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THE PROPER FOCUS FOR FDA REGULATIONS: WHY THE FUNDAMENTAL RIGHT TO SELF-PRESERVATION SHOULD ALLOW TERMINALLY ILL PATIENTS WITH NO TREATMENT OPTIONS TO ATTEMPT TO SAVE THEIR LIVES

Alissa Puckett*

IN May of 2006, the District of Columbia Court of Appeals ("D.C. Circuit") held that competent, terminally ill patients had a fundamental right under the Due Process Clause "to informed access to potentially life saving drugs where no alternative, government-approved treatment option exists."¹ The case was originally remanded for a determination on whether the Food and Drug Administration ("FDA") regulations were narrowly tailored, but has been set for rehearing en banc based on the appellees' petition.² The D.C. Circuit's initial holding raised important questions about the rights of the terminally ill and how far government drug regulation extends. To minimize expansion of such a precedent, the case is likely to reach the Supreme Court.³ This comment argues that the Supreme Court may find that the right to self-preservation is a fundamental right, and that the Court should hold that this right extends to access to experimental drugs for terminally ill patients with no other treatment options. If the Court recognizes the asserted right, substantive due process requires the government's compelling interest in

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2. Id.
3. The Court would most likely grant certiorari to address concerns about expansion of precedent and its application to palliative care issues. Interview with Linda S. Eads, Associate Professor of Law, Southern Methodist University, in Dallas, Tex. (Feb. 2, 2007). The Appellees likely requested a rehearing en banc to strengthen a future petition for certiorari.
protecting the public from dangerous drugs to be narrowly tailored. The current FDA regulations are arbitrarily enforced and overbroad for terminally ill patients without treatment alternatives. A terminally ill patient who has exhausted all other treatment options should be allowed to access experimental drugs in an attempt to save her life.

Part I discusses the importance of the Court’s holdings in *Cruzan v. Director, Missouri Department of Health* 4 and *Washington v. Glucksberg*, 5 as well as the two-part test provided in *Glucksberg*, to determine whether an unenumerated right is fundamental under the Due Process Clause. Part II delineates FDA regulations and case law regarding treatment access for terminally ill patients. Part III reviews the D.C. Circuit’s original holding in *Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach* 6 and the *Glucksberg* analysis used by the panel to determine that there must be a complementary, fundamental “right to life.” 7 Part IV argues that, based on precedent, the Supreme Court should hold that there is a fundamental right to self-preservation, and that the Court should extend that right to include access to experimental drugs for terminally ill patients who do not have approved treatment options available. Part V argues that if the Court holds that the terminally ill have a fundamental right to access experimental treatment when there are no approved alternatives, the FDA regulations are not narrowly tailored for these patients.

I. SUBSTANTIVE DUE PROCESS

United States Supreme Court substantive due process jurisprudence does not provide a clear method of determining whether an asserted, unenumerated right is fundamental. 8 The Court has used several different methods to determine whether a fundamental right exists, without providing a clear test for the lower courts to apply. 9 When a case asserts a “new” fundamental right, it is currently unclear how lower courts are expected to reach a decision or properly define the right asserted. 10

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8. See, e.g., John F. Basiak, Jr., *Inconsistent Levels of Generality in the Characterization of Unenumerated Fundamental Rights*, 16 U. FLA. J.L. & Pub. Pol’y 401, 406 (2005) (arguing that there is no “inherent mechanism of interpretation” for unenumerated fundamental rights, leaving the lower federal courts to “characterize these rights in whatever manner they see fit” and making the interpretation “inherently susceptible to manipulation”).
9. Id.
10. See Seeley v. State, 940 P.2d 604, 630 (Wash. 1997) (Sanders, J., dissenting) (stating that “simply labeling the interest has proven dispositive because strict scrutiny is virtually impossible to pass while rational basis is virtually impossible to fail”); see also Basiak,
the majority of cases not dealing with sexuality or same-sex marriage, courts have followed the two-part test provided in Washington v. Glucksberg,11 which includes properly defining the asserted right and analyzing legal history and tradition to determine whether the right is fundamental under the Due Process Clause.12 Abigail Alliance used the Glucksberg test to find a fundamental right to self-preservation for terminally ill patients who exhausted all other treatment options before requesting access to Phase II clinical trial drugs from the FDA.13 To do this, the D.C. Circuit first inferred a fundamental right to self-preservation from prior Supreme Court decisions, and then extended that right to access to medical treatment in a narrowly defined situation.14 The D.C. Circuit inferred a fundamental right to self-preservation from the Supreme Court's holding in Cruzan.15

Cruzan held that the State could require a clear and convincing evidence standard for guardians trying to discontinue nutrition and hydration of a person in a persistent vegetative state, based on the State's interest in "protect[ing] and preserv[ing] human life."16 To reach its holding, the Court assumed that a competent person had a constitutionally protected right to refuse lifesaving hydration and nutrition based on liberty interest articulated in prior decisions.17 The Court discussed a number of cases that recognized the common-law right to self-determination,18 then stated that it was beyond dispute that the Due Process Clause "protect[ed] an interest in life as well as an interest in refusing life-sustaining medical treatment."19

Based on this interest in life, and the assumed right to refuse medical treatment, Glucksberg later held that the terminally ill did not have a constitutional right to assisted suicide.20 The Court acknowledged estab-

supra note 8, at 406; but see Adam Winkler, Fatal in Theory and Strict in Fact: An Empirical Analysis of Strict Scrutiny in the Federal Courts, 59 Vand. L. Rev. 793, 822 (2006) (showing strict scrutiny is not always fatal and has up to a 50% survival rate in the federal courts).

11. 521 U.S. 702 (1997); see Brian Hawkins, Note, The Glucksberg Renaissance: Substantive Due Process Since Lawrence v. Texas, 105 Mich. L. Rev. 409, 411 (2006) (surveying 188 unenumerated, fundamental rights cases decided after Lawrence v. Texas, 539 U.S. 558 (2003), and finding that the majority of courts follow Glucksberg unless an issue specifically involving sexuality or same-sex marriage is being addressed); see, e.g., Williams v. Att'y Gen. of Ala., 378 F.3d 1232 (11th Cir. 2004).


14. Id. at 477-78.

15. Id. at 479-84.


17. Id. at 278-79.

18. Id. at 269-70 (quoting Schloendorff v. Soc'y of N.Y. Hosp., 105 N.E. 92, 93 (N.Y. 1914) ("Every human being of adult years and sound mind has a right to determine what shall be done with his own body . . . ."); In re Quinlin, 355 A.2d 647 (N.J. 1976), cert. denied sub nom., Garger v. New Jersey, 429 U.S. 922 (1976) ("On balance, the right to self-determination ordinarily outweighs any countervailing state interests, and competent persons generally are permitted to refuse medical treatment, even at the risk of death.").

19. Id. at 281.

lishing several unenumerated fundamental rights and liberty interests beyond the Bill of Rights, including the right to marry, to have children, to direct the education and upbringing of one's children, to marital privacy, to use of contraception, to bodily integrity, and to abortion.\textsuperscript{21} The Court also expressed extreme reluctance to recognize new substantive due process rights because the “guideposts” for how to do so were “scarce and open-ended,” requiring the “exercise [of] utmost care” to avoid expressing individual policy preferences.\textsuperscript{22}

\textit{Glucksberg} followed the “established method” of substantive due process analysis, merging language from previous cases to create a two-part test for determining whether the asserted “right to die” was fundamental.\textsuperscript{23} First, there had to be a “careful description” of the fundamental liberty interest being asserted.\textsuperscript{24} And second, the right or liberty had to be “deeply rooted in this Nation’s history and tradition”\textsuperscript{25} and “implicit in the concept of ordered liberty,” such that “neither liberty nor justice would exist if they were sacrificed.”\textsuperscript{26} These threshold requirements saved time by avoiding complex balancing of competing interests: if no fundamental right was found, rational basis review only required a reasonable relation to a legitimate state interest.\textsuperscript{27}

\textbf{A. Careful Description of the Liberty Interest Being Asserted}

Respondents defined the asserted right as “the existence of a liberty interest protected by the Fourteenth Amendment which extends to a personal choice by a mentally competent, terminally ill adult to commit physician-assisted suicide.”\textsuperscript{28} They asserted a “liberty to choose how to die” and a right to “control one’s final days.”\textsuperscript{29} The Court took issue with

\begin{itemize}
\item \textsuperscript{21} \textit{Id.} at 720 (citing Planned Parenthood of Se. Pa. v. Casey, 505 U.S. 833 (1992) (plurality opinion) (right to have an abortion); Eisenstadt v. Baird, 405 U.S. 438 (1972) (right to contraception for single individuals); Loving v. Virginia, 388 U.S. 1 (1967) (right to marry); Griswold v. Connecticut, 381 U.S. 479 (1965) (right to contraception for married individuals); Rochin v. California, 342 U.S. 165 (1952) (right to bodily integrity); Skinner v. Oklahoma \textit{ex rel.} Williamson, 316 U.S. 535 (1942) (right to procreate); Pierce v. Soc’y of Sisters, 268 U.S. 510 (1925) (right to direct the upbringing and education of one’s children); Meyer v. Nebraska, 262 U.S. 390 (1923) (right to control the education of one’s children)).
\item \textsuperscript{22} \textit{Glucksberg}, 521 U.S. at 720 (quoting Collins v. City of Harker Heights, 503 U.S. 115, 125 (1992)).
\item \textsuperscript{23} Id. at 720–22.
\item \textsuperscript{24} Id. at 721 (quoting Reno v. Flores, 507 U.S. 292, 302 (1993)); \textit{Collins}, 503 U.S. at 125; \textit{Cruzan}, 497 U.S. at 277–78. Note that this element is listed second in \textit{Glucksberg}, but the Court began its analysis with this element.
\item \textsuperscript{25} \textit{Glucksberg}, 521 U.S. at 721 (quoting Moore v. City of E. Cleveland, 431 U.S. 494, 503 (1977) (plurality opinion)).
\item \textsuperscript{26} Id. (quoting Palko v. Connecticut, 302 U.S. 319, 325–26 (1937)).
\item \textsuperscript{27} Id. at 722. See Williamson v. Lee Optical of Okla., 348 U.S. 483, 487–88 (1955) (explaining that for rational basis review, the law “need not be in every respect logically consistent with its aims to be constitutional. It is enough that there is an evil at hand for correction, and that it might be thought that the particular legislative measure was a rational way to correct it!”).
\item \textsuperscript{28} Id. at 708.
\item \textsuperscript{29} Id. at 722.
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respondents' definition, finding it imprecise, and crafted the question as “whether the ‘liberty’ specially protected by the Due Process Clause includes a right to commit suicide which itself includes a right to assistance in doing so.” 30 The Court explained that the reference to Cruzan as a “right to die” case was incorrect, since the Court was “more precise” in assuming only that “the Constitution granted competent persons a constitutionally protected right to refuse lifesaving hydration and nutrition.” 31 No other guidance was provided on how to determine the proper definition for an asserted right.

B. History, Tradition, and Ordered Liberty

The Court then analyzed “our Nation’s history, legal traditions, and practices” regarding suicide. 32 The right to suicide was not a part of the National history or legal tradition, but anti-suicide provisions were “consistent and enduring themes of our philosophical, legal, and cultural heritages.” 33 Additionally, even though common law punishments such as criminal-forfeiture for individuals who committed suicide were removed during colonial times, the prohibition for assisted suicide remained. 34 Glucksberg acknowledged that most states had recently reexamined their assisted suicide bans due to medical and technological advances, yet reaffirmed them based on the state’s interest in “the sanctity of life.” 35

Glucksberg also rejected the argument that the long legal tradition protecting an individual’s right to refuse treatment recognized in Cruzan could be interpreted to stand for the ability to “hasten death” 36 or “transmuted into a right to assistance” to commit suicide. 37 The Cruzan decision was based on legal tradition and the common law rule that forced medication was battery—“entirely consistent” with history and constitutional tradition. 38 The Court also discarded the Ninth Circuit’s conclusion that Casey supported a right to physician-assisted suicide by recognizing a liberty involving “the most intimate and personal choices a

30. Id. at 723. See Brandon R. Johnson, Note, “Emerging Awareness” After the Emergence of Roberts: Reasonable Societal Reliance in Substantive Due Process Inquiry, 71 BROOK. L. REV. 1587, 1630 n. 88 (2006) (stating that a “precise definition of the right questioned has been seen as vital to those opposed to the extension of substantive due process protections”); see, e.g., Williams v. Att’y Gen. of Ala., 378 F.3d 1232, 1239 (11th Cir. 2004), cert. denied, 543 U.S. 1152 (2005).
32. Id. at 710 (referencing Planned Parenthood of Se. Pa. v. Casey, 505 U.S. 833, 849-50 (1992); Cruzan, 497 U.S. at 269-79; Moore v. City of E. Cleveland, 431 U.S. 494, 503 (1977) (plurality opinion)).
33. Id. at 711.
34. Id. at 714-16.
35. Id. at 715-16 (acknowledging that most states heavily weighed the Model Penal Code drafters’ recognition of the threat assisted suicide posed to the “interests in the sanctity of life that are represented by the criminal homicide laws”) (emphasis added).
36. Id. at 725.
37. Id. at 726.
38. Id. at 725.
person may make in a lifetime.” Similarly, respondents’ argument that Casey’s recognition that liberty provided “the right to define one’s own concept of existence, of meaning, of the universe, and of the mystery of human life” did not “warrant the sweeping conclusion that any and all important, intimate, and personal decisions [were] so protected.”

C. THE FUNDAMENTAL RIGHTS ANALYSIS

Based on these findings, the asserted right to assisted suicide was neither fundamental nor protected under the Due Process Clause. Thus, Washington’s assisted suicide ban was not subject to strict scrutiny and only needed to be rationally related to legitimate government interests. The State met the rational basis test easily. Washington had “unquestionably important and legitimate” interests, including an “unqualified interest in the preservation of human life”; an interest in protecting “vulnerable groups” from coercion, prejudice, stereotypes, and “societal indifference”; and a reasonable fear that allowing assisted suicide would lead to voluntary or involuntary euthanasia. The Court did acknowledge Justice Stevens’s concurrence in the judgment and his refusal to “foreclose the possibility that an individual plaintiff seeking to hasten her death, or a doctor whose assistance was sought, could prevail in a more particularized challenge.” The majority opinion did not “absolutely foreclose such a claim,” although the claim would have to be “quite different” from the one asserted in Glucksberg.

Five justices signed on to the Court’s reasoning in Glucksberg, although there was no dissent. Justice O’Connor was the fifth vote, and she also issued a concurring opinion to explain that the Court’s decision did not address whether a mentally competent person “experiencing great suffering [had] a constitutionally cognizable interest in controlling the circumstances of his or her imminent death.” O’Connor also stressed that the

39. Id. at 726–27 (quoting Planned Parenthood of Se. Pa. v. Casey, 505 U.S. 833, 851 (1992)).
40. Id. (quoting Casey, 505 U.S. at 851).
41. Id. at 727.
42. Id. at 728. The Court also noted that the fundamental-rights-based analytical method was proper and that Casey’s reliance on Justice Harlan’s dissent in Poe v. Ullman, 367 U.S. 497, 543 (1961), did not indicate that the Court had “jettison[ed]” the “established approach.” Glucksberg, 521 U.S. at 722 n. 17.
43. Id. at 728. See Williamson v. Lee Optical of Okla., 348 U.S. 483, 487–88 (1955) (explaining that for rational basis review, the law “need not be in every respect logically consistent with its aims to be constitutional. It is enough that there is an evil at hand for correction, and that it might be thought that the particular legislative measure was a rational way to correct it”).
44. Glucksberg, 521 U.S. at 728 (quoting Cruzan v. Dir., Mo. Dep’t of Health, 497 U.S. 261, 282 (1990)).
45. Id. at 732 (citing Compassion in Dying v. Washington, 49 F.3d 586, 593 (9th Cir. 1995)).
46. Id. at 728–35.
47. Id. at 735 n. 24.
48. Id.
49. Id. at 736 (O’Connor, J., concurring). Justice Ginsburg concurred with O’Connor, while Justice Breyer joined O’Connor’s concurrence except as it joined the opinion of the Court. Id.
law did not keep dying patients from receiving palliative care, "even when doing so would hasten their deaths."\textsuperscript{50}

Justice Stevens, concurring in the judgment, stated that the individual's right to physical autonomy, including refusing medical treatment, "will give way to the State's interest in preserving human life" in most cases.\textsuperscript{51} But, in unique circumstances, such as in \textit{Cruzan}, he stressed the individual's freedom to refuse a particular kind of unwanted treatment, to remain dignified, and to "determin[e] the character of the memories that will survive long after [one's] death."\textsuperscript{52} Stevens quoted his dissent in \textit{Meachum v. Fano}, stating that it is "self-evident" that men have unalienable liberty rights protected by the Due Process Clause, rather than "particular rights or privileges conferred by specific laws or regulations."\textsuperscript{53} He emphasized that individuals who no longer have the option of deciding whether to live or die have a "constitutionally protected interest that may outweigh the State's interest in preserving life at all costs."\textsuperscript{54} He also noted that palliative care may not alleviate all pain and suffering.\textsuperscript{55}

The Court assumed a right to refuse medical treatment for competent adults in \textit{Cruzan}, then determined the right to refuse medical treatment did not extend to physician assisted suicide in \textit{Glucksberg}. \textit{Glucksberg}, however, did not decide whether a mentally competent person who was experiencing great suffering could control the circumstances of his death. And even Stevens's concurrence in the judgment recognized that the State's compelling interest in life required "preserving life at all costs."\textsuperscript{56} Therefore, it can be inferred that since the State's compelling interest includes a right to self-preservation, it encompasses the right to attempt to save one's life by accessing experimental medical treatment when there are no approved alternatives. Nonetheless, the FDA's current policies, along with case law in almost all jurisdictions, do not recognize such a right.

\section*{II. TREATMENT ACCESS FOR THE TERMINALLY ILL}

The FDA is responsible for ensuring that unapproved drugs, drugs that are unsafe or ineffective for their purported use, are not distributed in the United States.\textsuperscript{57} The United States has the most demanding prescription

\begin{itemize}
  \item \textsuperscript{50} \textit{Id.} at 737–38 (O'Connor, J., concurring). Palliative care relieves or soothes symptoms of a disease without providing a cure. \textit{The American Heritage Dictionary of the English Language} (4th ed. 2004); \textit{see Vacco v. Quill}, 521 U.S. 793, 802 (stating that aggressive palliative care that may hasten a patient's death is legal since the purpose "is, or may be, only to ease [the] patient's pain").
  \item \textsuperscript{51} \textit{Glucksberg}, 521 U.S. at 742 (Stevens, J., concurring in the judgment).
  \item \textsuperscript{52} \textit{Id.} at 743 (Stevens, J., concurring in the judgment).
  \item \textsuperscript{53} \textit{Id.} at 744 n.10 (Stevens, J., concurring in the judgment) (quoting \textit{Meachum v. Fano}, 427 U.S. 215, 230 (1976) (Stevens, J., dissenting)).
  \item \textsuperscript{54} \textit{Id.} at 745 (Stevens, J., concurring in the judgment) (quoting \textit{Meachum}, 427 U.S. at 230) (Stevens, J., dissenting).
  \item \textsuperscript{55} \textit{Id.} at 747 (Stevens, J., concurring in the judgment) (quoting \textit{Meachum}, 427 U.S. at 230) (Stevens, J., dissenting).
  \item \textsuperscript{56} \textit{Id.} at 745 (Stevens, J., concurring in the judgment).
  \item \textsuperscript{57} \textit{See Veronica Henry, Problems with Pharmaceutical Regulation in the United States}, 14 J. Legal Med. 617, 618 (1993).
\end{itemize}
drug approval process in the world, with most new drugs taking approximately seven to ten years to reach the market.\textsuperscript{58} Drug regulation began in 1906, when the Wiley Act, also known as the Pure Food and Drugs Act, was signed into law and prohibited misbranded or adulterated food and drugs in interstate commerce.\textsuperscript{59} The law did not prohibit false therapeutic claims, but only claims about the identity or composition of drugs.\textsuperscript{60} In 1937, 107 people, including children, died after ingesting a drug that contained a poisonous liquid base.\textsuperscript{61} Based in part on this incident, Congress passed the Federal Food, Drug and Cosmetic Act ("FDCA") in 1938 to require drug manufacturers to prove the safety of a drug for its intended use before the drug would be allowed on the market.\textsuperscript{62} Clinical trials were allowed without prior approvals.\textsuperscript{63} In 1962, partly in response to the Thalidomide tragedy,\textsuperscript{64} Congress added safety requirements to the drug approval process, including applications for approval before a clinical trial could be conducted, as well as proof that a drug was safe and effective before the drug could be marketed.\textsuperscript{65} The FDA has provided detailed regulations controlling the clinical testing of "new" drugs.\textsuperscript{66}

A. WHAT IS A "NEW" DRUG?

Until the FDA's application and approval process is completed, the FDCA prohibits drug manufacturers from introducing "new" drugs into the market.\textsuperscript{67} A "new" drug is any substance covered under the FDCA not "generally recognized, among experts . . . as safe and effective for use under the conditions prescribed . . . in the labeling."\textsuperscript{68} For a drug to be approved by the FDA, drug manufacturers must provide "substantial" evidence from controlled clinical trials that the drug will have its intended effect.\textsuperscript{69}

\begin{itemize}
\item \textsuperscript{58} Id. at 617.
\item \textsuperscript{59} Id. at 618; Jon Scott Batterman, Note, Brother Can You Spare a Drug: Should the Experimental Drug Distribution Standards Be Modified in Response to the Needs of Persons with AIDS?, 19 Hofstra L. Rev. 191, 196 (1990). A drug is misbranded if the labeling is false or misleading or does not have accurate directions and warnings about proper use. See 21 U.S.C. § 352 (2006). A drug may be adulterated for several reasons, including unsanitary contents or packaging conditions, composition of the container rendering the contents dangerous, banned coloring or additives, and misrepresentation of strength or ingredients. See 21 U.S.C. § 351 (2006).
\item \textsuperscript{60} Henry, supra note 57, at 618.
\item \textsuperscript{61} Id. at 619.
\item \textsuperscript{62} Id.; Batterman, supra note 59, at 197–98.
\item \textsuperscript{63} See Batterman, supra note 59, at 200–01 (stating that because clinical trials did not require prior approval, Thalidomide was distributed in the United States for experimental testing, resulting in several children being born with deformed or missing limbs). Eight thousand European mothers who took the drug to relieve morning sickness gave birth to deformed babies. Henry, supra note 57, at 619.
\item \textsuperscript{64} Batterman, supra note 59, at 200–01; Henry, supra note 57, at 619.
\item \textsuperscript{65} Batterman, supra note 59, at 200–01; Henry, supra note 57, at 619.
\item \textsuperscript{67} Id.
\item \textsuperscript{69} Id. § 355(d).
\end{itemize}
B. CLINICAL TRIALS: PURPOSE AND TIME FRAMES

The FDA has established four levels of testing required before new drugs can receive approval to be marketed in the United States: one on animals and three on humans.\textsuperscript{70} Animal testing shows the effect and toxicity of the new drug.\textsuperscript{71} If the tests are promising, a drug developer must submit an Investigational New Drug ("IND") application to the FDA for clinical testing.\textsuperscript{72} The IND application becomes effective within thirty days unless the FDA takes action to deny the application.\textsuperscript{73}

Clinical trials are conducted in three phases. Phase I, which takes approximately one year to complete, is generally conducted on twenty to eighty healthy human subjects to determine safety, the metabolism of the drug, and side effects.\textsuperscript{74} Phase II trials, which last about two years, are conducted on 100 to 300 subjects to determine effectiveness, short-term side effects, and dosage levels.\textsuperscript{75} Phase II participants have the specific disease and are divided into treatment and control groups.\textsuperscript{76} Phase III generally lasts around three years, involves several thousand subjects, and determines long-term side effects, effectiveness over time, the risk-benefit relationship of the drug, and a basis for physician labeling.\textsuperscript{77} Phase III subjects are also divided into treatment and control groups. Generally, including animal testing, completing all phases of the required clinical trials takes a minimum of seven years.

Gaining access to a clinical trial is difficult.\textsuperscript{78} There are a limited number of spaces available for Phases II and III, and drug companies require a patient to be in a certain stage of the disease, at least eighteen years of age, and, in some cases, to not have taken certain drugs or treatments.\textsuperscript{79} Recognizing the problem for terminally ill patients, the FDA has two exceptions to circumvent the clinical trial process: the treatment IND and the compassionate IND or "fast track."\textsuperscript{80}

\begin{thebibliography}{99}
\bibitem{71}Myers, supra note 70, at 313–14.
\bibitem{73}Id. § 355(i)(2).
\bibitem{74}See Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach, 445 F.3d 470, 473 (2006); Henry, supra note 57, at 621; Myers, supra note 70, at 314.
\bibitem{75}See Abigail Alliance, 445 F.3d at 473; Henry, supra note 57, at 621; Myers, supra note 70, at 314.
\bibitem{76}Henry, supra note 57, at 621; Myers, supra note 70, at 314.
\bibitem{77}Abigail Alliance, 445 F.3d at 473; Batterman, supra note 59, at 222; Henry, supra note 57, at 621; Myers, supra note 70, at 314.
\bibitem{78}See Myers, supra note 70, at 310 (providing a real-life example of an AIDS patient disqualified from participating in clinical studies due to his medical condition); see also Abigail Alliance, 445 F.3d at 474 (noting that spaces in clinical trials are very limited compared to need).
\bibitem{79}Abigail Alliance, 445 F.3d at 474 (alleging the type of patient who qualifies for a clinical trial is limited); Myers, supra note 70, at 310.
\end{thebibliography}
C. EXCEPTIONS AND ACCESS TO DRUGS IN CLINICAL TRIALS

The treatment IND program expanded access to unapproved drugs and allowed doctors to prescribe such drugs to patients as if they were enrolled in a clinical trial.81 The purpose of the program is to provide terminal patients with earlier access to experimental drugs while maintaining the balance between the State's interest in health and safety and the individual's right to life.82 There are four criteria for receiving permission for a treatment IND: (1) the drug sought must be intended to treat a serious or life-threatening illness, (2) an alternative drug or therapy must not be available to treat the illness at that stage, (3) the drug must have completed or be completing investigation under a controlled clinical trial, and (4) the sponsor of the clinical trial must be actively pursuing marketing approval for the drug.83 The treatment IND has several advantages, the main one being the patient's ability to access drugs two to three years earlier.84 The program provides some relief for desperately ill patients, but there are still problems with limited access due to stringent regulations.85

The compassionate IND/"fast track" exception is a discretionary permit allowing a terminally ill patient who is unresponsive to approved therapy to access an unapproved drug currently being tested in clinical trials.86 The FDA requires detailed recordkeeping, extensive protocols, a demonstration that the benefits of the treatment outweigh any risks involved, and that the manufacturer provide the drug free of charge.87 Compassionate INDs are limited and not very popular with drug companies, particularly after the drug Ganciclovir was approved for AIDS treatment under a compassionate IND and then not approved for marketing based on data from the compassionate-use physicians.88 The compassionate-use program slowed down the clinical trial process since doctors were reluctant to enroll a patient in a controlled clinical trial where the patient was just as likely to receive a placebo or standard therapy as the new drug.89

81. Batterman, supra note 59, at 222.
82. Id. at 223.
83. Id. at 223–24.
84. Other advantages include allowing drug companies to charge for the drugs, giving them an incentive to produce the drugs, and allowing more market competition for smaller drug companies. Henry, supra note 57, at 624.
85. Id. at 625; Batterman, supra note 59, at 224–25.
86. 21 U.S.C. § 356 (2006); Batterman, supra note 59, at 225; Myers, supra note 70, at 314–15.
87. Myers, supra note 70, at 315.
88. See id. at 315, 317 (discussing how drug companies were reluctant to participate in IND exception programs after a drug was not approved because there were not enough appropriate test subjects available for the controlled Phase III trial); see also Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach, 445 F.3d 470, 474 (D.C. Cir. 2006) (alleging that compassionate-use programs are available only to a "fraction of those in desperate need").
89. Myers, supra note 70, at 315–16 (noting that physicians preferred the compassionate-use program for ganciclovir over enrolling patients in a Phase III clinical trial where the patient might end up in a control group receiving a placebo or standard treatment).
If patients are unable to gain access to a clinical trial, treatment IND program, or compassionate-use program, they can file a new drug application with the FDA for access if the drug is already available overseas. Although this is generally unsuccessful, patients are not allowed to sue the FDA for access until after the proper administrative procedures have been followed. Patients generally sue for a right to access medication or treatment under substantive due process.

D. Case Law Addressing Access to Treatment or Medications

With very few exceptions, federal and state courts have held that patients do not have a constitutional right to access treatment or medications under the Due Process Clause. A brief overview of some of these cases is provided below.

1. Federal Cases

   a. United States v. Rutherford

   The closest the United States Supreme Court came to deciding this issue was in United States v. Rutherford. In Rutherford, terminally ill cancer patients sued for access to Laetrile, a cancer drug not approved as safe and effective by the FDA. The District Court had held that "by denying cancer patients the right to use a nontoxic substance in connec-

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90. See, e.g., Carnohan v. United States, 616 F.2d 1120, 1122 (9th Cir. 1980).
91. Id.; see also Abigail Alliance, 445 F.3d at 473-74.
92. See, e.g., Sammon v. N.J. Bd. of Med. Exam'rs, 66 F.3d 639, 645 n. 10 (3d Cir. 1995) (finding that, "[i]n the absence of extraordinary circumstances," a State's restrictions on a patient's choice of a particular treatment only requires rational basis review); Mitchell v. Clayton, 995 F.2d 772, 776 (7th Cir. 1993) (holding patients have no constitutional right to treatment by uncertified acupuncturists); N.Y. State Ophthalmological Soc'y v. Bowen, 854 F.2d 1379, 1389, 1391-92 (D.C. Cir. 1988) (upholding the government's change in Medicare regulations banning the use of an assistant surgeon during cataract operations since the constitutional right to privacy did not protect all choices made by patients and their physicians regarding medical treatment), cert. denied, 490 U.S. 1098 (1989); Smith v. Shalala, 954 F. Supp. 1, 2-4 (D.D.C. 1996) (finding that the government did not have an affirmative obligation to provide dying patients access to experimental medical drugs where the patient was already receiving the drug and the treatment was working, but his doctor had provided it outside FDA protocols; the FDA's refusal to approve continued treatment was rationally related to furthering the FDA's interest in protecting public health and safety); Garlic v. U.S. Food & Drug Admin., 783 F. Supp. 4, 5 (D.D.C. 1992) (holding that there was "no support" for the claim that the FDA's barring use of unapproved medications violated the constitutional right to liberty or privacy), appeal dismissed, 986 F.2d 546 (D.C. Cir. 1993); Kulsar v. Ambach, 598 F. Supp. 1124, 1125-26 (W.D.N.Y. 1984) (holding that Rutherford v. United States and Carnohan v. United States barred the plaintiff's claim of a constitutional right of privacy violation since a patient taking a drug the FDA ordered removed from the marketplace did not have a right to select a particular treatment or medication, even where the medication was successfully treating his hypoglycemic disorders); but see Andrews v. Ballard, 498 F. Supp. 1038, 1057 (S.D. Tex. 1980) (holding that plaintiffs had a constitutional right to obtain acupuncture treatment and that the challenged law was "not necessary to serve the State's interest in protecting the patient's health”).
94. Id. at 546.
tion with their personal health,” the Commissioner had “infringed” on constitutionally protected interests. The Tenth Circuit did not address the constitutional issue, holding that the terms safety and effectiveness had “no reasonable application to terminally ill cancer patients” and approving the District Court’s injunction. The Supreme Court reversed and remanded, finding no provision in the FDCA exempting drugs used to treat the terminally ill.

The Court found that Congress intended to protect individuals with “fatal illnesses” from fraudulent cures and that the congressional record for the FDCA indicated that experimental drugs used to treat cancer “in its last stages” fell within the statute. The FDA never made an exception for drugs used to treat the terminally ill and Congress “could have reasonably intended to shield terminal patients from ineffectual or unsafe drugs.” The majority expressed safety concerns for terminally ill patients and was particularly focused on the fact that allowing access to the drugs would allow a patient with a “potentially fatal disease” to reject conventional therapy “in favor of a drug with no demonstrable curative properties.” Thus, the Court concurred with the FDA Commissioner, concluding that exempting drugs with no proven effectiveness “‘would lead to needless deaths and suffering among . . . patients characterized as ‘terminal’ who could actually be helped by legitimate therapy.’” Finally, patients without conventional therapy options were not foreclosed from experimental cancer drugs because access to clinical trials was available and monitored according to the FDCA’s “explicit provision for carefully regulated use of certain drugs not yet demonstrated safe and effective.”

95. Id. at 550.
96. Id. at 550–51 (quoting Rutherford v. United States, 582 F.2d 1234, 1236 (10th Cir. 1978)).
97. Id. at 551.
98. Id. at 552–53.
99. Id. at 553, 555.
100. Id. at 555–56. The majority also expressed concerns over the definition of “terminally ill.” Id. at 556–57. This issue is not addressed in this comment but will need to be defined for the Court to find a fundamental right exists for treatment access. A number of states have statutes defining “terminally ill.” See, e.g., CAL. HEALTH & SAFETY CODE § 1568.01(l) (West 2000 & Supp. 2007) (terminal illness “means a medical condition resulting from a prognosis of a life expectancy of one year or less, if the disease follows its normal course”); ME. REV. STAT. ANN. tit. 18-A, § 5-801(t) (1998 & Supp. 2006) (terminal condition “means an incurable and irreversible condition that, without the administration of life-sustaining treatment, in the opinion of the primary physician, will result in death within a relatively short time”); NEV. REV. STAT. § 449.0195 (Supp. 2005) (terminally ill “means a medical diagnosis made by a physician that a person has an anticipated life expectancy of not more than 12 months”); but see CONN. GEN. STAT. § 52-191C (2005) (terminally ill “means in the final stage of an incurable or irreversible medical condition which will result in death within a relatively short time, in the opinion of the attending physician”); GA. CODE ANN. § 31-7-172(12) (Supp. 2006) (terminally ill “means that the individual is experiencing an illness for which therapeutic intervention directed toward cure of the disease is no longer appropriate, and the patient’s medical prognosis is one in which there is a life expectancy of six months or less”).
102. Id. at 558–59.
On remand, the Tenth Circuit stated that it would “serve no useful purpose” to revisit the substantive due process issue from the District Court because although it was clear that the decision whether to have treatment was a protected right, the “selection of a particular treatment, or at least a medication,” did not override the government’s interest in protecting public health.103

b. Carnohan v. United States104

A cancer patient who sued for the right to obtain and use a cancer drug lost when the Ninth Circuit held: (1) that the FDA was responsible for determining whether or not a drug qualified as a “new” drug, and (2) that cancer patients had to follow administrative procedure by seeking approval and being rejected by the Secretary of Health and Welfare before suing in the courts.105 Carnohan did not address the constitutional right of privacy and personal liberty claims based on the Tenth Circuit’s holding in Rutherford,106 stating in dicta that individuals did not have the right to obtain drugs “free of the lawful exercise of government police power.”107

c. Cowan v. United States108

Based on the Supreme Court’s holding in Rutherford,109 the District Court of Oklahoma denied a terminally ill AIDS patient with no other treatment options access to an experimental drug in Cowan v. United States.110 Cowan rejected the plaintiff’s argument for a right to whatever treatment he wished due to his terminal condition and denied that the FDA’s prohibitions violated his rights under the Constitution.111 Cowan also expressed concern for the welfare and safety of patients desperate to live, noting that “permit[ting] terminally ill patients to seek any type of treatment regardless of the effectiveness . . . would create a cottage industry existing solely to provide potential panaceas to highly vulnerable patients.”112

103. Rutherford v. United States, 616 F.2d 455, 457 (10th Cir. 1980), cert. denied, 449 U.S. 937 (1980). Note that the Tenth Circuit discussed the issue in a single paragraph and did not perform a substantive due process analysis to reach its holding.
104. Carnohan v. United States, 616 F.2d 1120 (9th Cir. 1980).
105. Id. at 1121–22.
106. 616 F.2d 455 (10th Cir. 1980).
107. Carnohan, 616 F.2d at 1122.
110. Cowan, 5 F. Supp. 2d at 1238.
111. Id. at 1242.
112. Id.
2. State Cases

a. People v. Privitera

The defendants in People v. Privitera were charged with selling and prescribing an unapproved drug intended to alleviate or cure cancer. The California Supreme Court held that medical treatment was not within the "important decisions" recognized by the United States Supreme Court as falling within the right of privacy and, therefore, the "asserted right to obtain drugs of unproven efficacy is Not [sic] encompassed by the right of privacy embodied in either the federal or the state Constitutions." Privitera relied on FDA findings that patients pursuing access to unapproved drugs were "coming to legitimate therapy too late" and "needlessly [dying] of cancer."

In Privitera there was also a strong dissent that found the right to privacy supported a fundamental right "to acquire and to use needed medication." The dissent relied heavily on Justice Brandeis's dissenting opinion in Olmstead v. United States: "the right to be let alone [is] the most comprehensive of rights and the right most valued by civilized men. To protect, that right, every unjustifiable intrusion by the government upon the privacy of the individual, whatever the means employed, must be deemed a violation . . . ." The dissent also concluded that there was "no compelling reason shown to override the patient's or the doctor's fundamental right of choice in the treatment setting."

b. Seeley v. State

Following Carnohan, Rutherford, and Privitera, which all found that there was not a fundamental right of access to medication, Seeley found the plaintiff's claimed "right to have marijuana prescribed as a preferred medical treatment for the nausea and vomiting associated with

113. See, e.g., In re Guess, 393 S.E.2d 833, 840 (N.C. 1990) (finding no fundamental right to receive unorthodox medical treatment, including homeopathic treatment).
115. Id. at 921.
116. Id. at 921–22.
117. Id. at 924 (quoting CAL. HEALTH & SAFETY CODE § 1700 (West 1979)). This case was decided before United States v. Rutherford, 442 U.S. 544 (1979), and took issue with the lower courts' holdings in Rutherford v. United States, 582 F.2d 1234 (10th Cir. 1978). Id. at 924–25.
118. Id. at 927, 933 (Bird, C.J., dissenting) (quoting Whalen v. Roe, 429 U.S. 589, 603 (1977)).
119. Id. at 932 (quoting Olmstead v. United States, 277 U.S. 438, 478 (1928) (Brandeis, J., dissenting)).
120. Id. at 945.
121. 940 P.2d 604 (Wash. 1997) (en banc). Although this case deals with marijuana, the specific issue analyzed is the substantive due process right to privacy. Cases dealing with access to controlled substances are outside of the scope of this comment.
122. Carnohan v. United States, 616 F.2d 1120 (9th Cir. 1980).
The court instead defined the right as "the right to smoke marijuana." The plaintiff argued that a patient should have a fundamental right to have his physician prescribe drugs to relieve suffering, presumably based on O'Connor's Glucksberg concurrence, where she stressed that palliative care allowed suffering patients to obtain relief even when it resulted in death. The court stated that "if a terminally ill person does not have a fundamental right to physician assisted suicide," then the patient would also not have a "constitutionally protected right to receive a particular medical treatment over the rational objections of the state."

The dissent in Seeley, however, agreed with the plaintiff, arguing that denying the right requested was a "refusal of palliative relief to a dying man." The dissent also argued that the issue was not properly defined since the "proper focus of the constitutional inquiry is the group for whom the law is a restriction, not the group for whom the law is irrelevant."

c. Suenram v. Society of the Valley Hospital

Finally, in one of the very few cases to find a right to medical treatment, the Superior Court of New Jersey found a fundamental right of an "informed terminal cancer victim to choose which treatment she shall receive from a state-licensed physician." The court's decision was definitive, stating that the "right of the patient to choose or reject a cancer treatment on the advice of a licensed medical doctor, whether or not it is approved by the State or a hospital, could not be of a more fundamental nature." The decision to deny a person the "last opportunity to make a choice" about treatment "would display a lack of understanding of the meaning of the individual's rights in our free society."

With few exceptions, federal and state courts have held that state regulations were rationally related to a legitimate government interest in health and safety. But the decisions are all interrelated, with the Tenth Circuit's decision in Rutherford applying no substantive due process analysis to a right to access unapproved drugs, and the Ninth Circuit's dicta in Carnohan being cited as precedent for denying the existence of a fundamental right to medication or medical treatment. The courts based their

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125. Seeley, 940 P.2d at 612.
126. Id.
127. Id.
129. Seeley, 940 P.2d at 619 n.20 (citing Glucksberg, 521 U.S. at 720-21).
130. Id. at 624 (Sanders, J., dissenting).
131. Id. at 624 & n.8 (Sanders, J., dissenting) (quoting Planned Parenthood of Se. Pa. v. Casey, 505 U.S. 833, 894 (1992)).
133. Id. at 147.
134. Id. at 148.
135. Id.
decisions in part on fear that patients would use unapproved treatments and needlessly die when another approved alternative was available. These cases can be distinguished, therefore, when applied to terminally ill patients who have exhausted all approved treatment options.

Based on this precedent, the Abigail Alliance ("Alliance") first sought approval from the FDA for new regulations allowing access to drugs for terminally ill patients.\textsuperscript{136} After the request was denied, the Alliance filed a Citizen Petition and received an acknowledgement from the FDA but no response, which allowed them to challenge the FDA's policies in federal court and eventually convince a D.C. Circuit panel that there is a fundamental right to access medical treatment or medication in limited circumstances.\textsuperscript{137}

III. \textit{ABIGAIL ALLIANCE AND THE GLUCKSBERG ANALYSIS}

The panel in \textit{Abigail Alliance} based its holding on the \textit{Glucksberg} two-part test.\textsuperscript{138} First, the carefully described right was defined as the "right of a mentally competent, terminally ill adult patient to access potentially life-saving post-Phase I investigational new drugs, upon a doctor's advice, even where that medication carries risks for the patient."\textsuperscript{139} Second, after analyzing legal history and tradition, the court found that the government did "not block access to new drugs throughout the greater part of our Nation's history."\textsuperscript{140} Third, the Supreme Court's decision in \textit{Cruzan} assumed the right to refuse life-sustaining medical treatment; therefore, a similar right could be inferred to access potentially life-sustaining medication where no government-approved treatment options existed.\textsuperscript{141} The key in both \textit{Abigail Alliance} and \textit{Cruzan} was the "patient's right to make the decision about her life free from government interference."\textsuperscript{142}

Prior to performing \textit{Glucksberg}'s "more restrictive" analysis, the D.C. Circuit outlined the Supreme Court's two "distinct approaches" to determining a fundamental right.\textsuperscript{143} The first, involving cases focused on personal dignity and autonomy, dealt with "the most intimate and personal

\begin{itemize}
  \item \textsuperscript{137} \textit{Id}. The decision was vacated for rehearing en banc on appellees' petition. Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach, No. 04-5350, 2006 U.S. App. LEXIS 28974, at *1 (D.C. Cir. Nov. 21, 2006).
  \item \textsuperscript{138} \textit{Abigail Alliance}, 445 F.3d at 472.
  \item \textsuperscript{139} \textit{Id}.
  \item \textsuperscript{140} \textit{Id}.
  \item \textsuperscript{141} \textit{Id}.
  \item \textsuperscript{142} \textit{Id}.
  \item \textsuperscript{143} \textit{Id}. at 476. In most cases, plaintiffs attempting to extend concepts of autonomy or the right of privacy from \textit{Roe v. Wade}, 410 U.S. 113 (1973), or \textit{Planned Parenthood of Se. Pa. v. Casey}, 505 U.S. 833 (1992), have been unsuccessful. See, e.g., Compassion in Dying v. Washington, 79 F.3d 790, 812–16 (9th Cir. 1996), \textit{rev'd subnom} Washington v. Glucksberg, 521 U.S. 702 (1997); Seeley v. State, 940 P.2d 604, 623–32 & n. 12 (Wash. 1997) (Sanders, J., dissenting) (arguing that \textit{Casey} stands for an "affirmative due process right to obtain medical intervention").
\end{itemize}
choices a person may make in a lifetime." The second referenced the Nation's history and tradition under the more restrictive _Glucksberg_ analysis, which required: (1) that a fundamental right be "objectively, 'deeply rooted in this Nation's history and tradition . . . and implicit in the concept of ordered liberty, such that neither liberty nor justice would exist if [it] were sacrificed," and (2) that the court provide a "careful description of the fundamental liberty interest."

A. CAREFUL DESCRIPTION OF THE LIBERTY INTEREST BEING ASSERTED

The D.C. Circuit accepted the Alliance's definition of the question presented as follows:

Whether the Due Process Clause protects the right of terminally ill patients to make an informed decision that may prolong life, specifically by use of potentially life-saving new drugs that the FDA has yet to approve for commercial marketing but that the FDA has determined, after Phase I clinical human trials, are safe enough for further testing on a substantial number of human beings.

_Abigail Alliance_ noted that the Supreme Court had not settled on how precise the "carefully defined" right had to be, but interpreted prior decisions as indicating that courts should "proceed with care in examining substantive due process claims." In fact, the court appreciated the Alliance's narrow definition, based on rights to privacy, liberty, and life, which did not include an unfettered right of access to drugs, a right to receive treatment from the government, or a right at the government's expense.

B. HISTORY, TRADITION, AND ORDERED LIBERTY

In analyzing history and tradition, the court based its findings on "ancient" common law principles, including the right to self-preservation, the doctrine of necessity, and the law's recognition of "extraordinary measures" allowing an individual to take action when faced with death, even

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144. _Abigail Alliance_, 445 F.3d at 476 (quoting _Casey_, 505 U.S. at 851; citing _Roe v. Wade_, 410 U.S. 113 (1973); _Eisenstadt v. Baird_, 405 U.S. 438 (1972); _Griswold v. Connecticut_, 381 U.S. 479 (1965)).


146. _Id._ at 477 (quoting _Glucksberg_, 521 U.S. at 721–23). In a footnote, the court dismissed _Lawrence v. Texas_ as precedent, noting that reading _Lawrence_ as limiting history and tradition to the "last half century would gut the purpose of the _Glucksberg_ test" and that other circuits treated _Glucksberg_ as controlling after _Lawrence_ or refused to view _Lawrence_ as a substantive due process decision. _Id._ at 477 n. 8; see also, _Hawkins_, supra note 11, at 425–44 (discussing why courts choose to ignore or distinguish _Lawrence_ as precedent when dealing with substantive due process cases not addressing issues such as gay rights or sexual liberty).

147. _Abigail Alliance_, 445 F.3d at 477–78.

148. _Id._

149. _Id._ at 478.
allowing the individual to "impinge upon the rights of others." The court discussed precedent allowing destruction of property in order to save life and the common law tradition of liability for interfering with efforts to preserve or save life, stating that the FDA's regulations "interfere[d] with efforts that could save a terminally ill patient's life." The lack of history of drug regulation in the United States also showed that there was no government interference with access to drugs for over half the Nation's history, and there were no limitations based on effectiveness until 1962. In fact, patients used drugs for unapproved purposes, also known as off-label use, all the time.

The D.C. Circuit found a fundamental right was implied by the "[Supreme] Court's conclusion in Cruzan that due process protects a person's right to refuse life-sustaining treatment." Based on the Supreme Court's finding of a "right to die" in Cruzan, the "logical corollary" was a freedom to decide whether to take drugs that might prolong one's life. Like Cruzan, the Alliance was asking the government to change its policy to avoid violating the right of self-preservation. If there was a right to refuse life-sustaining treatment, then "the same liberty interest must include the complementary right of access to potentially life-sustaining medication, in light of the explicit protection accorded to 'life.'" The court again noted the narrow definition provided by the Alliance, stating that the right was not a general right to life-saving treatment, but rather "access to investigational new drugs that have cleared Phase I trials."

The majority also properly distinguished its due process holding from other cases: Carnohan was dicta while Rutherford was based on a request for access to a new drug that had not been approved for human testing. The Alliance was merely seeking the "same right of access enjoyed by those terminally ill patients lucky enough to secure a spot in Phase II trials."

150. Id. at 480.
151. Id.
152. Id. at 481-83.
153. Id. at 483. Off-label uses may include different routes of administration, special patient populations not mentioned in the labeling (such as children), modified dosing schedules or therapy durations, and treatment of a disease not indicated in approved labeling. Lars Noah, Informed Consent and the Elusive Dichotomy Between Standard and Experimental Therapy, 28 AM. J. L. & MED. 361, 397-98 (2002).
154. Abigail Alliance, 445 F.3d at 484.
155. Id.
156. Id.
157. Id. at 484-85.
158. Id. at 485 n. 26. Seventy percent of drugs submitted for clinical trials fail in Phase I; thirty-three percent fail in Phase II. Henry, supra note 57, at 621.
159. Carnohan v. United States, 616 F.2d 1120, 1122 (9th Cir. 1980) (rejecting the appeal as an unripe claim based on FDA procedure, but noting in dicta that the right of privacy did not give individuals the right to access an unapproved cancer drug).
160. Rutherford v. United States, 616 F.2d 455, 457 (10th Cir. 1980) (holding that the choice of a particular medication or treatment was not a fundamental right and that the government's "interest in protecting public health" controlled).
161. Abigail Alliance, 445 F.3d at 486.
162. Id.
In dissent, Judge Griffith categorized the right at issue as a “fundamental right to procure and use an experimental drug before the FDA and scientific community have evaluated its scientific and medical risks and corresponding benefits as called for in the FDCA.” He argued that common law tradition was insufficient to establish a fundamental right, that history shows the right was not deeply rooted, since drugs were regulated since the “early part of the last century,” and that the FDA was entitled to make the decision on whether “blanket access to experimental drugs would present unacceptable scientific and medical risks.” Additionally, the history of the FDCA did not provide a right to procure or to use experimental drugs; it only established that the government had not always regulated drugs. The dissent also distinguished the majority’s reliance on Cruzan, arguing that the “right to die” could not provide a complementary right for informed access to unapproved drugs, since no patient could be truly informed about the risks or potential benefits posed.

C. The Fundamental Rights Analysis

The case was remanded to the District Court for a decision on whether the government’s compelling interest as defined by the FDA was narrowly tailored. The D.C. Circuit, however, later accepted the Alliance’s petition for rehearing en banc and vacated the original decision. If, as predicted, Abigail Alliance reaches the Supreme Court, whether there is a fundamental right subject to strict scrutiny may be determinative, but the Court could find a fundamental right and still hold that the government’s compelling interest is narrowly tailored.

IV. ARGUMENT

In order to reach a determination on whether the government’s compelling interest is narrowly tailored, the Supreme Court must first find a fundamental right to self-preservation, then find that self-preservation in-
cludes the right to access medical treatment and medication in limited circumstances. The Court has previously recognized the “sanctity” of self-determination,\textsuperscript{171} declared points at which the State’s compelling interest in life outweighs autonomy,\textsuperscript{172} and assumed the right to refuse medical treatment in particular circumstances,\textsuperscript{173} indicating that the Court may also be willing to infer an individual’s right to attempt to save his or her life. On the other hand, the Court has not been “friendly” toward recognizing new fundamental rights, and has not provided much guidance on how courts are expected to define asserted rights or analyze history and tradition.\textsuperscript{174} If the Court accepts the narrow definition provided by the Alliance for a fundamental right to self-preservation that includes a right to access treatment or medicine for terminally ill patients who have exhausted all other treatment options, as well as the D.C. Circuit's original analysis of legal history and tradition, the Court could declare the asserted right fundamental. This section begins with the foundational principles justifying a fundamental right to self-preservation, including access to medication or medical treatment, then looks at Supreme Court jurisprudence regarding the “right to die,” and how the right asserted in \textit{Abigail Alliance} meets the \textit{Glucksberg} substantive due process test.

A. There Is a Fundamental Right of Self-Preservation

The District Court in \textit{Abigail Alliance} rejected the argument that a complementary right to choose life could be implied from the right to refuse medical treatment assumed in \textit{Cruzan} because the Alliance’s asserted right involved access to “potentially life-saving medication.”\textsuperscript{175} An affirmative right could not be inferred from the freedom from government imposition, and without a fundamental right, the District Court found the FDA policy was rationally related to a legitimate government interest.\textsuperscript{176} The D.C. Circuit disagreed and found a fundamental right to choose life and the method of treatment, relying in part on William Blackstone’s right to “‘personal security,’” which encompassed the right to self-preservation.\textsuperscript{177}

\begin{itemize}
\item \textsuperscript{171} \textit{Cruzan v. Dir., Mo. Dep’t of Health}, 497 U.S. 261, 269 (1990).
\item \textsuperscript{172} \textit{See} Planned Parenthood of Se. Pa. \textit{v. Casey}, 505 U.S. 833, 875–76 (1992) (finding that the state's interest in life outweighed a woman's right to autonomy when the fetus is viable, unless carrying to term threatens the life or health of the mother).
\item \textsuperscript{173} \textit{Cruzan}, 497 U.S. at 278–79.
\item \textsuperscript{174} \textit{See} Washington \textit{v. Glucksberg}, 521 U.S. 702, 720 (1997); Basiak, \textit{supra} note 8, at 403 (“When asked to recognize a fundamental right under the Due Process Clause of the Fourteenth Amendment, the U.S. Supreme Court has failed to articulate a substantial justification for the level of generality in characterizing the legal issue.”); Ertel, \textit{supra} note 169, at 104 (the Supreme Court “might reverse because the Court is not that friendly toward not-before-recognized constitutional rights.”).
\item \textsuperscript{175} \textit{Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach}, 445 F.3d 470, 474–75 (D.C. Cir. 2006).
\item \textsuperscript{176} \textit{Id.} at 475.
\item \textsuperscript{177} \textit{Id.} at 480 (quoting \textit{William Blackstone}, 1 \textit{Commentaries} *125,*130).
\end{itemize}
The concept of self-preservation exists in both religion and philosophy. In medieval times, self-preservation was seen as a duty enjoined by divine law that implied a right of self-defense. Self-preservation was an inalienable right that could not be surrendered or given up by an individual due to a compact with God. Philosopher John Locke argued that the right to self-preservation existed and required everyone “to preserve himself.” The Declaration of Independence states that all men are “endowed by their Creator with certain unalienable Rights” that include “Life, Liberty and the pursuit of Happiness.” The Framers implemented a Constitution with laws that recognized certain inalienable rights, including the right to life, and provided a certain level of legal protection and status for that right. The inalienable right to life has been referred to as “the right to have rights” and as “necessary to the exercise of all social privileges.”

The principle of self-determination originates from the inalienable right to life and provides “a fundamental right to the sole control of his or her person.” Liberty includes not having the State “dictate the manner in which the duty to live . . . is fulfilled.” The medical community bases the majority of treatment decisions on the right to self-determination, requiring that a patient be made aware of all his treatment options and make his own decision about self-preservation, including whether to refuse treatment or proceed with the treatment he has chosen. The patient’s choice of treatment, or refusal, is his alone.

Cruzan recognized the “sanctity” of self-determination: “No right is held more sacred, or is more carefully guarded, by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law.” The concepts of privacy and liberty

179. See id. at 389–90.
180. Id. at 386.
181. The DECLARATION OF INDEPENDENCE para. 2 (U.S. 1776).
185. In re Guardianship of Browning, 568 So. 2d 4, 10 (Fla. 1990).
186. Myers, supra note 178, at 390.
188. See Thor v. Superior Court, 855 P.2d 375, 383 (Cal. 1993) (“It is antithetical to our scheme of ordered liberty and to our respect for the autonomy of the individual for the State to make decisions regarding the individual’s quality of life. It is for the patient to decide such issues.”); Myers, supra note 178, at 390 (arguing that if “an individual has cancer, he is accountable to God alone for the manner in which he treats his disease . . . . If he believes that a different therapy is appropriate, the choice is his”).
also recognize a fundamental right of self-determination,\textsuperscript{190} and the choice of whether to live or die is "as central to individual self-determination as anyone can imagine."\textsuperscript{191} Since the right of self-determination has already been recognized by the Supreme Court, giving the individual a right to control his or her own person, the logical corollary includes a right to save one's own life.

B. **Supreme Court Jurisprudence on the Right to Die and the Fundamental "Right to Live"**

Three Supreme Court cases deal with patients' choices of whether to live or die: \textit{Cruzan}, \textit{Glucksberg}, and \textit{Vacco v. Quill}.\textsuperscript{192} \textit{Cruzan} inferred a right to refuse medical treatment, while both \textit{Glucksberg} and \textit{Vacco} held that the State's interest in preserving and protecting life outweighed the individual's right to end her life with assistance from a physician.\textsuperscript{193} All of the so-called "right to die" cases rejected the idea that an individual’s right to self-determination included a right to medical assistance to die.\textsuperscript{194} In \textit{Cruzan}, the State was permitted to require clear and convincing evidence before a guardian was allowed to order removal of life-saving hydration and nutrition. In \textit{Glucksberg} and in \textit{Vacco}, the State's interest in the inalienable right to life outweighed a patient's desire to die with the help of a physician. Justice O'Connor's concurring opinion in \textit{Glucksberg},\textsuperscript{195} however, stressed the importance of the availability of palliative care to relieve patients' suffering, even where such pain management might result in death.\textsuperscript{196}

Palliative care is an accepted medical practice to ease a patient's pain and suffering, and it was the key reason behind O'Connor's vote. Without such a practice in place, the reasoning behind \textit{Glucksberg} may have been different, particularly since the importance of palliative care was acknowledged by three other Justices.\textsuperscript{197} Suffering involves much more than physical pain: "[I]t is a mix of the physical, emotional, existential, and psychological."\textsuperscript{198} By denying a terminally ill patient the right to live, or the right to attempt to save her life by accessing experimental drugs,
the current FDA regulations may sentence to death those who have ex-
hausted all approved treatment options. In addition, a patient's emo-
tional and psychological suffering due to her inability to ever know if she
did everything possible to attempt to save her life is cruel to the individ-
ual and to her family. As Justice Stevens stated: "The constitutional
protection for the human body is surely inseparable from concern for the
mind and spirit that dwell therein." The interest in mitigating suffer-
ning, through palliative care, along with autonomy, integrity, and liberty
concerns, justifies a right to medical intervention. The right to self-
preservation, the right to life, demands the opportunity to save one's life
so long as it does not infringe on the rights of others.

The Supreme Court has not addressed whether there is a fundamental
right to life, most likely because it is an inalienable right that has not
needed to be addressed. The Court has recognized the State's interest
in life and what appears to be a fundamental right to life several times.
In Cruzan, the Court relied on the right to life to assume there was a
reciprocal, limited "right to die." Glucksberg recognized that the State
had an "unqualified interest in the preservation of human life." Vacco
recognized the State's "valid and important public interests," in-

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199. See James Bopp, Jr. & Daniel Avila, The Due Process "Right to Life" in Cruzan
and Its Impact on "Right-to-Die" Law, 53 U. Pitt. L. REV. 193, 202 (1991) (stating that a
decision to withhold live-saving treatment "may constitute a deprivation of life. That depr-
rivation may be intentional if the treatment is nonburdensome and effective."); Brian C.
Goebel, Note, Who Decides if There is "Triumph in the Ultimate Agony"? Constitutional
Theory and the Emerging Right to Die with Dignity, 37 Wm. & Mary L. Rev. 827, 830, 875
(1996) (arguing that an individual should be able to control the circumstances surrounding
her own death and that the Eighth Amendment "prohibits a government from inflicting
unnecessary pain and suffering during the dying process and from deliberately denying
prisoners medical assistance that would alleviate their pain and suffering"). In 1980, the
delay in approval time for new drugs was estimated to have cost as many as 45,000 to
70,000 lives of heart-attack victims who could not access beta-blockers, 7,000 deaths for
arthritis sufferers with bleeding ulcers, and thousands of other deaths due to delays for
access to blood thinners and AIDS drugs. Myers, supra note 70, at 322–23.

200. See Goebel, supra note 199, at 875 (arguing that based on the constitutionally pro-
tected interest in mitigating suffering, the dignity interest provided under the Eighth
Amendment should protect an individual's interest in avoiding a lingering death).

201. Cruzan v. Dir., Mo. Dep't of Health, 497 U.S. 261, 343 (1990) (Stevens, J.,
dissenting).

supra note 199, at 876–79 (arguing for a right to assisted suicide based on autonomy and
liberty interests).

203. See Bopp & Avila, supra note 199, at 198 (discussing that Cruzan did not require
the state to Nancy Cruzan had chosen to live or direct the state to come to her
defense to protect Nancy's life. The state's interest in life arose "naturally and separately
from any exercise of government authority or personal liberty").

204. See, e.g., Vacco v. Quill, 521 U.S. 793, 808–09 (1997); Washington v. Glucksberg,
521 U.S. 702, 728–32 (1997); Cruzan, 497 U.S. at 282; Casey, 505 U.S. at 875–76 (quoting
Roe v. Wade, 410 U.S. 113, 162 (1973) (recognizing that the State's "important and legiti-
mate interest[s] in preserving and protecting the health of the pregnant woman [and] in
protecting the potentiality of human life") (alterations in original)); Johnson v. Zerbst, 304
U.S. 458, 462 (1938).

205. Cruzan, 497 U.S. at 282.

cluding preserving life. State courts have also recognized this important "fundamental" right.

It is illogical to deny rights to citizens, such as a right to assisted suicide, based on the State’s overwhelming, compelling interest in preserving life, and then argue that the State has the ability to deny an individual the ability to attempt to save his or her own life. If the State’s interest in preserving the sanctity of life outweighs other rights and interests, including the right to refuse medical treatment in individual cases, it is difficult to argue that such an overwhelming right ends when applied to terminally ill patients without other treatment options. The Court has already recognized that the lives of the terminally ill are no less valued than the lives of others, and where access to treatment does not pose a danger or hardship to others, there is simply not a justifiable reason to deny someone the ability to try to save her life.

But the question of how far the right to life extends is the crux of the issue. In most cases, courts have found no right to treatment or access to medication based on the State’s compelling interest in protecting the patient from harm. These courts, including the Supreme Court, have based this decision on fear that patients would choose an unproven drug over proven treatment methods and "needlessly" die. The access right defined by the Alliance directly addresses this issue by ensuring that this will not happen.

C. DOES ABIGAIL ALLIANCE MEET THE GLUCKSBERG TEST?

1. Careful Description of the Liberty Interest Being Asserted

The Alliance’s careful definition of the asserted right ensured it did not include an “unfettered” right of access to drugs, where the State’s com-

207. Vacco, 521 U.S. at 808–09.

208. See, e.g., McKay v. Bergstedt, 801 P.2d 617, 623 (Nev. 1990) (“The State’s interest in preserving all human life, including that of a particular patient, should not be suspended or minimized under any conditions.”); In re Westchester Co. Med. Ctr., 531 N.E.2d 607, 613 (N.Y. 1988) (holding the right to live is a natural right); Montalvo v. Borkovec, 647 N.W.2d 413, (Wis. 2002) (holding that the state’s interest "in preserving life is of paramount significance").

209. See V. Anthony Unan, The Right to Choose an Unproven Method of Treatment, 13 Loy. L. A. L. Rev. 227, 235 (1979) (pointing out the irony that courts in some cases will protect the right to refuse medical treatment where the treatment would save the patient’s life, but refuse to protect the right of a terminally ill patient to take an experimental drug to attempt to save his life).

210. See, e.g., Cruzan, 497 U.S. at 284; Jacobson v. Massachusetts, 197 U.S. 11, 27, 37 (1905) (holding that under the principle of self-defense, the State could require mandatory smallpox vaccinations to protect public health and safety); Commonwealth v. Kallinger, 580 A.2d 887, 888–93 (Pa. Commw. Ct. 1990) (holding that based on the State’s interests in preserving human life and preventing suicide, the state could force nutrition and medical treatment on a prisoner trying to starve himself to death while serving a life sentence).


212. The Supreme Court recognized a right to refuse treatment if it endangered the individual’s health, but found that right was outweighed in Jacobson v. Massachusetts by the danger posed to others. Jacobson, 197 U.S. at 27, 39. The community was allowed to act in self-defense against a smallpox epidemic. Id. at 27.
pelling interest in protecting the public from taking dangerous drugs would be narrowly tailored under the FDA regulations. The asserted right also did not include the right to receive treatment from or at the government’s expense. Both are extremely important to avoid public policy concerns where the government would be unable to comply for both healthcare and budgetary reasons. The right as defined is extremely narrow, and should be successful since the law applies only to “the group for whom the law is a restriction, not the group for whom the law is irrelevant.”

Generally, where the Supreme Court has provided a narrow definition of a fundamental right the petitioners have lost, while a broad definition by the Court has resulted in a victory for the petitioners. The petitioners’ definitions of the asserted right in most of those cases, however, have generally been based on broad claims of rights involving autonomy or liberty. In Abigail Alliance, the asserted right was very narrowly defined, which makes it easier to argue that the FDA regulations are not narrowly tailored within the State’s compelling interest. This argument is strengthened by precedent establishing the State’s compelling interest in protecting the sanctity of life and by Glucksberg’s requirement of a narrowly defined right.

2. History, Tradition, and Ordered Liberty

The history and tradition argument is more difficult. Although a traditional Glucksberg analysis requires looking at past legal history, therefore recognizing the right to self-preservation and the State’s compelling interest in life, as well as the lack of government interference with access to medication, it also requires looking at current trends. The fact that it was not necessary before 1962 to regulate drugs in the manner now enforced by the FDA does not mean that the current regulations are not narrowly tailored. In fact, the FDA has a strong argument, based on history with drugs such as Thalidomide and Laetrile, that adding regulations was

214. Compare Glucksberg, 521 U.S. at 722 (defining the right at issue as “a right to commit suicide which itself includes a right to assistance in doing so”), and Bowers v. Hardwick, 478 U.S. 186, 190 (1986) (defining the right at issue as “a fundamental right of homosexuals to engage in sodomy . . . invalidat[ing] the laws of many States that still make such conduct illegal and have done so for a very long time”), with Lawrence v. Texas, 539 U.S. 558, 564 (2003) (discussing homosexual sodomy, but defining the asserted right as “whether the petitioners were free as adults to engage in private conduct in the exercise of their liberty under the Due Process Clause. . . .”), and Moore v. City of E. Cleveland, 431 U.S. 494, 501–04, 505 (1977) (plurality opinion) (refusing to accept the state’s argument that the constitutional right to live together as a family included only the nuclear family of a couple and their dependent children, because the “sanctity of the family” included the tradition of uncles, aunts, cousins, and grandparents sharing the household).
215. See Casey, 505 U.S. at 877.
217. The government not proscribing conduct is not dispositive, since the “absence of regulation could be attributable to a liberty interest that is deeply rooted . . .” but another explanation such as technology might apply. Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach, 445 F.3d 470, 479 (D.C. Cir. 2006).
necessary to protect public health and safety. Furthermore, medical care has changed dramatically in the past forty years. The FDA’s argument, however, is undermined by its arbitrary enforcement of the regulations, when the agency accepts off-label use of drugs and has created treatment IND and compassionate-use programs to circumvent the very regulations they argue are necessary to protect the public, including the terminally ill, from taking dangerous drugs.

Stare decisis may be an issue in Abigail Alliance, since Rutherford established that the FDCA did not exempt from FDA regulation drugs used to treat the terminally ill from FOA regulation, and a number of lower court cases have followed Rutherford and refused to recognize a right to access medication or treatment. However, Rutherford did not discuss, or rule on, the substantive due process argument posed in Abigail Alliance, and although the Tenth Circuit, on remand, held there was no right to access medication, it did not perform a substantive due process analysis. Additionally, the Supreme Court based its Rutherford ruling in part on fear of patients using unapproved drugs in lieu of traditional treatment and the assumption that access to clinical trials or other exceptions were available in desperate situations. Therefore, the Court may distinguish Rutherford from Abigail Alliance on the substantive due process argument and the asserted right, not requiring it to overrule Rutherford to reach a decision.

3. The Fundamental Rights Analysis

To date there has not been a decision in any court on whether the FDA regulations are narrowly tailored under strict scrutiny. Assuming the D.C. Circuit upholds the panel decision finding a fundamental right, Abigail Alliance is likely to reach the Supreme Court based on expansion concerns for such a precedent, particularly in regard to palliative care. The D.C. Circuit’s decision would also create a split between the circuits about whether there is a fundamental right to access to medication or treatment. The Supreme Court may choose to rely on the analysis performed in Abigail Alliance to find a fundamental right, or use the dissent’s argument to explain why the right is not fundamental. The dissent’s argument is flawed, though, since it was based on an asserted right for “blanket access” to experimental drugs and argued that access could potentially be harmful, resulting in no patients having enough information to give informed consent. The Alliance did not ask for blanket access to drugs, but only requested access when a terminally ill patient

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218. Rehearing en banc was set for March 1, 2007. Abigail Alliance, No. 04–5350, 2006 U.S. App. LEXIS 29148, at *1 (D.C. Cir. Nov. 21, 2006). If the D.C. Circuit affirms the panel decision, the case will most likely be remanded to the District Court for a decision on whether the FDA regulations are narrowly tailored, unless certiorari is granted solely on the fundamental right issue.

219. Rutherford did not perform an analysis of the defined right or examined the history and tradition behind it. Rutherford v. United States, 616 F.2d 455, 457 (10th Cir. 1980), cert. denied, 449 U.S. 937 (1980).
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had no other treatment options. Based on the dissent’s argument, no patient in a clinical trial, or using a drug prescribed for off-label use, can give informed consent because there is no way of knowing what the effect will be until after the drug has been taken.

Although the Court seems to have already recognized a fundamental right to life, based on continual deference to the State’s compelling interest in life, it could hold that the right to life does not extend to a right of access to treatment or medication on policy grounds. The slippery slope argument regarding illegal narcotics harm to the healthcare system by creating exceptions for drug regulation, and problems with the scientific process required in clinical trials will all be raised. The D.C. Circuit dismissed the narcotics argument in its original opinion, stating that the Alliance had requested access to Phase II clinical trial drugs already declared safe for human testing by the FDA, not drugs banned by the FDA or the Controlled Substances Act. Since the Supreme Court has already held the FDA regulations apply to medications for the terminally ill, it could deny an affirmative right of access based on Rutherford and hold that the State’s compelling interest in ensuring the public’s health and safety does not allow exceptions to drug regulations. If the right is not fundamental, the FDA regulations will meet the test for rational basis review. The Court may also distinguish Rutherford and recognize a right to access to medications applying only in narrow circumstances, similar to Casey, where the law only applies to terminally ill individuals seeking experimental treatment when they have run out of options and not to the public at large or even to terminally ill patients with approved alternatives.

Under a Glucksberg analysis, then, it is possible that the Court will find a fundamental right based on the narrow definition of the right asserted and the history and tradition supporting a lack of government interference in the past, as well as a number of exceptions to FDA regulations in the present. The Court should affirm that there is a fundamental right to life and to self-preservation, and may hold that there is a fundamental right to attempt to save one’s life by accessing medication and treatment. Even if the Court declares there is a fundamental right to life that includes limited access to medical treatment and medication, the Court may still find that the FDA regulations satisfy strict scrutiny. The next section discusses why the Court should find that the FDA regulations are not narrowly tailored.

220. The dissent in Abigail Alliance argued that the majority’s holding would lead to medicinal use of marijuana or stem cell research. Abigail Alliance, 445 F.3d at 499 (Griffith, J., dissenting).

221. Id. at 477 n.9.

222. Planned Parenthood of Se. Pa. v. Casey, 505 U.S. 790, 833 (1992) (stating that the constitutional analysis “does not end with the one percent of women upon whom the statute operates; it begins there . . . . The proper focus of the constitutional inquiry is the group for whom the law is a restriction, not the group for whom the law is irrelevant.”).

223. Sunstein, supra note 191, at 1137 (recognizing the Court could acknowledge the fundamental right to self-determination yet still find the government’s compelling interest outweighed that right).
V. THE FDA REGULATIONS ARE NOT NARROWLY TAILORED FOR TERMINALLY ILL PATIENTS WITHOUT OTHER TREATMENT OPTIONS

The government has a compelling interest in the sanctity of life and in the public’s health and safety, which includes ensuring that people do not take dangerous drugs and that drug regulations are uniformly applied. When applied generally to patients, including the terminally ill, these important, compelling interests are narrowly tailored. The FDA regulations, however, are simply not narrowly tailored to the government’s compelling interest when applied to terminally ill patients who do not have approved treatment options available.\(^\text{224}\) The balance tips from the FDA to terminally ill patients once they have exhausted all approved treatment options because that is when the situation directly restricts the patients’ rights to self-preservation. Until all other options are exhausted, the FDA regulations do not harm or restrict those individuals. Once the available options are exhausted, however, the “proper focus” becomes the “group for whom the law is a restriction, not the group for whom the law is irrelevant.”\(^\text{225}\) Based on the current regulations, there are several reasons why terminally ill patients should be able to access Phase II clinical trial drugs if they have exhausted all approved treatments and are able to pay for the medication.\(^\text{226}\)

First, the State has no need to protect patients from receiving possibly ineffective treatment when taking the medication may save the patient’s life and is the only option left to try. A State cannot justify depriving a citizen of life by denying treatment that may sustain life in order to protect public health when the public is not at risk.\(^\text{227}\) The FDA will most likely argue that it should be able to deny access to experimental drugs based on an individual’s inability to prove the treatment does, in fact, sustain life.\(^\text{228}\) The individual would be required to demonstrate that all other treatment options have been exhausted and unsuccessful before requesting access to experimental drugs; therefore, the FDA’s argument should be rejected on the grounds that a drug may sustain the patient’s life where the patient will definitely die without the drug.\(^\text{229}\) Until the FDA can prove the treatment does not sustain life, it has, in fact, proven that the drug is safe to test in humans by completing a review of the Phase I clinical trial process. Seventy percent of drugs submitted for clinical trials fail in Phase I; but only thirty-three percent fail in Phase II.\(^\text{230}\)

\(^{224}\) See Batterman, supra note 59, at 207.

\(^{225}\) Casey, 505 U.S. at 894.

\(^{226}\) The need for individuals to pay for the medication is based on public policy concerns and the principle that there is no right to government aid, even when the individual is being deprived of life, liberty, or property. Rust v. Sullivan, 500 U.S. 173, 201 (1991).

\(^{227}\) See Bopp & Avila, supra note 199, at 221–22. See also Jacobson v. Massachusetts, 177 U.S. 11, 39 (1905) (allowing the State to require vaccinations for contagious diseases due to the public health risk).

\(^{228}\) Bopp & Avila, supra note 199, at 221–24.

\(^{229}\) Id.
A non-treatment directive does not pose an "abandonment of the desire for life" by the State, since the underlying disease causes death rather than the lack of treatment. The Court could still find the regulations narrowly tailored in this instance. This argument, however, asserted by Justice Stevens in his *Cruzan* dissent, is based on the assumption that the patient does not wish to live if his life is artificially prolonged with machines or feeding tubes. It is therefore not viable for terminally ill patients who wish to fight for their lives, since not taking a number of medications would result in death, including blood pressure medication, beta blockers, or insulin shots.

Justice O'Connor's concurrence in *Glucksberg* recognized a right to die, but found that the State's interest in protecting life outweighed that right if a person was not experiencing great suffering and palliative care was available. If the State's interest in protecting life outweighs the right to die, or the right to decide when to die, it should be difficult for the State to argue it also has the right to deny medical treatment, particularly palliative care, to someone who wants to live. The FDA's argument, though, would most likely be that the State is protecting everyone's health and safety by requiring clinical trials to determine the effectiveness of drugs prior to placing them on the market. Prior disasters with medications such as Laetrile, which resulted in a number of cancer patients postponing chemotherapy treatments and "needlessly" dying, support the FDA's claim that the regulations protect the public from dangerous drugs. The narrow right defined here, however, requires patients to exhaust all approved remedies before requesting access to experimental treatments. The FDA's standard argument and the concerns expressed in *Rutherford* and *Privitera* simply do not apply: no patient will have the opportunity to seek out an experimental treatment while ignoring an approved, "effective" treatment that could save her life.

Second, the FDA arbitrarily enforces the regulations. The FDA already makes exceptions for all patients through off-label drug use and clinical trials, and additional exceptions are made for patients with life-threatening conditions through compassionate-use and treatment IND

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231. *Cruzan v. Dir., Mo. Dep't of Health*, 497 U.S. 261, 343 (1990) (Stevens, J., dissenting); *see also*, Bopp & Avila, *supra* note 199, at 207 (arguing that "withholding futile care differs from withholding effective care because in the former case death would occur even if treatment were provided" and that the State must deliberately interfere for the due process clause to be implicated).
232. *See Shelly Cohen, Note, De-Moralizing Death: A Humanistic Approach to the Sanctity of Life*, 14 ELDER L. J. 91, 114 (2006) (noting that the underlying disease causes death argument cannot be as accepted when "medicine itself deviates from what could be called natural" and that dying a "natural death" is no longer an option for anyone who takes medication to prolong life, whether for hypertension, diabetes, or other health problems).
234. *See Bopp & Avila, supra* note 199, at 221–22.
programs. It is estimated that half of all prescriptions are for uses not approved by the FDA, particularly chemotherapy agents used to treat cancer. The American Medical Association has stated that a physician who is aware of an off-label use of a drug but does not prescribe it for that use may be subject to medical malpractice liability. Congress acknowledged off-label use and “authorized Medicaid reimbursement for drugs that appear in certain medical compendia,” even where the FDA has not approved that use for labeling. The FDA, therefore, approves of physicians prescribing approved cancer drugs to patients with completely different types of cancer and in different stages of the disease than that for which the drug has been proven safe or effective. If the FDA allows all patients, particularly cancer patients, to take drugs for unapproved, off-label uses, its argument against providing Phase II clinical trial drugs to patients without other treatment options is arbitrary and cannot stand.

In Informed Consent and the Elusive Dichotomy Between Standard and Experimental Therapy, Lars Noah argues that patients are, in fact, subjects in medical research at all times. Physicians cannot be sure of a drug’s effect on an individual patient or whether the patient will have an allergic reaction or suffer side effects more intense than those shown in clinical trials, much less whether the drug will be effective for the individual. The FDA interferes with a patient’s right to live when it denies a terminally ill patient with no other options access to an experimental drug that has been proven safe for testing on humans. Because the FDA already allows physicians to prescribe drugs not proven effective for patients, the effectiveness requirement is arbitrary and not narrowly tailored for patients who will die without treatment and have no other options.

Similarly, the FDA allows terminally ill patients to take experimental drugs in a clinical trial setting where the drugs have been proven safe for testing. In Phase II trials, hundreds of people are given the opportunity to decide whether to take these experimental treatments, in some cases even when other approved treatments are available. The argument that patients outside of an approved clinical trial group should not have the same right to decide to take an experimental drug, particularly when it is the only remaining treatment option, is disingenuous. The government cannot deny an individual the right to attempt to save her life when exceptions are made for the hundreds or thousands of people “lucky enough” to get into clinical trials.

237. Id.
238. Id.
239. Id. at 362–63.
240. Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach, 445 F.3d 470, 478 n.9 (“The FDA has determined, upon scientific analysis and evaluation, that certain Phase I investigational new drugs are sufficiently safe for expanded human testing in Phase II trials.”). Seventy percent of drugs submitted for clinical trials fail in Phase I; thirty-three percent fail in Phase II. Henry, supra note 57, at 621.
Finally, the compassionate-use and treatment IND programs are other exceptions that allow the terminally ill access to experimental drugs before the drugs have gone through the full clinical trial process. Although the programs are underutilized and the restrictions are almost as strict as the clinical trial programs, the FDA has recognized that the current regulations infringe on an individual's right to life. If there is a fundamental right to access, the FDA's exceptions demonstrate that the agency already knows its regulations are not narrowly tailored for desperate patients without other treatment options.

The FDA's strongest argument is that allowing access to unapproved medications has proven problematic in the past, may harm the scientific accuracy of clinical trials, slow down the clinical trial process, and do more harm than good to the public in the long run. The compassionate-use problem with Ganciclovir supports the FDA's argument, yet these patients do not have other options available, and the Court will not look to the effect on the public, but rather on the individuals directly burdened.

VI. CONCLUSION

The Supreme Court could recognize a fundamental right to self-preservation, but whether the Court will find that this right extends to access to experimental drugs for terminally ill patients with no other treatment options is debatable. If the Court does find that the asserted right is constitutional in this limited circumstance, they may still hold that the government's compelling interest in protecting the public from dangerous drugs is narrowly tailored. Substantive due process, however, requires that the government's compelling interest in protecting the public from dangerous drugs be narrowly tailored to no more than what is required, and the FDA's current regulations are overbroad for terminally ill patients without other treatment options. Because the FDA allows so many exceptions, it is unlikely that such arbitrary enforcement of the current regulations can be considered narrowly tailored. The proper focus is on terminally ill patients without other treatment options. When a terminally ill patient has exhausted all approved treatment options, she should be allowed to attempt to save her life by accessing an experimental drug.
Articles