "the sanctity of the family" to specific right to determine extended family living arrangements).

Id. (citations omitted).

¹⁵⁴ Steven R. Salbu, *Off-Label Use, Prescription, and Marketing of FDA-Approved Drugs*:

is based on pre-market stringent testing for safety and efficacy because of the history of disastrous consequences with inadequately-tested, marketed drugs.¹⁵⁵ The dissent in *Abigail I* discussed the mechanics of the FDA's current policies regulating new drugs:

Phase I involves the initial introduction of a new drug into human subjects. . . . In addition to addressing the effectiveness of a new drug, Phase II studies are used "to determine the common short-term side effects and risks associated with the drug." Phase III studies "gather . . . additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug." The FDA further requires some drugs to go through Phase IV studies, which "delineate additional information about the drug's risks, benefits, and optimal use."¹⁵⁶

The FDA's testing procedures are front-loaded with stringent testing before marketing, presumably to prevent the type of disasters that begot the enabling legislation at the foundation of the FDA.¹⁵⁷

The FDA's approach of front-loaded testing is a policy that makes sense when the only goal is making sure the drugs that do go to market are safe and effective. Safety and efficacy should be important if the majority of drug manufacturers seek approval for unsafe or ineffective drugs. One journal reported that "11 percent of drugs—and only 6 percent of cancer drugs—that enter clinical testing are ultimately approved; the rest either prove to be too toxic or do not work."¹⁵⁸ This means that the vast majority of drugs submitted for approval by drug manufacturers are ultimately ineffective at increasing the health of the patient, and in some cases, the drugs are actually adverse to a patient's health. The FDA's policy of front-loaded testing is reasonable, but this does not mean it is the optimal way of balancing the needs of terminally ill patients with public health.¹⁵⁹

The FDA's policies can be characterized as a form of "[r]egulatory paternalism."¹⁶⁰ The policies allow the agency to act as a gatekeeper that must approve all drugs before they can enter the market, which gives the agency the authority to limit which drugs

An Assessment of Legislative and Regulatory Policy, 51 FLA. L. REV. 181, 183 (1999).

¹⁵⁵ See *supra* Part II.

¹⁵⁶ *Abigail I*, 445 F.3d at 488–89 (Griffith, J., dissenting) (citations omitted).

¹⁵⁷ *Id.* at 482–83 (majority opinion).

¹⁵⁸ Susan Okie, *Access Before Approval—A Right to Take Experimental Drugs?*, 355 NEW ENG. J. MED. 437, 439 (2006).

¹⁵⁹ See *id.* at 439–40.

¹⁶⁰ Michael D. Greenberg, *Information, Paternalism, and Rational Decision-Making: The Balance of FDA New Drug Approval*, 13 ALB. L.J. SCI. & TECH. 663, 674 (2003).

patients and their doctors may choose for the treatment of an illness.¹⁶¹ This amounts to paternalism considering “the extent that individual freedom is subordinated to the licensing discretion of a government agency.”¹⁶² Based on the FDA’s statutory history and the motivations for the agency’s power, the entire aim of the FDA is to protect a vulnerable public from unscrupulous drug manufacturers and charlatans.¹⁶³

This, however, ignores an important function of the FDA’s new drug approval process. When the FDA requires proof of safety and efficacy, it also “generate[s] rigorous and systematic data on drug safety and effectiveness.”¹⁶⁴ Though this data is necessary to the FDA’s primary function as a gatekeeper for the public safety, it also accomplishes an important task for even those who decry the paternalistic aspect of the FDA’s policies: it provides information about new drugs that independent doctors and patients need to evaluate the safety and effectiveness of drugs on their own.¹⁶⁵ And though one may adopt the position that the FDA’s paternalistic priority is ill-conceived and may believe that all individuals should be personally responsible for regulating which types of treatments a physician may administer, that individual, in order to act rationally, would still need basic information about the safety and efficacy of new drugs.

Ultimately, the FDA relies on a paternalistic motivation and justifies its authority “based on the premise that certain kinds of information about new drugs do not exist *a priori*, and are not likely to be generated in a free market.”¹⁶⁶ This allows the FDA to be the sole entity to ensure that necessary safety and efficacy information about new drugs exists.¹⁶⁷ It does not necessarily follow, however, that the FDA is the only entity capable of making rational decisions about how to use information about new drugs once it is generated and disseminated to doctors and patients. This is not to say that the FDA should not pass judgments on the proper use of new drugs after they go through a Phase I clinical trial that ensures basic safety standards are satisfied; the FDA just should not make their recommendations mandatory, thereby substituting their judgment for those of competent, adult patients in consultation with their doctors. The FDA’s substituted judgment is especially problematic for terminally ill individuals, who have no reason to care about the results of comprehensive clinical trials that test for proven efficacy or long-term side effects of new drugs, but instead care only about Phase I trials that test for immediate adverse reactions.¹⁶⁸ The

¹⁶¹ See *id.* at 671.

¹⁶² *Id.* at 672.

¹⁶³ See *supra* notes 106–24 and accompanying text.

¹⁶⁴ Greenberg, *supra* note 160, at 673.

¹⁶⁵ See *id.* at 672.

¹⁶⁶ *Id.* at 674.

¹⁶⁷ See *id.*

¹⁶⁸ When someone is terminally ill, the main concern about a new drug is that it is not so dangerous as to immediately kill them in the hope that it may prolong life, even if the side

“orthodoxy of the FDA clinical trial scheme” can be reasonably—though not necessarily—considered a waste of time for patients who face imminent death.¹⁶⁹

Were the FDA to relinquish its paternalistic role to accommodate a right to access treatment, society would need to trust that terminally ill patients would for the most part make rational decisions based on informed consent.¹⁷⁰ In *Glucksberg*, the Court recognized that the government may have an appropriate interest in “protecting the vulnerable from coercion.”¹⁷¹ In denying that there was a right to physician-assisted suicide, the Court emphasized the primacy of state interests over individual liberty when it warned that “[l]egalizing physician-assisted suicide would pose profound risks to many individuals who are ill and vulnerable.”¹⁷² The Court noted that the main threat to the ability of terminally ill patients to make rational medical decisions was that “many [terminally ill patients] might resort to [suicide] to spare their families the substantial financial burden of end-of-life health-care costs.”¹⁷³ This concern is justifiable and validates the government’s paternalistic concern when erring on the side of preserving life over individuals choosing death; but in the case of the right to access treatment, patients are also erring on the side of prolonging life, and in fact, it is their driving motivation.¹⁷⁴ Patients should not be allowed to make reckless decisions but should be allowed, in consultation with their doctor, to choose from various new drug treatments that have passed Phase I safety trials.¹⁷⁵

The concern in *Glucksberg* for vulnerable populations does highlight that the right to access treatment can be limited by certain safeguards that protect legitimate government interests, and the Abigail Alliance recognized these limits.¹⁷⁶ For review, these safeguards include limiting access to only terminally ill patients,¹⁷⁷ who are the only

effects were to eventually prove to be fatal in the long run (beyond the initial estimated time of death). See Complaint, *supra* note 1, at 5–6.

¹⁶⁹ Greenberg, *supra* note 160, at 675.

¹⁷⁰ Although the FDA’s current process does assist patients in obtaining information about treatments. See *id.* at 671, 674.

¹⁷¹ *Washington v. Glucksberg*, 521 U.S. 702, 731–32 (1997).

¹⁷² *Id.* at 732 (quoting NY STATE TASK FORCE ON LIFE & THE LAW, WHEN DEATH IS SOUGHT: ASSISTED SUICIDE AND EUTHANASIA IN THE MEDICAL CONTEXT 77–82 (May 1994)).

¹⁷³ *Id.*

¹⁷⁴ See *Abigail I*, 445 F.3d 470, 472 (D.C. Cir. 2006), *rev’d en banc*, 495 F.3d 695 (D.C. Cir. 2007), *cert. denied*, 76 U.S.L.W. 3189 (U.S. Jan. 14, 2008) (No. 07-444).

¹⁷⁵ It may be helpful to think access to pre-Phase I experimental drugs or access to experimental drugs without a doctor’s recommendation are akin to the type of reckless disregard for life that was unprotected in *Glucksberg*. See *Glucksberg*, 521 U.S. at 729–30 (discussing how the government has a legitimate interest in preventing the harm posed by the disregard for life involved in suicide).

¹⁷⁶ See *Abigail I*, 445 F.3d at 472 (noting that access would be limited to drugs that had undergone Phase I clinical human trials).

¹⁷⁷ For one accepted standard of what it means to be terminally ill, see Oregon Death with

population with the support of the fundamental right of self-preservation and, thus, have interests strong enough to defeat paternalistic governmental concerns. However, because terminally ill patients are vulnerable to coercion in making important medical decisions,¹⁷⁸ the right to access treatment may include other safeguards, such as limiting access to post-Phase I drugs, thereby ensuring some basic safety precautions have been met when patients take experimental drugs;¹⁷⁹ limiting access to patients who have a doctor's prescription, thereby bolstering patients' informed consent by requiring expert advice when they make their medical decisions;¹⁸⁰ and limiting access to competent, adult patients.¹⁸¹

B. Balancing Access with Safety

The next consideration is what type of practical problems occur because the FDA's policy is reactive to public outrage concerning medical disasters rather than a more level-headed approach. Society pays a price for the extra costs incurred when regulations err on the side of stringent pre-market safety and efficacy, and these costs, including delays in access, highlight some of the shortfalls in the FDA's current policy.¹⁸² There are also direct costs to individual patients, though these costs indirectly affect everyone because anyone may contract a life-threatening illness.

The first burden to consider is the economic price society pays for the stringent assurances of safety and efficacy. Consider that “[w]hile the FDA’s exercise of regulatory authority over prescription drugs and medical devices has increased the safety and reliability of drugs . . . these benefits are not without costs. . . . [They] require[] exhaustive testing and substantial scientific evidence of safety and efficacy

Dignity Act, OR. REV. STAT. § 127.800 § 1.01(12) (2005) (defining terminally ill as having “an incurable and irreversible disease that has been medically confirmed and will, within reasonable medical judgment, produce death within six months”).

¹⁷⁸ See *supra* notes 171–73 and accompanying text.

¹⁷⁹ *Abigail I*, 445 F.3d at 472.

¹⁸⁰ *Id.*

¹⁸¹ *Id.*

¹⁸² James L. Zelenay, Jr., *The Prescription Drug User Fee Act: Is a Faster Food and Drug Administration Always a Better Food and Drug Administration?*, 60 FOOD & DRUG L.J. 261, 274 (2005). These costs include:

First, industry pointed out, longer review times translated into greater R&D costs. . . . Second, and more importantly, industry pointed out that for each extra month that FDA took to review an NDA, the manufacturer lost a month in marketing a drug with patent protection and, therefore, without any generic competition. . . . Third, due to the drug lag, many manufacturers felt compelled to move their facilities overseas so they could capture earlier market profits.

Id.

before [the FDA] will approve any new product.”¹⁸³ Though this increased safety and efficacy is desirable in itself, it may not be desirable when considered beyond a vacuum of unlimited resources.¹⁸⁴ The costs of testing for new chemical compounds that have never been approved by the FDA can be especially high.¹⁸⁵ For example, approval of the food additive Olestra took twenty-one years, 100,000 pages of research data, and development costs of 300 million dollars.¹⁸⁶ This cost is the average price tag for the development of new drugs in general, though the average time from the first clinical trials to FDA approval is eight and a half years.¹⁸⁷ The effect of the high costs of testing before the drug can be sold on the market is clear: only companies with vast financial resources can afford to invest in new drug treatments, reducing the overall availability of new drugs.¹⁸⁸ The FDA has little incentive to reduce the costs of testing, because the agency is likely to conclude from its entire statutory history that Congress only pays attention to the effectiveness of the FDA’s regulations when marketed drugs cause medical disasters.¹⁸⁹

The cost of drug testing itself may be substantial, but the opportunity cost for the time it takes to do the testing exacerbates the problem. Drug manufacturers now have to obtain government approval before *any* marketing of new drugs.¹⁹⁰ When one considers that “th[e] increase in [FDA] regulation was accompanied by an increase in the amount of time it took for a pharmaceutical company to proceed from the discovery of a new drug to FDA approval. . . . [and that] [t]he delays were more staggering . . . than most had expected,” the financial impact is significant.¹⁹¹ Drug manufacturers should be allowed to market these new drugs once initial safety testing, done in Phase I, determines that the drugs are not immediately harmful. This also assumes that drug manufacturers should be allowed to charge terminally ill patients for the right to use experimental drugs. That initial flow of money could help pay for expanded testing later on. Thus, the right to access treatment may actually help defray development costs.¹⁹²

¹⁸³ Charles J. Walsh & Alissa Pyrich, *Rationalizing the Regulation of Prescription Drugs and Medical Devices: Perspectives on Private Certification and Tort Reform*, 48 RUTGERS L. REV. 883, 886 (1996).

¹⁸⁴ See, e.g., Elizabeth C. Price, *Teaching the Elephant to Dance: Privatizing the FDA Review Process*, 51 FOOD & DRUG L.J. 651, 656–57 (1996).

¹⁸⁵ *Id.*

¹⁸⁶ *Id.* at 657. It is important to note that the additive was not meant for treatment of an imminently life-threatening illness but as a fat substitute. *Id.* at 657 & n.40.

¹⁸⁷ *Id.* at 656.

¹⁸⁸ *Id.* at 657.

¹⁸⁹ See *id.* at 655.

¹⁹⁰ See Promotion and Charging for Investigational Drugs, 21 C.F.R. § 312.7(d)(1) (2007) (outlawing drug manufacturers from promoting an IND as safe and from charging patients for investigational drugs under an IND without FDA approval).

¹⁹¹ Zelenay, *supra* note 182, at 261.

¹⁹² See *supra* notes 77–83 and accompanying text for a discussion of how the right to

Aside from the financial downsides of the FDA's policy, there are consequences for terminally ill patients who cannot wait for investigational drugs to be proven safe, or even scientifically effective, over the long-term.¹⁹³ The FDA's policies "prohibit access to investigational therapies for noninvestigational purposes. In effect, patients lose access to potential treatments while anxiously awaiting proof of efficacy."¹⁹⁴ Some staggering estimates indicate that the delay caused by regulatory testing can be devastating for terminally ill patients: one libertarian think tank, the Cato Institute, estimated that "FDA delays in allowing US marketing of drugs . . . have cost the lives of at least 200,000 Americans."¹⁹⁵ This is not surprising considering that the FDA is not primarily concerned with lives that might have been saved by access to experimental drugs, especially when the delay in access is caused by stringent testing standards developed to avoid the media frenzy resulting from harms caused by under-investigated drugs.¹⁹⁶ That does not mean, however, that there are not deaths that would not happen but for delays caused by pre-market testing or that it would not be worthwhile to find a meaningful solution that reconciles giving terminally ill patients access to experimental drugs and protecting the public from reckless drug manufacturers rushing unproven drugs to market.

The FDA's pre-market review and approval process imposes a significant barrier to access to new drugs for terminally ill patients who do not qualify for clinical trials of experimental drugs.¹⁹⁷ The FDA attempted to provide at least one alternative pathway for terminally ill patients to use new drugs through an informal process that created a "compassionate use Investigational New Drug [IND] exemption."¹⁹⁸ This exemption was designed to "treat serious or immediately life-threatening diseases or conditions without adequate available therapy."¹⁹⁹ Exemptions were provided to patients "on a case-by-case basis" and depended on the discretion of the FDA and a pharmaceutical company to provide the experimental drug.²⁰⁰ In 1987, the FDA

access treatment is narrowly defined so as to not place a positive burden on the government to provide experimental drugs to indigent patients.

¹⁹³ Complaint, *supra* note 1, at 6–8 (reviewing the cases of terminally ill patients that gave rise to the suit by Abigail Alliance).

¹⁹⁴ 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, 106 (1995).

¹⁹⁵ Daniel Green, *Obstacle Course for Drug Producers: Pressure for Reform of the US Food and Drug Administration is Growing*, FIN. TIMES (London), Aug. 21, 1995, at 12.

¹⁹⁶ See *supra* notes 107–23 and accompanying text.

¹⁹⁷ Michael D. Greenberg, *AIDS, Experimental Drug Approval, and the FDA New Drug Screening Process*, 3 N.Y.U. J. LEGIS. & PUB. POL'Y 295, 315 (2000).

¹⁹⁸ *Id.* at 315–16.

¹⁹⁹ Expanded Access to Investigational Drugs for Treatment Use, 71 Fed. Reg. 75,148 (proposed Dec. 14, 2006) (to be codified at 21 C.F.R. pt. 312).

²⁰⁰ Greenberg, *supra* note 197, at 316.

formalized and revised the compassionate use IND procedure, providing broader access to new drugs when certain criteria are met.²⁰¹ The criteria included whether the intended disease was life-threatening and whether there were other approved treatment alternatives.²⁰² This IND regulation, thus, embodies some of the goals the Abigail Alliance sought in its right to access treatment.²⁰³

The AIDS crisis in the 1980s provided the impetus for increased use of this IND regulation.²⁰⁴ At the onset of the epidemic, contracting AIDS was akin to receiving a death sentence because of the lack of any effective conventional treatment.²⁰⁵ The FDA's statutory framework, having been previously constructed in response to disasters involving drugs already on the market, now had to respond to AIDS patients for whom "the possibility that an experimental treatment could be unsafe or ineffective became largely irrelevant."²⁰⁶ The FDA allowed its first IND exemption for certain AIDS patients even before the 1987 IND regulations, which once in effect, expanded the opportunities for other AIDS patients.²⁰⁷

The FDA's expanded access to treatment, however, still had many shortfalls. AIDS patients sometimes complained that the IND treatment programs for certain drugs were not broad enough.²⁰⁸ For example, some patients were excluded from a study of a drug called Trimetrexate because conventional treatments, though not effective, were not adverse.²⁰⁹ This distinction seems arbitrary because patients in both circumstances still needed treatment beyond the conventional treatments and both were facing life-threatening illnesses. This example also demonstrates one of the benefits of making access to treatment a fundamental right; the right removes some FDA discretion, which can be used to impose seemingly arbitrary restrictions on who gains access to experimental drugs if the agency is out-of-touch with the needs of terminally ill patients.²¹⁰

Congress made mild changes to the approval process for experimental drugs when it passed the Food and Drug Administration Modernization Act of 1997 (FDAMA).²¹¹ The purpose of the FDAMA was to respond to "concerns about inconsistent policies,

²⁰¹ Expanded Access to Investigational Drugs for Treatment Use, 71 Fed. Reg. 75,148.

²⁰² *Id.*

²⁰³ *Abigail I*, 445 F.3d 470 (D.C. Cir. 2006), *rev'd en banc*, 495 F.3d 695 (D.C. Cir. 2007), *cert. denied*, 76 U.S.L.W. 3189 (U.S. Jan. 14, 2008) (No. 07-444).

²⁰⁴ Greenberg, *supra* note 197, at 296.

²⁰⁵ *Id.*

²⁰⁶ *Id.*

²⁰⁷ *Id.* at 312, 318.

²⁰⁸ *Id.* at 320.

²⁰⁹ *Id.* at 320 n.146.

²¹⁰ *See id.* at 320.

²¹¹ Pub. L. No. 105-115, 111 Stat. 2296 (codified as amended in scattered sections of 21 U.S.C.).

inequitable access, and preferential access for certain categories of disease.”²¹² The changes were meant “to emphasize that ‘opportunities to participate in expanded access programs are available to every individual with a life-threatening or seriously debilitating illness for which there is not an effective, approved therapy.’”²¹³ The modifications included explicit statutory authority for the Secretary of Health and Human Services to “authorize the shipment of investigational drugs or investigational devices for the diagnosis, monitoring, or treatment of a serious disease or condition in emergency situations.”²¹⁴

Federal law also allows patients, acting through their physicians, to request new drugs from pharmaceutical companies when certain conditions are met.²¹⁵ The first condition is whether the patient’s physician has determined that the probable risk of the investigational drug is less than or equal to the probable risk of the unabated progression of the disease for which no conventional therapy is successful.²¹⁶ The second condition is whether there is “sufficient evidence of safety and effectiveness” for the requested investigational drug as determined by the Secretary.²¹⁷ The third condition is whether the Secretary believes the emergency provision of the investigational drug will interfere with the beginning, continuance, or completion of clinical trials.²¹⁸ And the final condition is whether the drug manufacturer submits to the Secretary an appropriate protocol, describing how the patient will use the investigational drug.²¹⁹

After having met all of the above qualifications, the Secretary can allow the use of a new drug for the patient if *seven* different factors are met.²²⁰ Some initial problems

²¹² Expanded Access to Investigational Drugs for Treatment Use, 71 Fed. Reg. 75,149 (proposed Dec. 14, 2006) (to be codified at 21 C.F.R. pt. 312).

²¹³ *Id.* (citing Joint Explanatory Statement of the Comm. of Conference *in H. REP. NO.* 105-399, at 100 (1997)).

²¹⁴ 21 U.S.C. § 360bbb(a) (2000).

²¹⁵ *Id.* § 360bbb(b).

²¹⁶ *Id.* § 360bbb(b)(1).

²¹⁷ *Id.* § 360bbb(b)(2).

²¹⁸ *Id.* § 360bbb(b)(3).

²¹⁹ *Id.* § 360bbb(b)(4).

²²⁰ *Id.* § 360bbb(c). The seven factors include: (1) the drug is intended to treat a life-threatening or serious illness; (2) there is no comparable or satisfactory alternative treatment for the illness or stage of disease from which the patient is suffering; (3) the drug is under investigation for the illness that is the subject of the proposed use or the drug has completed all clinical trials necessary for approval; (4) the drug manufacturer is actively pursuing market approval for the investigational drug for the use the patient is requesting the drug to help cure; (5) the emergency provision of the investigational drug will not interfere with ongoing clinical trials; (6) when the drug is used to treat a serious disease, there must be some evidence of safety or efficacy; and, (7) when the drug is used to attempt to treat a life-threatening illness, “the available scientific evidence, taken as a whole, provides a reasonable basis to conclude that the investigational drug . . . may be effective for its intended use and

with this Act are apparent when considered in the context of the case of Abigail Burroughs. The first drug Abigail's physician attempted to procure for her was Erbitux.²²¹ Erbitux was in a clinical trial to treat colon cancer, not Abigail's cancer of the head and throat.²²² Abigail could not procure the drug under the FDAMA because it would be in violation of section 561(c)(3) as it was under investigation for treating a different type of cancer than Abigail's type.²²³ This result seems arbitrary when one considers that the physician proposed Erbitux for Abigail because her cancer cells expressed the same type of receptors Erbitux targeted in colon cancer cells.²²⁴

When one considers the time frame from the initial diagnosis of a life-threatening disease to death another problem emerges. First, the patient must try conventional treatments in order to invoke the FDAMA.²²⁵ Then, the patient's doctor must find a drug that may reasonably be helpful, convince the manufacturer to provide the drug, develop a protocol for the drug's use, and convince the Secretary that it meets the criteria of the FDAMA.²²⁶ Consider that Abigail, after unsuccessfully trying conventional treatments, lived for only three months before her death.²²⁷ The right to access treatment should shorten the time frame it would take to get access to investigational drugs once conventional therapies fail because there would not have to be bureaucratic approval requiring the satisfaction of up to ten criteria. Recall that the right to access treatment would not be absolute; safeguards in the FDAMA would limit the scope of the right if the application of the right is contrary to "narrowly tailored 'compelling interest[s].'"²²⁸ Patients should also be required to have a physician recommend a new drug that, though of unproven efficacy via clinical trials, is reasonably expected by some degree of medical reasoning to be useful for the patient.

One last important provision of the FDAMA is that it allows the Secretary to "inform national, State, and local medical associations and societies, voluntary health associations, and other appropriate persons about the availability of an investigational drug."²²⁹ The purpose of this provision was "[t]o specifically address concerns that physicians and their patients are often unaware of the availability of investigational

would not expose patients to an unreasonable and significant risk of illness or injury." *Id.*

²²¹ See *supra* text accompanying note 4.

²²² See *supra* text accompanying notes 2, 5.

²²³ See *supra* text accompanying notes 2, 5.

²²⁴ See *supra* text accompanying note 4.

²²⁵ 21 U.S.C. §§ 360bbb(b)(1), 369bbb(c)(2).

²²⁶ See *supra* notes 215–19 and accompanying text.

²²⁷ See *supra* notes 1–8 and accompanying text.

²²⁸ *Abigail I*, 445 F.3d 470, 486 (D.C. Cir. 2006) (noting that once a fundamental right is recognized, the government can burden it in specific circumstances), *rev'd en banc*, 495 F.3d 695 (D.C. Cir. 2007), *cert. denied*, 76 U.S.L.W. 3189 (U.S. Jan. 14, 2008) (No. 07-444).

²²⁹ 21 U.S.C. § 360bbb(c)(7).

drugs under access programs.”²³⁰ If patients had a right to access treatment, programs that spend valuable resources on publicizing these governmental access programs would not be necessary because doctors who treat terminally ill patients would know that patients who did not respond to conventional therapies and who could afford to buy the investigational drugs would have de facto access to any post-Phase I drug the doctor thinks might treat the illness.

The government may nobly desire to prohibit drug manufacturers from marketing new, unproven drugs to terminally ill people because of concerns that unscrupulous manufacturers will only be selling false hope to patients who are at their most vulnerable. This type of paternalism does not fairly reflect the liberty interests of patients concerning medical decisions.²³¹ The FDA’s policy needs to balance concern for pre-market safety and efficacy with the knowledge that, unless there is a policy that broadly lets terminally ill patients gain early access to the most promising investigational drugs, every delay in getting the successful drugs to market costs the lives of terminally ill patients.²³² The FDA can accommodate the right to access treatment in keeping with its primary concern of protecting the public.

V. PRESCRIPTION FOR CHANGE

This goal of this Note is not to lay out a comprehensive regulatory scheme for implementing the right to access treatment, but some consideration of specific recommendations is necessary to demonstrate how this right can be implemented as a matter of policy. With that in mind, the FDA’s current conservative approach manages to attract criticism from two types of special interest advocates.²³³ This is a dilemma because “[t]he [FDA] is caught in pincers between two intense political pressures: demands from the industry and the political right to move faster and faster in approving drugs, and rising insistence from consumer groups and the left to show more caution.”²³⁴ These two concerns, though seemingly diametrically opposed, are not irreconcilable. In fact, the FDA’s optimal policy should be a compromise between the needs of manufacturers, the public, and terminally ill patients.

Abigail I and *II* represent only the litigation component of the plaintiff’s drive for the right to access treatment.²³⁵ A legislative proposal by the Abigail Alliance

²³⁰ Expanded Access to Investigational Drugs for Treatment Use, 71 Fed. Reg. 75,149 (Dec. 14, 2006) (to be codified at 21. C.F.R. pt. 312).

²³¹ See *supra* Part III.

²³² See *supra* notes 190–95 and accompanying text.

²³³ Rochelle Sharpe, *FDA Tries to Find Right Balance on Drug Approvals*, WALL ST. J., Apr. 20, 1999, at A24.

²³⁴ *Id.*

²³⁵ See, e.g., Press Release, Abigail Alliance, Abigail Alliance Supports ACCESS Act (Nov. 10, 2005), available at http://abigail-alliance.org/AbigailAlliancesupportsACCESSAct_1_.pdf.

details a policy of how the FDA could accommodate industry and patient concerns at the beginning of the approval process.²³⁶ The proposal establishes a three tier system for access to experimental drugs: Tier 1 approval is based on Phase I testing and preclinical evidence;²³⁷ “Tier 2 approval would correspond to today’s [FDA] accelerated approval;”²³⁸ and Tier 3 approval to what is currently full approval.²³⁹ This system, which accommodates the right to access treatment, would essentially make access to drugs available on a spectrum in which drugs become more publicly available as they are proven by the FDA to be safer and more effective.

Part of the solution involves improving safety and efficacy testing at the end of the process, rather than front-loading all of the testing at the beginning.²⁴⁰ The result of current FDA policies is that “[i]n practice, pharmaceutical companies have simply not completed the definitive followup studies mandated by accelerated approval status.”²⁴¹ As the FDA requires so much testing from drug manufacturers before a drug can be marketed to the public, complacency can set in after a drug is approved for a specific use because the FDA has limited requirements for ensuring post-approval safety and efficacy.²⁴² However, this complacency can be avoided by easing the strict prohibition on marketing experimental drugs at the front end, thus giving drug manufacturers an initial cash flow from their new drugs, while allowing the FDA to reserve the right to require more testing before the drug has full approval to test the market.²⁴³ Specifically, one report recommended that the FDA can increase the variety of safety and efficacy information the public has about new drugs if it “reevaluate[s] safety . . . within five years after initial approval . . . and the agency . . . [has] authority to place a wider range of restrictions on drugs it deems risky.”²⁴⁴ The improvement in the timing of various phases of drug testing does not mean other adjustments should not be made. Scholars argue that “Congress should amend the FDAMA to require the FDA to establish and maintain a qualified clinical trial

²³⁶ Okie, *supra* note 158, at 439.

²³⁷ *Id.* Tier 1 drugs “could be marketed for seriously ill patients who had exhausted other treatment options, if they waived the right to sue the manufacturer and permitted collection of their clinical data.” *Id.*

²³⁸ *Id.*

²³⁹ *Id.*

²⁴⁰ See *Abigail I*, 445 F.3d 470, 488–89 (D.C. Cir. 2006) (Griffith, J., dissenting) (summarizing FDA drug approval procedures), *rev’d en banc*, 495 F.3d 695 (D.C. Cir. 2007), *cert. denied*, 76 U.S.L.W. 3189 (U.S. Jan. 14, 2008) (No. 07-444).

²⁴¹ Perrin, *supra* note 194, at 146.

²⁴² *Id.* (“Dr. Ellen Cooper, Director of Clinical Research at the American Foundation for AIDS Research, states that ‘[o]nce a drug is on the market . . . companies feel less compelled to conduct expensive studies to show it is effective.’”).

²⁴³ See Shankar Vedantam, *FDA Told U.S. Drug System Is Broken; Expert Panel Calls for Major Changes*, WASH. POST, Sept. 23, 2006, at A1.

²⁴⁴ *Id.* at A8.

registry. It should also grant the FDA power to mandate and enforce private drug manufacturers to participate in the registry.”²⁴⁵ The more information publicly available, the easier it would be for doctors and patients to make informed medical decisions, and the easier it would be to accommodate the right to access treatment.

Despite the decision of the Court of Appeals for the D.C. Circuit to rehear *Abigail I* en banc in 2007 and reverse the judgment of the court upholding the right to access treatment,²⁴⁶ the FDA has not ignored the court’s prior decision and made a decision to review and propose a modification to its policies regarding access to INDs for the terminally ill.²⁴⁷ The new proposal “make[s] it easier for researchers, drug companies and research institutes to determine how much they could charge patients getting drugs early.”²⁴⁸ In proposing a change in the regulations governing experimental drugs, the FDA sought to “increase awareness and knowledge of expanded access programs . . . [to] make investigational drugs more widely available in appropriate situations.”²⁴⁹

The changes the FDA proposed in its new rule are curious because the rule “aims to clarify, and thereby expand, the situations in which expanded access to unapproved drugs could be available.”²⁵⁰ As this Note explored, the main problems regarding the right to access treatment for terminally ill patients are not simply the result of a lack of publicity about existing laws and programs. It is difficult to comment on the particular changes because the rule has not been finalized yet.²⁵¹ The FDA, however, still has too much discretion in determining which details of an IND use affect the availability of a new drug for terminally ill patients. For example, proposed rule 21 C.F.R. § 312.305(a) makes the showing of safety and efficacy of drugs for terminally ill patients dependent on the size of the population for which the drug will be distributed, requiring a higher showing of safety and efficacy as the size of the targeted population grows.²⁵² Whether there is one Abigail Burroughs or one thousand who are in need of the same type of cure, the situation does not change for the individual patient who faces imminent death and rationally decides she has nothing to lose in assuming the risks of trying a new drug. And though FDA employee Janet Woodcock noted that “[w]e’re simplifying the process,”²⁵³ Frank Burroughs, Abigail’s

²⁴⁵ Amanda J. Dohrman, Note, *Rethinking and Restructuring the FDA Drug Approval Process in Light of the Vioxx Recall*, 31 J. CORP. L. 203, 217 (2005).

²⁴⁶ *Abigail II*, 495 F.3d 695 (D.C. Cir. 2007), *cert. denied*, 76 U.S.L.W. 3189 (U.S. Jan. 14, 2008) (No. 07-444).

²⁴⁷ Rob Stein, *FDA Reveals Plan for Wider Access to Experimental Drugs*, WASH. POST, Dec. 12, 2006, at A10.

²⁴⁸ *Id.*

²⁴⁹ Expanded Access to Investigational Drugs for Treatment Use, 71 Fed. Reg. 75,149 (Dec. 14, 2006) (to be codified as 21 C.F.R. pt. 312).

²⁵⁰ *Id.* at 75,150.

²⁵¹ *See id.* at 75,147.

²⁵² *Id.* at 75,151.

²⁵³ Stein, *supra* note 247, at A10.

father, remained skeptical of whether the newly proposed FDA rule respects the individual rights of terminally ill patients.²⁵⁴ He advised that “[t]aking current policy and putting it into [formal] regulation does nothing to help many cancer patients and others with serious life-threatening illness that could be helped.”²⁵⁵

CONCLUSION

This Note demonstrated that there is a need for a right to access treatment that it is constitutionally permitted and that the FDA can and should accommodate this right with its primary concern for the safety of new drug treatments. Imagine having cancer and, after unsuccessfully trying every conventional treatment, your doctor recommends an experimental drug that may be your only chance, albeit a minuscule chance, of surviving longer than six months. Would you care whether this drug had no proven history of efficacy, but a doctor believes there is still some small likelihood that it may be beneficial? Would you care that it may have side effects that could prove to be harmful in the long-run? For some terminally ill patients, the answer to all these questions is “no.” Others may say “yes” and choose to avoid taking any risks in experimental drugs. But for a terminally ill patient who wants to assume the risks and take this last chance at survival, the FDA either delays the process by requiring the patient to go through lengthy bureaucratic procedures or flat out denies this opportunity.

The Supreme Court already recognizes a right to refuse life-saving treatment.²⁵⁶ A terminally ill patient is free to refuse treatment, even if it means hastening death and contradicting the government’s interest in managing risks that threaten the lives of its terminally ill citizens. This precedent, grounded in our nation’s legal history and other substantive due process jurisprudence, strongly implies that a terminally ill patient should be free to decide to pursue treatment, even if it contradicts the government’s interest in managing risks that threaten the lives of all its citizens.

There are two final examples in support of the right to access treatment, without which, this Note would be incomplete. J. Scott Ballenger, the lead counsel for the Abigail Alliance in its appeal to the Supreme Court, provided two examples in a recent lecture of how the right of self-preservation is embedded in both our substantive due process and common law jurisprudence.²⁵⁷ First, the Court in *Roe v. Wade*, and every court hearing an abortion case since *Roe*, has developed a legal framework regulating abortion that included a permanent exemption from government intervention when the abortion was necessary to preserve the life or health of the mother.²⁵⁸ This

²⁵⁴ *Id.*

²⁵⁵ *Id.*

²⁵⁶ *Cruzan v. Dir., Mo. Dep’t of Health*, 497 U.S. 261, 278 (1990).

²⁵⁷ Podcast: Should the Government Insert Itself Between Dying Patients and Unproven Therapies?, Policy Forum held by the Cato Institute (Sept. 25, 2007), available at <http://www.cato.org/podcasts/>.

²⁵⁸ *Id.*

exemption was not based on the right of privacy or supporting autonomy in family planning, but was based on a common law right of self-defense.²⁵⁹ This exemption is grounded in the right of an individual to preserve his own life and trumps almost any state interest, including the state's strong interest in the life of a fetus during the third trimester.²⁶⁰ The right to access treatment is grounded in the same fundamental right of self-defense that grounds the right to have an abortion when the pregnancy threatens the life of the mother.

Second, imagine a law that made it illegal for a woman confronted with a rapist to fight back.²⁶¹ The governmental interest behind such a law could be that: (1) fighting back against a rapist increases the risk that a woman will face life-threatening harm, (2) the government has a legitimate interest in preventing women from increasing the risk of death they face when confronted with a third party attacker, or (3) the governmental interest trumps the woman's decision, though made in good faith, that fighting back is her best option to preserve her life because such a decision is often futile.²⁶² Such a law may seem practically infeasible, but assuming that fighting back does in fact increase the likelihood of death and even assuming that fighting back is often futile, would not the law still be likely to be unconstitutional? Which right would one invoke to challenge the constitutionality of such a law? It seems that one would have to rely on a right of self-defense found in both common law principles and modern substantive due process jurisprudence.²⁶³ There is no difference between the rapist in the prior example and cancer cells that threaten terminally ill patients represented by the Abigail Alliance except that the latter is played out over a longer time frame and the government has prevented terminally ill patients from fighting back.

It is important to keep in mind that giving terminally ill patients access to experimental drugs is not akin to giving them a cure that will stave off or even prevent death. Every patient who takes an investigational new drug should have realistic expectations about the probabilities of obtaining an effective treatment and the probabilities of being subject to a treatment that hastens her death. It might even be helpful to discourage characterizing the right to access treatment as giving hope to terminally ill patients, because for some patients, it may be more painful to have their hopes dashed by the realities of the low success rate of investigational new drugs. How this type of personal crisis affects a patient depends on how the patient defines herself. Because the choice is so personal, so fundamental to who a person is, it is to these patients the choice of whether to take a chance on a new drug should be offered. The FDA can still protect its important function of acting as a gatekeeper in approving new drugs for most situations. But it is not just a matter of compassion to

²⁵⁹ *Id.*

²⁶⁰ *Id.*

²⁶¹ *Id.*

²⁶² *Id.*

²⁶³ *Id.*

allow competent, adult, terminally ill patients to be the gatekeepers of their own bodies when they have nothing left to lose; it is a matter of preserving human dignity.